EPA Registration # 82415-2

Volume 1

KANEBO STATUS AS OF 7-25-1994

SCIENCE DISCIPLINE	59824-1 (AC)	59824-2 (AZ)	59824-3 (A)
Environmental Fate	Pending w Reg since 07/94	Pending w Reg since 07/94	Pending w Reg since 07/94
Fish/Wildlife	Satisfied	Satisfied	Satisfied
Toxicology	Satisfied	Pending W Reg (Acutes 7/94)	Satisfied
Chemistry	Satisfied	Satisfied	Satisfied
Efficacy	n/a	n/a	n/a
Label	Registered	Registered	Registered

Tox: Williams
Fish: Heather
Fate: Silvia

1. AS DISCUSSED WITH THE ASSIGNED REVIEWER, REREGISTRATION HAS TOP PRIORITY AND NO NEW TIME FRAMES HAVE BEEN ESTABLISHED.
2. ISSUE THAT THESE PRODUCTS ARE MEE-TOO IS NOT ENTIRELY CORRECT. IF WAS DISCUSSED IN A MEETING WITH THE REGISTRANT AND THEIR AGENTS THAT THAT THE FIRST PRODUCT WILL BE TREATED AS A NEW USE, AND THAT THE OTHER TWO PRODUCTS WILL TRAVEL TOGETHER AS A MEE-TOO. SINCE THE FIRST PRODUCT IS STILL CLASSIFIED AS A NEW USE, IT IS PREMATURE TO REASSIGNED THE OTHER TWO PRODUCTS UNTIL ALL THE DATA HAS BEEN REVIEWED FOR THE FIRST PRODUCT.
3. SINCE THE MEETING, ZINC ON ONE OF THE PRODUCTS IS NOW CLASSSIFIED AS A ACTIVE INGREDIENT AND WHETHER ONE OF THE TWO CAN BE TREATED AS MEE-TOO IS EVEN MORE REMOTE.

NOTE TO FILE: EXPOSURE NOT A CONCERN ACCORDING TO THE ANTIMICROBIAL DATA CALL IN FOR SILVER THEREFORE ZINC AND COPPER ALSO WILL BE TREATED SAME WAY.

FISH FOR A WILL BE COVERED BY AC (WHEN AC'S REVIEW IS FINISHED)
TOX FOR A (CHRONIC) WILL ALSO BE COVERED BY AC'S REVIEW. 3/8/93

KANEBO STATUS AS OF 10-26-92

SCIENCE DISCIPLINE	59824-R (AC)	59824-E (AZ)	59824-G (A)
Environmental Fate	In review (1st) since 10/90	In Review (1st) since 10/91	In review (1st) since 10/91
Fish/Wildlife	Pending with Kanebo	Pending with Kanebo	Pending with Kanebo
Toxicology	In review (2nd) since 3/92	In review (1st) since 10/91	In review (1st) since 10/91
Chemistry	Satisfied	Satisfied	Satisfied
Efficacy	n/a	n/a	n/a
Label	pending	pending	pending

Tox: Williams
Fish: Heather
Fate: Silvia

1. AS DISCUSSED WITH THE ASSIGNED REVIEWER, REREGISTRATION HAS TOP PRIORITY AND NO NEW TIME FRAMES HAVE BEEN ESTABLISHED.
2. ISSUE THAT THESE PRODUCTS ARE MEE-TOO IS NOT ENTIRELY CORRECT. IF WAS DISCUSSED IN A MEETING WITH THE REGISTRANT AND THEIR AGENTS THAT THAT THE FIRST PRODUCT WILL BE TREATED AS A NEW USE, AND THAT THE OTHER TWO PRODUCTS WILL TRAVEL TOGETHER AS A MEE-TOO. SINCE THE FIRST PRODUCT IS STILL CLASSIFIED AS A NEW USE, IT IS PREMATURE TO REASSIGNED THE OTHER TWO PRODUCTS UNTIL ALL THE DATA HAS BEEN REVIEWED FOR THE FIRST PRODUCT.
3. SINCE THE MEETING, ZINC ON ONE OF THE PRODUCTS IS NOW CLASSSIFIED AS A ACTIVE INGREDIENT AND WHETHER ONE OF THE TWO CAN BE TREATED AS MEE-TOO IS EVEN MORE REMOTE.

10/17/91 PESTICIDE PRODUCT INFORMATION SYSTEM 15:05:01
COMPANY NUMBER SEARCH

059824 KANEBO ZEOLITE U.S.A., INC

350 FIFTH AVENUE SUITE 2018
NEW YORK , NY 10118
CONTACT: KUNIO KAMEDA PHONE: 212 244 1506
COUNTRY: USA
TYPE STATUS: MA
CHANGED REASON CODE: DATE LAST CHANGED: 901010 BY USER: RVL
TRANSFER FROM NBRS:

AGENT INFORMATION
FEDERAL REGULATORY CONSULTANT INC

2045 N 15TH ST SUITE 108
ARLINGTON , VA 22201
CONTACT: ARTURO CASTILLO PHONE: 703 525 3232

ENTER Y TO REVIEW HISTORY DATA:
PF1=HELP PF3=PREVIOUS MENU PF9=REPORT ERRORS
PF10=MAIN N&A MENU ENTER=CONTINUE CNQ03IP
4B A LINE 22 COL 34

Ciba Specialty Chemicals
North America
Regulatory Services

Ciba

April 13, 2005

via Federal Express

US Environmental Protection Agency
Document Processing Desk
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202-4501

Attention: Mr. Marshall Swindell (PM33)

Dear Mr. Swindell:

Pursuant to 40 CFR 152.135, this submission requests the transfer of three registered antimicrobial products on behalf of Kanebo Chemical Industries, Ltd. These products are being transferred to Fuji Chemical Industries, Ltd., which is a spinoff of Kanebo. The products transferred are Bactekiller AC, EPA Reg. No. 59824-1; Bactekiller AZ, EPA Reg. No. 59824-2; and Bactekiller A, EPA Reg. No. 59824-3. In addition an EPA Establishment number has been applied for Fuji Chemical Industries Ltd., and is pending.

In support of the product transfer request, the following documents are submitted:

- Notarized Transfer Agreement between Kanebo USA Inc. (Kanebo Chemical Industries, Ltd) and Fuji Chemical Industries, Ltd. [Per 40 CFR 152.135(b)]
- Notarized Affirmation Statement from Kanebo USA Inc. [Per 40 CFR 152.135(c)]
- Authorized agent letter allowing Ciba Specialty Chemicals Corp. to represent Kanebo/Fuji
- Copy of the Application for Registration for a Foreign Pesticide Producing Establishment

Please be advised that due to the nature of the spinoff, no English sales/transfer contract is available between Kanebo Chemical Industries, Ltd. and Fuji Chemical Industries, Ltd.

Should you have any questions or wish further information, do not hesitate to contact me directly at (336) 801-2603.

Respectfully,

Thomas Barber
Authorized Agent for Kanebo/Fuji Chemical Industries, Ltd.

NOW
82415-2

4090 Premier Drive
High Point, NC 27265

Tel. 336-801-2603
Fax 336-801-2056

Fuji Chemical Industries, Ltd.
Alte Building Higobashi
15-27, Edobori 1-Chome, Nishi-Ku, Osaka 550-0002, Japan
Phone: +81(6)6444-3920 Fax: +81(6)6444-3916

Transfer Agreement

1. **KANEBO U.S.A., INC.** (1120 Avenue of the Americas, 4th fl, New York, NY 10036-, hereinafter "the Transferor") transfers irrevocably to **Fuji Chemical Industries, Ltd.** (ALTE BUILDING HIGOBASHI (10FLR), 15-27, Edobori 1-Chome, Nishi-ku, Osaka 550-0002, Japan, hereinafter "the Transferee") all right, title, and interest in the following EPA registrations (hereinafter "Registrations").

The Products Being Transferred

Product name	EPA registration number
BACTEKILLER AC	59824-00001
BACTEKILLER AZ	59824-00002
BACTEKILLER A	59824-00003

2. The transferred Registrations shall not serve as collateral or otherwise secure any loan or other payment arrangement or executory promise.

3. The Registrations shall not revert to the Transferor unless a new transfer agreement is submitted to and approved by the Agency.

4. The Transferor and the Transferee understand that any false statement may be punishable under 18 U.S.C. 1001.

5. The general nature of the underlying transaction is Business Transfer from the Transferor to the Transferee.

6. The Transferee acknowledge that its rights and duties concerning the registration under FIFRA and 40 CFR §152.135 chapter (Transfer Of Registration) of FIFRA will be deemed by EPA to be the same as those of the Transferor at the time the transfer is approved.

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed in duplicate.

Kanebo U.S.A., INC.

By: _____

Name: Yasuhiro Yamashita

Title: President

Date: 3. 15. 2005

Fuji Chemical Industries, Ltd.

By: _____

Name: Hajime Takanashi

Title: Managing Director

Date: March 9, 2005

JOAN SANFILIPPO
Notary Public State of New York
No. 24-4652978
Cert. Filed in New York County
Commission Expires 1/31/2006
Joan Sanfilippo

FujiChem
Creative, Committed, Collaborative

Kanebo U.S.A., INC.
1120 Avenue of the Americas, 4th Floor, New York, NY 10036, U.S.A.
Phone 212.753.1300 Fax 212.753.1370

Affirmation

1. The person signing the Transfer Agreement is authorized by the registrant to bind the Transferor.

2. No court order prohibits the transfer, and that any required court approvals have been obtained.

3. The transfer is authorized under all relevant Federal, State and local laws and all relevant corporate charters, bylaws, partnerships, or other agreements.

We hereby affirm the above statements.

Kanebo USA., INC.

By: _____

Name: Yasuhiro Yamashita

Title: President

Date: 3. 15. 2005

JOAN SANFILIPPO
Notary Public State of New York
No 24-4652978
Cert Filed in New York County
Commission Expires 1/31/2006
Joan Sanfilippo

Fuji Chemical Industries, Ltd.
Alte Building Higobashi
15-27, Edobori 1-Chome, Nishi-Ku, Osaka 550-0002, Japan
Phone: +81(6)6444-3928 Fax: +81(6)6444-3916

January 14th, 2005

Mr. Marshall Swindell, PM-33
Office of Pesticide Programs (APPL)
Registration Division (7504C)
Environmental Protection Agency (EPA)
401 M Street, SW
Washington, DC 20460-0001

SUBJECT: Fuji Chemical Industries, Ltd. Zeolite Product Registration

Dear Mr. Swindell:

Fuji Chemical Industries, Ltd. ("Fuji"), previously Kanebo Chemical Industries, Ltd. (Kanebo U.S.A.,INC.) is designating Ciba® Expert Services, Ciba Specialty Corporation, 540 White Plains Road Tarrytown, New York 10591 as our agent in the submittal of their Backtekiller line of Zeolite products for EPA and state registrations.

Ciba® Expert Services has authority to act as our agent regarding these registrations.

Sincerely,

Hajime Takanashi
Managing Director
Fuji Chemical Industries, Ltd.

FujiChem
Creative, Committed, Collaborative

Ciba Specialty Chemicals
North America
Regulatory Services

Ciba

March 31, 2005

via Federal Express

Michelle Stevenson
US Environmental Protection Agency
Agriculture Division
1200 Pennsylvania Ave. NW
Washington, DC 20004

Re: Application for Registration for a Foreign Pesticide Producing Establishment

Dear Ms. Stevenson:

Enclosed is an application for an EPA Establishment Number for Fuji Chemical Industries, Ltd's facility in Osaka, Japan. Ciba Specialty Chemicals Corp. Expert Services has been authorized by Fuji as the agent acting on their behalf in this matter (letter of authorization enclosed).

Should you have any questions or wish further information, do not hesitate to contact me directly at (336) 801-2603.

Respectfully,

Tom Barber
Authorized Agent for Fuji Chemical Industries, Ltd.

4090 Premier Drive
High Point, NC 27265

Tel. 336-801-2603
Fax 336-801-2056

EPA

United States
Environmental Protection Agency
Washington, DC 20460

FORM APPROVED
OMB NO. 2070-0078

Application for Registration of Pesticide-Producing and Device-Producing Establishments

Section 7, Federal Insecticide, Fungicide, and Rodenticide Act, (7 U.S.C. 136e)

Note: Read all instructions before completing.

1. Company Name: Fuji Chemical Industries, Ltd.	11. EPA Company
2. Company Name *(if different from 1)*: Ciba Specialty Chemicals Corp. (Agent)	12. Company D & B No.: N/A
Company Headquarters Location	13. Enter Appropriate Ownership code: 4 1 - Individual 2 - Partnership 3 - Cooperative Association 4 - Corporation 5 - Other
3. Street Address: Fuji Chemical Industries, Ltd., 2-19-10 Shodaiohtani	
4. City: Osaka; 5. State or County: Japan; 6. Zip Code: 573-1153	
Company Headquarters Mailing Address (If identical to above, write SAME)	14. State or Country of Incorporation: Japan
7. Street or PO Box Address: Ciba Specialty Chemicals Corp., 4090 Premier Drive	15. Date of Incorporation (Month, Day, Year): 12/20/04
8. City: High Point; 9. State or Country: NC; 10. Zip Code: 27265	

NAME, SITE LOCATION, and MAILING ADDRESS of EACH NEW PRODUCING ESTABLISHMENT

16. Establishment Name: Fuji Chemical Industries, Ltd.		EPA Est. No. (EPA use only)	
17. Establishment Site Address: 2-19-10 Shodaiohtani	18. City: Osaka	19. State or Country: JPN	20. Zip Code: 573-1153
21. Establishment Mailing Address	22. City	23. State or Country	24. Zip Code
25. NAICS Code.		26. D & B No.	
16. Establishment Name		EPA Est. No. (EPA use only)	
17. Establishment Site Address	18. City	19. State or Country	20. Zip Code
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21. Establishment Mailing Address	22. City	23. State or Country	24. Zip Code
25. NAICS Code.		26. D & B No.	

EPA USE

27. NAME of Company Officer: Thomas Barber	28. Telephone Number: (336) 801-2603	EPA USE ONLY	Received date Postmark date
29. E-mail Address (Optional): tom.barber@cibasc.com	30. FAX Number (Optional): (336) 801-2056		Signature
31. TITLE of Company Officer: Authorized agent for Fuji Chemical Ind., Ltd.	32. Date Signed (Month, Day, Year): 3/31/05		Region
33. SIGNATURE of Company Officer: Th M			Review Date

EPA Form 3540-8 (Rev. 04-01) Previous editions are obsolete.

Fuji Chemical Industries, Ltd.
Alte Building Higobashi
15-27, Edobori 1-Chome, Nishi-Ku, Osaka 550-0002, Japan
Phone: +81(6)6444-3928 Fax: +81(6)6444-3916

March 18th, 2005

Mr. Marshall Swindell, PM-33
Office of Pesticide Programs (APPL)
Registration Division (7504C)
Environmental Protection Agency (EPA)
401 M Street, SW
Washington, DC 20460-0001

SUBJECT: Fuji Chemical Industries, Ltd. Establishment Number Application

Dear Mr. Swindell:

Fuji Chemical Industries, Ltd. ("Fuji") is designating Ciba® Expert Services, Ciba Specialty Chemicals Corporation, 4090 Premier Drive High Point, North Carolina 27261 as our agent in the submittal of Application of our facility Establishment Number.

Ciba® Expert Services has authority to act as our agent regarding these registrations.

Sincerely,

Hajime Takanashi
Managing Director
Fuji Chemical Industries, Ltd.

Ciba Specialty Chemicals
North America
Regulatory Services

Ciba

April 13, 2005

via Federal Express

US Environmental Protection Agency
Document Processing Desk
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202-4501

Attention: Mr. Marshall Swindell (PM33)

Dear Mr. Swindell:

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- Notarized Transfer Agreement between Kanebo USA Inc. (Kanebo Chemical Industries, Ltd) and Fuji Chemical Industries, Ltd. [Per 40 CFR 152.135(b)]
- Notarized Affirmation Statement from Kanebo USA Inc. [Per 40 CFR 152.135(c)]
- Authorized agent letter allowing Ciba Specialty Chemicals Corp. to represent Kanebo/Fuji
- Copy of the Application for Registration for a Foreign Pesticide Producing Establishment

Please be advised that due to the nature of the spinoff, no English sales/transfer contract is available between Kanebo Chemical Industries, Ltd. and Fuji Chemical Industries, Ltd.

Should you have any questions or wish further information, do not hesitate to contact me directly at (336) 801-2603.

Respectfully,

Thomas Barber
Authorized Agent for Kanebo/Fuji Chemical Industries, Ltd.

4090 Premier Drive
High Point, NC 27265

Tel. 336-801-2603
Fax 336-801-2056

Fuji Chemical Industries, Ltd.
Alte Building Higobashi
15-27, Edobori 1-Chome, Nishi-Ku, Osaka 550-0002, Japan
Phone: +81(6)6444-3920 Fax: +81(6)6444-3916

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BACTEKILLER AZ	59824-00002
BACTEKILLER A	59824-00003

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3. The Registrations shall not revert to the Transferor unless a new transfer agreement is submitted to and approved by the Agency.

4. The Transferor and the Transferee understand that any false statement may be punishable under 18 U.S.C. 1001.

5. The general nature of the underlying transaction is Business Transfer from the Transferor to the Transferee.

6. The Transferee acknowledge that its rights and duties concerning the registration under FIFRA and 40 CFR §152.135 chapter (Transfer Of Registration) of FIFRA will be deemed by EPA to be the same as those of the Transferor at the time the transfer is approved.

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed in duplicate.

Kanebo U.S.A., INC.

By: _____

Name: Yasuhiro Yamashita

Title: President

Date: 3. 15. 2005

Fuji Chemical Industries, Ltd.

By: _____

Name: Hajime Takanashi

Title: Managing Director

Date: March 9, 2005

JOAN SANFILIPPO
Notary Public State of New York
No 24-4652978
Cert Filed in New York County
Commission Expires 1/31/2006
Joan Sanfilippo

FujiChem
Creative, Committed, Collaborative

Kanebo U.S.A., INC.
1120 Avenue of the Americas, 4th Floor, New York, NY 10036, U.S.A.
Phone 212.753.1300 Fax 212.753.1370

Affirmation

1. The person signing the Transfer Agreement is authorized by the registrant to bind the Transferor.

2. No court order prohibits the transfer, and that any required court approvals have been obtained.

3. The transfer is authorized under all relevant Federal, State and local laws and all relevant corporate charters, bylaws, partnerships, or other agreements.

We hereby affirm the above statements.

Kanebo USA., INC.

By: _____

Name: Yasuhiro Yamashita

Title: President

Date: 3. 15. 2005

JOAN SANFILIPPO
Notary Public State of New York
No 24-4652978
Cert Filed in New York County
Commission Expires 1/31/2006
Joan Sanfilippo

Fuji Chemical Industries, Ltd.
Alte Building Higobashi
15-27, Edobori 1-Chome, Nishi-Ku, Osaka 550-0002, Japan
Phone: +81(6)6444-3928 Fax: +81(6)6444-3916

January 14th, 2005

Mr. Marshall Swindell, PM-33
Office of Pesticide Programs (APPL)
Registration Division (7504C)
Environmental Protection Agency (EPA)
401 M Street, SW
Washington, DC 20460-0001

SUBJECT: Fuji Chemical Industries, Ltd. Zeolite Product Registration

Dear Mr. Swindell:

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Ciba® Expert Services has authority to act as our agent regarding these registrations.

Sincerely,

Hajime Takanashi
Managing Director
Fuji Chemical Industries, Ltd.

FujiChem
Creative, Committed, Collaborative

Ciba Specialty Chemicals
North America
Regulatory Services

Ciba

March 31, 2005

via Federal Express

Michelle Stevenson
US Environmental Protection Agency
Agriculture Division
1200 Pennsylvania Ave. NW
Washington, DC 20004

Re: Application for Registration for a Foreign Pesticide Producing Establishment

Dear Ms. Stevenson:

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Should you have any questions or wish further information, do not hesitate to contact me directly at (336) 801-2603.

Respectfully,

Tom Barber
Authorized Agent for Fuji Chemical Industries, Ltd.

4090 Premier Drive
High Point, NC 27265

Tel. 336-801-2603
Fax 336-801-2056

EPA

United States
Environmental Protection Agency
Washington, DC 20460

FORM APPROVED
OMB NO. 2070-0078

Application for Registration of Pesticide-Producing and Device-Producing Establishments

Section 7, Federal Insecticide, Fungicide, and Rodenticide Act, (7 U.S.C. 136e)

Note: Read all instructions before completing.

1. Company Name: Fuji Chemical Industries, Ltd.	11. EPA Company
2. Company Name *(if different from 1)*: Ciba Specialty Chemicals Corp. (Agent)	12. Company D & B No.: N/A
Company Headquarters Location	13. Enter Appropriate Ownership code: 4 1 - Individual 2 - Partnership 3 - Cooperative Association 4 - Corporation 5 - Other
3. Street Address: Fuji Chemical Industries, Ltd., 2-19-10 Shodaiohtani	
4. City: Osaka; 5. State or County: Japan; 6. Zip Code: 573-1153	
Company Headquarters Mailing Address (If identical to above, write SAME)	14. State or Country of Incorporation: Japan
7. Street or PO Box Address: Ciba Specialty Chemicals Corp., 4090 Premier Drive	15. Date of Incorporation (Month, Day, Year): 12/20/04
8. City: High Point; 9. State or Country: NC; 10. Zip Code: 27265	

NAME, SITE LOCATION, and MAILING ADDRESS of EACH NEW PRODUCING ESTABLISHMENT

16. Establishment Name: Fuji Chemical Industries, Ltd.		EPA Est. No. (EPA use only)	
17. Establishment Site Address: 2-19-10 Shodaiohtani	18. City: Osaka	19. State or Country: JPN	20. Zip Code: 573-1153
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25. NAICS Code.		26. D & B No.	
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21. Establishment Mailing Address	22. City	23. State or Country	24. Zip Code
25. NAICS Code.		26. D & B No.	

EPA USE

27. NAME of Company Officer: Thomas Barber	28. Telephone Number: (336) 801-2603	EPA USE ONLY	Received date Postmark date
29. E-mail Address (Optional): tom.barber@cibasc.com	30. FAX Number (Optional): (336) 801-2056		Signature
31. TITLE of Company Officer: Authorized agent for Fuji Chemical Ind., Ltd.	32. Date Signed (Month, Day, Year): 3/31/05		Region
33. SIGNATURE of Company Officer: Th M			Review Date

EPA Form 3540-8 (Rev. 04-01) Previous editions are obsolete.

THIS IS PAGE 1 OF 1

Fuji Chemical Industries, Ltd.
Alte Building Higobashi
15-27, Edobori 1-Chome, Nishi-Ku, Osaka 550-0002, Japan
Phone: +81(6)6444-3928 Fax: +81(6)6444-3916

March 18th, 2005

Mr. Marshall Swindell, PM-33
Office of Pesticide Programs (APPL)
Registration Division (7504C)
Environmental Protection Agency (EPA)
401 M Street, SW
Washington, DC 20460-0001

SUBJECT: Fuji Chemical Industries, Ltd. Establishment Number Application

Dear Mr. Swindell:

Fuji Chemical Industries, Ltd. ("Fuji") is designating Ciba® Expert Services, Ciba Specialty Chemicals Corporation, 4090 Premier Drive High Point, North Carolina 27261 as our agent in the submittal of Application of our facility Establishment Number.

Ciba® Expert Services has authority to act as our agent regarding these registrations.

Sincerely,

Hajime Takanashi
Managing Director
Fuji Chemical Industries, Ltd.

DECISION PKG. NO. 335174 SUBM. DUE DATE 1/21/04

SUBMISSION BAR CODE # 748511 REVIEWER MT

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 59824-2 PM 33 ACTION CODE 302

DESCRIPTOR Response to PRN2001-1 **FQPA** ✓ **NFQPA** ____

[ ] CHILD RESISTANT PACKAGING: [ ] REQUIRED [ ] NOT REQUIRED

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL [ ] RESTRICTED USE

DATE ON APPLICATION*	EPA RECEIVE DATE	PM RECEIVE DATE
10/22/03	10/29/03	10/24/03

METHOD OF SUPPORT		FORMULATORS EXEMPTION	
[ ] CITE-ALL	[ ] SELECTIVE	[ ] SUBMITTED	[ ] NOT SUBMITTED
[ ] NOT SUBMITTED	[ ] N/A	[ ] N/A	

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
ACUTE TOX.				
RASSB TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER: :				

STATUS ____

RESPONSE CODE 17 RESPONSE DATE DEC 17 2003

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 17 2003

Kanebo Zeolite U.S.a., Inc.
350 Fifth Avenue, Suite 2018
New York, N.Y. 10118

AGENT: Olivia D. Laird
501 S. Lincoln Avenue
Sterling, VA 20164-2024

Attention: Osamu Hasegawa, President

Subject: Bactekeller AZ
EPA Registration No. 59824-2
Amendment Dated October 22, 2003

The amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

- In response to PR Notice 2001-1

General Comments

A stamped copy of the accepted labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimcrobials Division (7510C)

Enclosure

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

(Front Panel Rev. 10/21/03)

BACTEKILLER AZ

(Silver-Zinc Zeolite)

BACTEKILLER AZ is an antimicrobial powder for commercial and industrial use designed to be incorporated into various materials during varying stages of the manufacturing process to impart antimicrobial activity to the manufactured materials. For more details of the various materials refer to the supplemental labeling for uses of Bactekiller AZ.

ACTIVE INGREDIENT:

Silver as elemental 3.5%
Zinc as elemental 6.1%
INERT INGREDIENTS: 90.4%
TOTAL 100.0%

***From zinc sodium alumino silicate complex**

Keep Out of Reach of Children

CAUTION

FIRST AID STATEMENTS
◆ **IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person to sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
◆ **IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
◆ **If Inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice.
◆ **IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
◆ **Have the product container or label with you when calling a poison control center or doctor, or going for treatment.** ◆ **In case of emergency, call the National Pesticide Telecommunications Network at 1 (800) 858-7378.** **Emergency Phone: (81) 6-6348-5031, Osaka, Japan, Kanebo Gohsen, LTD.**

Net Contents: 10 lbs; 20 lbs; or 100 lbs.

EPA REG.NO. 59824-2
EPA EST. NO. 59824-JP-001

Kanebo U.S.A.INC.
693 Fifth Avenue, 17th Floor
New York, NY 10022 U.S.A.
Tel:(0212)339-9700

ACCEPTED

DEC 17 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 5-9814-2

BACTEKILLER AZ
(Silver-Zinc Zeolite)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful if swallowed. Avoid contact with skin, eyes, or clothing. Avoid contamination of cooking utensils and food preparation surfaces.

ENVIRONMENTAL HAZARDS: this product is toxic to fish. Keep out of any natural body of water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge unused material into natural bodies of water unless in accordance with a NPDES permit.

STORAGE AND DISPOSAL: Do not store in area accessible to children. Do not store in place where food or feed may come in contact with the product. Keep away from direct su nlight. Unused material should be disposed of on site or an approved waste disposal facility.

CONTAINER DISPOSAL: Empty container thoroughly and rinse with water. Dispose in regular trash collection.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

ACCEPTED
DEC 17 2003
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 59824-2

BLENDING AND FORMULATING INSTRUCTIONS FOR THE LISTED MATERIALS

BACTEKILLER AZ is a silver zinc zeolite powder designed to be incorporated into various materials at various stages of their manufacturing process to impart antimicrobial properties to the manufactured materials. The powder can be incorporated into the materials as an integral part of the finished products throughout their entire thickness,or as a film over the surfaces of the manufactured materials,depending on the particular method of manufacture of the finished materials and needs of the manufacturer.

Bactekiller AZ may be incorporated into the following materials at the specified Maximum In hibitory Concentrations (MIC) on a dry weight basis of finished products.

APPLICATION	MIC
Plastic Film: (Non food use only and no water pipes) P Polypropylene, Polyvinyl chloride, Polyacetate, and Polyester	1.50%
Paint: (water base and solvent base)	1.50%
Paper coating: (non food packaging paper, no food contact) (not for paper production use)	1.50%
Adhesive: (non food contact) plywood adhesives	2.00%
Synthetic Fibers: Polyester, Nylon, Polypropylene, Acrylic, and Rayon	1.50%
Pigments: Dyestuffs and inks	1.00%

Textile Finishing and Manufacturing 0.75%

For details in *blending* BACTEKILLER AZ with these materials refer to supplemental labeling.

(SUPPLEMENTAL LABELING Rev. 10/21/03)

BACTEKILLER AZ
(Silver-Zinc Zeolite)

Claims: Bactekiller AZ is to be incorporated into the following materials at suitable stages of the manufacturing process to impart antimicrobial activity to the treated materials, and thus make them self sanitized to suppress the growth of bacteria and mold responsible for unpleasant odors and discoloration of the treated materials.

Fibers: polyester, polypropylene, nylon, polyethylene, acrylic, and rayon

Applications:
Home furnishings: mattress cover pads, sheets, blankets, quilt and pillow Fiberfill, curtain and drapery, carpet and carpet underlay, upholstery, wiping cloth, towels, bags, wall cover fabrics, cushion pads.

Apparel: Interlinings, industrial uniforms, coats and aprons, sports wear, sleepwear, stockings, socks, helmets, caps, gloves.

Industrial: brush bristles, shoe linings, artificial leather, filter (non food contact), book covers, sail cloth, and ropes.

Plastic Films and Molded Plastics:(non-food use only and no water pipes):
Types: polyester, polyamide, polypropylene, polyethylene, polysiloxane, polyethylene copolymer, polyvinyl alcohol, epoxy resin, phenol resin, polycarbonate, cellulose acetate, polystyrene, polyurethane, acrylic resin, methyl methacrylate, acrylonitrile butadiene styrene copolymer.

Applications:
Gloves, shower curtains, air ducts, cable wraps, protective covers, Non-food contact foam containers, brush handles, sponges, insulators, gaskets, non-food tubing, non-food contact containers and film, furniture.

Paper coatings (not for food packaging or for food contact), (Not for paper production use):
Types: Cellulosic, synthetic, specialty, reinforced.

Applications:
Wallpaper, non-food wrap, wiping towels, book covers, corrugated paper filters.

Paint: Water based, oil based paints: for interior surfaces

Adhesives: (Not for adhesives for paper or containers that will come in contact with food)

Aplications:
Adhesive for plywood manufacture, adhesive for cement tile and sealants.

ACCEPTED
DEC 17 2003
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 59821-2

Please read instructions on reverse before completing form. Form Approved OMB No. 2070-0060

EPA United States Environmental Protection Agency Washington, DC 20460

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number: 268934

Application for Pesticide - Section I

1. Company/Product Number: 59824-2
2. EPA Product Manager: Marshall Swindell
3. Proposed Classification: [X] None [ ] Restricted
4. Company/Product (Name): Bactekeller AZ
PM#: 31
5. Name and Address of Applicant *(Include ZIP Code)*
Kanebo Zeolite U.S.A., Inc.
350 Fifth Ave., Suite 2018
New York, New York 10118
[ ] *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Agency initiated amended in accordance with PR 2001-1.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: [X] Yes* [ ] No
** Certification must be submitted*

Unit Packaging: [ ] Yes [X] No
If "Yes" Unit Packaging wgt. No. per container

Water Soluble Packaging: [ ] Yes [X] No
If "Yes" Package wgt No. per container

2. Type of Container: [ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____

3. Location of Net Contents Information: [X] Label [ ] Container
4. Size(s) Retail Container: 10, 20 & 100 pounds
5. Location of Label Directions: [X] On Label [ ] On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: [X] Lithograph [X] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name: Olivia D. Laird
Title: President of Laird's Regulatory Consultants, Inc.
Telephone No. (Include Area Code): (703) 471-6590

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: for
3. Title: President
4. Typed Name: Osamu Hasegawa
5. Date: October 22, 2003
6. Date Application Received (Stamped)

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number: 268934

Application for Pesticide - Section I

1. Company/Product Number: 59824-2
2. EPA Product Manager: Marshall Swindell
3. Proposed Classification: [x] None [ ] Restricted
4. Company/Product (Name): Bactekeller AZ
PM#: 31
5. Name and Address of Applicant *(Include ZIP Code)*
Kanebo Zeolite U.S.A., Inc.
350 Fifth Ave., Suite 2018
New York, New York 10118
[ ] *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- [x] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Agency initiated amended in accordance with PR 2001-1.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[x] Yes* [ ] No	[ ] Yes [x] No	[ ] Yes [x] No	[x] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [x] Label [ ] Container
4. Size(s) Retail Container: 10, 20 & 100 pounds
5. Location of Label Directions: [x] On Label [ ] On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: [x] Lithograph [x] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Olivia D. Laird	President of Laird's Regulatory Consultants, Inc.	(703) 471-6590

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: for
3. Title: President
4. Typed Name: Osamu Hasegawa
5. Date: October 22, 2003

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

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1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
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4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

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Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

PM 31 59824-2 pg 1/6

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (TS-767)
WASHINGTON, DC 20460

NOTICE OF PESTICIDE: [X] REGISTRATION [ ] REREGISTRATION

(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

EPA REGISTRATION 59824-2

DATE OF ISSUANCE JUL 25 1994

TERM OF ISSUANCE

NAME OF PESTICIDE PRODUCT

Bactekiller AZ

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Kanebo Zeolite U.S.A. Inc.
350 Fifth Ave. Suite 2018
New York, NY 10118

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) and 3(c)(7)(B) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Submit the information as requested in our letter of March 15, 1993 (item #2). The six acute toxicity studies are still incomplete. The stability of the test material was not included in the study. Your submission dated June 23, 1993 did not include this information.

3. Submit acceptable Environmental Fate studies to support the uses declared on the label. Refer to our letter dated July 13, 1994.

4. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration No. 59824-2".

[X] ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

EPA Form 8570-6 (Rev. 5-76) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

b. Revise the phrase "... the manufacturing process to impart antimicrobial activity to the manufactured materials..."

to read: (two locations)

"...the manufacturing processs to preserve the integrity of the manufactured materials..."

c. Include the subheading: Pesticide Disposal. Place this heading under the Storage and Disposal Section.

d. Revise the entire Environmental Hazards section to read:

ENVIRONMENTAL HAZARDS
This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

e. Add the folllowing additional precautionary statements:

Causes eye irritation. Wash thouroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

f. Add the following descriptor to the top of the front panel:

A preservative for use in the manufacture of plastic films, paint (interior), paper coatings adhesives, synthetic fibers and pigments.

Submit five (5) copies of the final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Marshall Swindell
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosures

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

(Front Panel Label for BACTEKILLER AZ - EPA FS 59824-E)

BACTEKILLER AZ
Silver-Zinc Zeolite

BACTEKILLER AZ is an antimicrobial powder for commercial and industrial use designed to be incorporated into various materials during varying stage of the manufacturing process to impart antimicrobial activity to the manufactured materials. For more details of the various materials refer to the supplemental labeling for uses of Bactekiller AZ.

Active Ingredients	
Silver* as elemental	3.5 %
Zinc* as elemental	6.5 %
Inert Ingredients	90.0 %

* from silver-zinc sodium alumino silicate complex

KEEP OUT OF REACH OF CHILDREN
CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful if swallowed. Avoid contact with skin, eyes, or clothing. Avoid contamination of cooking utensils and food preparation surfaces.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, drink one or two glasses of water and induce vomiting by touching the back of the throat with finger. Repeat until vomit fluid is clear. Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person. If on skin, remove contaminated clothing and wash affected area with soap and water. If irritation persists,contact a physician. If in eyes, flush eyes for at least 15 minutes with water. If irritation persists contact a physician.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Keep out of any natural body of water. Do not contaminate water by cleaning od equipment or disposal of wastes. Do not discharge unused material into natural bodies of water unless in accordance with a NPDES permit.

STORAGE AND DISPOSAL: Do not store in areas accessible to children. Do not store in places where food or feed may come in contact with the product. Keep away from direct sunlight. Unused material should be disposed of on site or approved waste disposal facility.

CONTAINER DISPOSAL: Empty container thoroughly and rinse with water. Dispose in regular trash collection.

EPA Reg. No. 59824- EPA Est. No. 59824-JF-1

Net Contents: 10 lbs; 20 lbs; or 100 lbs.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUL 25 1994

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 59824-2

KANEBO ZEOLITE U.S.A.,INC.
350 Fifth Ave., Suite 2018
New York, N.Y. 10118

BEST AVAILABLE COPY

(Back Panel for Bactekiller AZ - EPA FS 59824-E)

BACTEKILLER AZ
Silver-Zinc Zeolite

DIRECTIONS FOR USE
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

BLENDING AND FORMULATING INSTRUCTIONS
FOR THE LISTED MATERIALS

BACTEKILLER AZ is a silver zinc zeolite powder designed to be incorporated into various materials at various states of their manufacturing process to impart antimicrobial properties to the manufactured materials. The powder can be incorporated into the materials as an integral part of the finished products throughout their entire thickness, or as a film over the surfaces of the manufactured materials, depending on the particular method of manufacture of the finished materials and needs of the manufacturer.

Bactekiller AZ may be incorporatedinto the following materials at the specific Maximum Inhibitory Concentrations (MIC) on a dry weight basis of finished products.

APPLICATION		MIC
Plastic,Film:	(non-food use only and no water pipes)	
	polyethylene, polypropylene, polyvinyl-chloride, polyacetate, and polyester	1.50 %
Paint:	(Water base and solvent base) (not for exterior paint)	1.50 %
Paper coating:	(non food packaging paper, no food contact) (not for paper production use)	1.50 %
Adhesive:	(non food contact) plywood adhesives	2.00 %
Synthetic Fibers:	polyester, nylon, polypropylene, Acrylic, and Rayon	1.50 %
Pigments:	dyestuffs and inks	1.00 %
Textile Finishing and Manufacturing		0.75 %

For details in blending BACTEKILLER AZ with these materials refer to supplemental labeling.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUL 25 1994

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 59824-2

BEST AVAILABLE COPY

SUPPLEMENTAL LABELING

BACTEKILLER AZ - PS 59824-E
(Silver-Zinc Zeolite)

Claims: Bactekiller AZ is to be incorporated into the following materials at suitable stages of the manufacturing process to impart antimicrobial activity to the treated materials and thus make them bacteriostatic against odor causing bacteria.

Fibers: polyester, polypropylene, nylon, polyethylene, acrylic and rayon

applications:
Home Furnishings: mattress cover pads, sheets, blankets, quilt and pillow fiber fill, curtain and drapery, carpet and carpet underlay, upholstery, wiping cloths, towels, bags, wallcover fabrics, and cushion pads.

Apparel: interlinings, industrial uniforms, coats and aprons, sportswear, sleepwear, stockings, socks, helmets, caps and gloves.

Industrial: brush bristles, shoe linings, artificial leather, filter (non food contact), book covers, sail cloth and ropes.

Plastic Films and Molded Plastics: (non-food use only and no water pipes)
Types: polyester, polyamide, polypropylene, polyethylene, polysiloxane, polyethylene copolymer, polyvinyl alcohol, epoxy resin, phenol resin, polycarbonate, cellulose acetate, polystyrene, polyurethane, acrylic resin, methyl methacrylate, acrylonitrile butadiene styrene copolymer.

Applications: gloves, shower curtains, [redacted] cable wraps, protective covers, non-food contact foam containers, brush handles, sponges, insulators, gaskets, non-food tubing, non-food contact containers and film, furniture.

Paper coating:(not for food packaging or for food contact)
(not for paper production use)
Types: cellulosic, synthetic, speciality, reinforced.

Applications: wall paper, non-food wrap, wiping towels, book covers, corrugated paper filters.

Paint: Water based and oil based paints for interior surface.(not for exterior paint)

Adhesives:(not for adhesive for paper or containers that will come in contact with food)
Applications: adhesive for plywood manufacture, adhesive for cement tile and sealants.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL 25 1994

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 59824-2

BEST AVAILABLE COPY

Receipt for Section 3

S: 748511

Regulatory Type: Product Registration - Section 3

Resubmission: Yes No

Application Type: Amendment

Company: 59824 KANEBO USA, INC

Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 59824-2 Product Name: BACTEKILLER AZ

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 22-Oct-2003 OPP Rec'vd Date: 23-Oct-2003

Front End Date: 24-Oct-2003 Risk Manager Send Date: 24-Oct-2003

Fast Track: Studies: New Ingredient:

Receipt Description:

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date:

Form B: Signature Date:

Print Letter

Enter More Information

Due 1/21/04

Rec # 335174

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 24, 2003

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OLIVIA D. LAIRD
501 S. LINCOLN AVENUE
STERLING, VA 20164-2024

PRODUCT NAME: BACTEKILLER AZ
COMPANY NAME: KANEBO USA, INC
OPP IDENTIFICATION NUMBER: 268934
EPA FILE SYMBOL: 59824-2
EPA RECEIPT DATE: 10/23/03

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 33, at (703) 308-6341.

Sincerely,

J. Wrice

Front End Processing Staff
Information Services Branch
Information Resources and Services Division

SUBMISSION BAR CODE # 5473689 REVIEWER MT

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 59824-2 PM 31 ACTION CODE 3W

DESCRIPTOR Corrected Final labels

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION
[ ] NON-RESIDENTIAL USE ONLY
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION	EPA RECEIVE DATE	PM RECEIVE DATE
09 15 94	09 15 94	09 15 94

METHOD OF SUPPORT

[ ] CITE-ALL
[ ] SELECTIVE
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

FORMULATORS EXEMPTION

[ ] SUBMITTED
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
TOXICOLOGY				
HED TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER				

STATUS

SEP 23 1994
SEP 26 1994

RESPONSE CODE 39 RESPONSE DATE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 23 1994

Kanebo Zeolite U.S.A. Inc.
350 Fifth Avenue, Suite 2018
New York, N.Y. 10118

Attn: Olivia Laird
Agent

Subject: BacteKiller AZ
EPA Registration No. 59824-2
Letter Dated Sepyember 15, 1994

The submitted final printed labels have been placed in your file. They have not been reviewed in accordance with PR Notice 82-2.

If you have any questions concerning this letter, please contact Martha Terry at (703) 305-6982.

Sincerely,

Marshall Swindell
Acting Product Manager 31
Antimicrobial Program Branch
Registration Division 7505C

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

(Front Panel Label)

BACTEKILLER AZ
Silver-Zinc Zeolite

BACTEKILLER AZ is a antimicrobial powder for commercial and industrial use designed to be incorporated into various materials during varying stages of the manufacturing process to preserve the intergity of the manufactured materials. A preservative for use in the manufacture of plastic films, paint (interior), paper coating, adfhesive, synthetic fibers and pigments. For more details of the various materials refer to the supplemental labeling for uses of Bactekiller AZ.

ACTIVE INGREDIENT:	
Silver * as elemental	3.5%
Zinc * as elemental	6.5%
INERT INGREDIENTS:	90.0%

* from silver-zinc sodium alunino silicate complex

KEEP OUT OF REACH OF CHILDREN
CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful if swallowed. Avoid contact with skin, eyes, or clothing. Avoid contamination of cooking utensils and food preparation surfaces. Causes eye irritation. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, drink one or two glasses of water and induce vomiting by touching the back of the throat with finger. Repeat until vomit fluid is clear. Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person. If on skin, remove contaminated clothing and wash affected area with soap and water. If irritation persists, contact a physician. If in eyes, flush eyes for at least 15 minutes with water. If irritation persists contact a physician.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment authority. For guidance contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL, Pesticide Disposal: Do not store in areas accessible to children. Do not store in places where food or feed may come in contact with the product. Keep away from direct sunlight. Unused material should be disposed of on site or an approved waste disposal facility.

CONTAINER DISPOSAL: Empty container thoroughly and rinse with water. Dispose in regular trash collection.

EPA Reg. No. 59824-2

EPA Est. No. 59824-JP-1

Net Contents: 10 lbs; 20 lbs; or 100 lbs.

KANEBO ZEOLITE U.S.A., INC.
350 Fifth Ave., Suite 2018
New York, N. Y. 10118

(Back Panel for Bactekiller AZ -EPA Reg. No. 59824-2)

BACTEKILLER AZ
Silver-Zinc Zeolite

DIRECTIONS FOR USE
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

BLENDING AND FORMULATING INSTRUCTIONS
FOR THE LISTED MATERIALS

BACTEKILLER AZ is a silver zinc zeolite powder designed to be incorporated into various materials at various stages of their manufacturing process to preserve the intergity of the manufactured materials. The powder can be incorporated into the materials as an integral part of the finished products throughout their entire thickness, or as a film over the surfaces of the manufactured materials, depending on the particular method of manufacture of the finished materials and needs of the manufacturer.

Bactekiller AZ may be incorporated into the following materials at the specified Maximum Inhibitory Concentrations (MIC) on a dry weight basis of finished products.

APPLICATION	MIC
Plastic Film: Non-food use only and no water pipes, Polyethylene, polypropylene, polyvinyl chloride, polyacetate, and polyester	1.50%
Paint (Water base and solvent base)	1.50%
Paper Coatings (non food packaging paper, no food contact) not for paper production use.	1.50%
Adhesive (non food contact): plywood adhesives	2.00%
Synthetic Fibers: Polyester, Nylon, Polypropylene, Acrylic, and Rayon	1.50%
Pigments: dyestuffs and inks	1.00%
Textile Finishing and Manufacturing	0.75%

For details in blending BACTEKILLER AZ with these materials refer to supplemental labeling.

SUPPLEMENTAL LABELING

BACTEKILLER AZ - EPA Reg. No. 59824-2
(Silver-Zinc Zeolite)

Claims: **Bactekiller AZ** is to be incorporated into the following materials at suitable stages of the manufacturing process to impart antimicrobial activity to the treated materials, and thus make them suppress the growth of bacteria and mold responsible for unpleasant odors and discoloration of the treated materials.

Fibers: Polyester, polypropylene, nylon, polyethylene, acrylic, rayon

applications:
home furnishings: mattress cover pads, sheets, blankets, quilt and pillow fiber fill, curtain and drapery, carpet and carpet underlay, upholstery, wiping cloths, towels, bags, wallcover fabrics, cushion pads

apparel: interlinings, industrial uniforms, coats and aprons, sportswear, sleepwear, stockings, socks, helmets, caps, gloves.

Industrial: brush bristles, shoe linings, artificial leather, filter (non food contact), book covers, sail cloth, ropes.

Plastic Films and Molded Plastics:

types: polyester, polyamide, polypropylene, polyethylene, polysiloxane, polyethylene copolymer, polyvinyl alcohol, epoxy resin, phenol resin, polycarbonate, cellulose acetate, polystyrene, polyurethane, acrylic resin, methyl methacrylate, acrylonitrile butadiene styrene copolymer.

Applications: gloves, shower curtains, cable wraps, protective covers, non-food contact foam containers, brush handles, sponges, insulators, gaskets, non-food tubing, non-food contact containers and film, furniture.

Paper Coatings (not for food packaging or for food contact): not for paper products
types: cellulosic, synthetic, specialty, reinforced

applications: wallpaper, non-food wrap, wiping towels, book covers, corrugated paper filters.

Paint: water based, oil based paints; for interior surfaces (not for exterior paint)

Adhesives (not for adhesives for paper or containers that will come in contact with food):

Applications: adhesive for plywood manufacture, adhesive for cement tile and sealants

LAIRD'S REGULATORY CONSULTANTS
Over 19 Years Experience and Expertise in
The Regulation of Pesticide Products

Mr. Marshall Swindell, 31
Environmental Protection Agency
Antimicrobial Branch
Registration Division (H7505C)
Office of Pesticide Programs
401 M Street, S. W.
Washington, D. C. 20460

August 11, 1994

SUBJECT: Bactekiller AZ
EPA REG. NO. 59824-2
final label in response to Reg. Notice of 7/25/94

Dear Mr. Swindell:

Enclosed please find five (5) copies of the final label for the product listed above for placement in the file.

Sincerely,

Olivia D. Laird
President

Permanized
PLOVER BOND
25% COTTON FIBER

Olivia D Laird ♦ 501 S Lincoln Ave, Sterling, VA 20164 ♦ 703/471-6590 ♦ 703/471-6269 (fax)

LAIRD REGULATORY CONSULTANTS
Over 19 Years Experience and Expertise in
The Regulation of Pesticide Products

Ms. Martha Delaney, PM 31
Environmental Protection Agency
Antimicrobial Program Branch
Registration division (7505C)
401 M Street, SW
Washington, D. C. 20460

September 15, 1994

SUBJECT: Bactekiller AC, EPA REG. NO. 59824-1
Bactekiller AZ, EPA REG. NO. 59824-2
Bactekiller A, EPA REG. NO. 59824-3
Your telephone call of August 14, 1994

Dear Ms. Delaney:

In response to your telephone call of September 14, 1994 I have herewith enclosed five copies of the revised labels for each of the products listed above. All references to water treatment have been deleted per your instructions. I trust this is sufficient to obtain approval.

Sincerely,

Olivia D. Laird
President

Olivia D Laird ♦ 501 S Lincoln Ave, Sterling, VA 20164 ♦ 703/471-6590 ♦ 703/471-6269 (fax)

SUBMISSION BAR CODE # 5473031 REVIEWER MT

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 59824-2 PM 31 ACTION CODE 3CU

DESCRIPTOR Final Labels

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION
[ ] NON-RESIDENTIAL USE ONLY
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION	EPA RECEIVE DATE	PM RECEIVE DATE
08 11 94	08 15 94	08 15 94

METHOD OF SUPPORT

[ ] CITE-ALL
[ ] SELECTIVE
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

FORMULATORS EXEMPTION

[ ] SUBMITTED
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
TOXICOLOGY				
HED TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER				

STATUS Called Agent to resubmit final labels in accordance to the draft labels that were accepted on 7/25/94.

RESPONSE CODE 38 RESPONSE DATE 9/13/94

KANEBO ZEOLITE U.S.A., INC.
350 Fifth Ave., Suite 2018
New York, N. Y. 10118

(Back Panel for Bactekiller AZ -EPA Reg. No. 59824-2)

BACTEKILLER AZ
Silver-Zinc Zeolite

DIRECTIONS FOR USE
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

BLENDING AND FORMULATING INSTRUCTIONS
FOR THE LISTED MATERIALS

BACTEKILLER AZ is a silver zinc zeolite powder designed to be incorporated into various materials at various stages of their manufacturing process to preserve the intergity of the manufactured materials. The powder can be incorporated into the materials as an integral part of the finished products throughout their entire thickness, or as a film over the surfaces of the manufactured materials, depending on the particular method of manufacture of the finished materials and needs of the manufacturer.

Bactekiller AZ may be incorporated into the following materials at the specified Maximum Inhibitory Concentrations (MIC) on a dry weight basis of finished products.

APPLICATION	MIC
Plastic Film: Polyethylene, polypropylene, polyvinyl chloride, polyacetate, and polyester	1.50%
Paint (Water base and solvent base)	1.50%
Paper (non food packaging paper, no food contact)	1.50%
Adhesive (non food contact): plywood adhesives	2.00%
Synthetic Fibers: Polyester, Nylon, Polypropylene, Acrylic, and Rayon	1.50%
Pigments: dyestuffs and inks	1.00%
Textile Finishing and Manufacturing	0.75%
Water Treatment (**not for drinking water**): to combat slime producing microorganisms in recirculating water cooling systems and in water processing water such water used in breweries to cool the outside of bottles and in canneries to cool the outside of cans	0.01%

For details in blending BACTEKILLER AZ with these materials refer to supplemental labeling.

(Front Panel Label)

BACTEKILLER AZ
Silver-Zinc Zeolite

BACTEKILLER AZ is a antimicrobial powder for commercial and industrial use designed to be incorporated into various materials during varying stages of the manufacturing process to preserve the intergity of the manufactured materials. A preservative for use in the manufacture of plastic films, paint (interior), paper coating, adfhesive, synthetic fibers and pigments. For more details of the various materials refer to the supplemental labeling for uses of Bactekiller AZ.

ACTIVE INGREDIENT:	
Silver * as elemental	3.5%
Zinc * as elemental	6.5%
INERT INGREDIENTS:	90.0%

* from silver-zinc sodium alunino silicate complex

KEEP OUT OF REACH OF CHILDREN
CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful if swallowed. Avoid contact with skin, eyes, or clothing. Avoid contamination of cooking utensils and food preparation surfaces. Causes eye irritation. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, drink one or two glasses of water and induce vomiting by touching the back of the throat with finger. Repeat until vomit fluid is clear. Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person. If on skin, remove contaminated clothing and wash affected area with soap and water. If irritation persists, contact a physician. If in eyes, flush eyes for at least 15 minutes with water. If irritation persists contact a physician.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment authority. For guidance contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL, Pesticide Disposal: Do not store in areas accessible to children. Do not store in places where food or feed may come in contact with the product. Keep away from direct sunlight. Unused material should be disposed of on site or an approved waste disposal facility.

CONTAINER DISPOSAL: Empty container thoroughly and rinse with water. Dispose in regular trash collection.

EPA Reg. No. 59824-2 EPA Est. No. 59824-JP-1

Net Contents: 10 lbs; 20 lbs; or 100 lbs.

SUPPLEMENTAL LABELING

BACTEKILLER AZ - EPA Reg. No. 59824-2
(Silver-Zinc Zeolite)

Claims: Bactekiller AZ is to be incorporated into the following materials at suitable stages of the manufacturing process to impart antimicrobial activity to the treated materials, and thus make them self sanitized to suppress the growth of bacteria and mold responsible for unpleasant odors and discoloration of the treated materials.

Fibers: Polyester, polypropylene, nylon, polyethylene, acrylic, rayon

applications:
home furnishings: mattress cover pads, sheets, blankets, quilt and pillow fiber fill, curtain and drapery, carpet and carpet underlay, upholstery, wiping cloths, towels, bags, wallcover fabrics, cushion pads

apparel: interlinings, industrial uniforms, coats and aprons, sportswear, sleepwear, stockings, socks, helmets, caps, gloves.

Industrial: brush bristles, shoe linings, artificial leather, filter (non food contact), book covers, sail cloth, ropes.

Plastic Films and Molded Plastics:

types: polyester, polyamide, polypropylene, polyethylene, polysiloxane, polyethylene copolymer, polyvinyl alcohol, epoxy resin, phenol resin, polycarbonate, cellulose acetate, polystyrene, polyurethane, acrylic resin, methyl methacrylate, acrylonitrile butadiene styrene copolymer.

Applications: gloves, shower curtains, cable wraps, protective covers, non-food contact foam containers, brush handles, sponges, insulators, gaskets, non-food tubing, non-food contact containers and film, furniture.

Paper (not for food packaging or for food contact):

types: cellulosic, synthetic, specialty, reinforced

applications: wallpaper, non-food wrap, wiping towels, book covers, corrugated paper filters.

Paint: water based, oil based paints; for interior surfaces (not for exterior paint)

Adhesives (not for adhesives for paper or containers that will come in contact with food):

Applications: adhesive for plywood manufacture, adhesive for cement tile and sealants

Water treatment (not for treating water for drinking purposes):

to combat slime producing microorganisms in recirculating cooling waters, water processing water, such as used in breweries to cool outside of bottles and cans in canneries

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION *(TS-767)*
WASHINGTON, DC 20460

NOTICE OF PESTICIDE: ☒ REGISTRATION ☐ REREGISTRATION

(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

EPA REGISTRATION: 59824-2

DATE OF ISSUANCE: JUL 25 1994

TERM OF ISSUANCE:

NAME OF PESTICIDE PRODUCT: Bactekiller AZ

NAME AND ADDRESS OF REGISTRANT *(Include ZIP code)*

Kanebo Zeolite U.S.A. Inc.
350 Fifth Ave. Suite 2018
New York, NY 10118

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) and 3(c)(7)(B) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Submit the information as requested in our letter of March 15, 1993 (item #2). The six acute toxicity studies are still incomplete. The stability of the test material was not included in the study. Your submission dated June 23, 1993 did not include this information.

3. Submit acceptable Environmental Fate studies to support the uses declared on the label. Refer to our letter dated July 13, 1994.

4. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration No. 59824-2".

☒ ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL | DATE

EPA Form 8570-6 (Rev. 5-76) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

b. Revise the phrase "... the manufacturing process to impart antimicrobial activity to the manufactured materials..."

to read: (two locations)

"...the manufacturing processs to preserve the integrity of the manufactured materials..."

c. Include the subheading: Pesticide Disposal. Place this heading under the Storage and Disposal Section.

d. Revise the entire Environmental Hazards section to read:

ENVIRONMENTAL HAZARDS
This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

e. Add the folllowing additional precautionary statements:

Causes eye irritation. Wash thouroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

f. Add the following descriptor to the top of the front panel:

A preservative for use in the manufacture of plastic films, paint (interior), paper coatings, adhesives, synthetic fibers and pigments.

Submit five (5) copies of the final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Marshall Swindell
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosures

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

(Front Panel Label for BACTEKILLER AZ - EPA FS 59824-E)

BACTEKILLER AZ
Silver-Zinc Zeolite

BACTEKILLER AZ is an antimicrobial powder for commercial and industrial use designed to be incorporated into various materials during varying stage of the manufacturing process to impart antimicrobial activity to the manufactured materials. For more details of the various materials refer to the supplemental labeling for uses of Bactekiller AZ.

Active Ingredients	
Silver* as elemental	3.5 %
Zinc* as elemental	6.5 %
Inert Ingredients	90.0 %

* from silver-zinc sodium alumino silicate complex

KEEP OUT OF REACH OF CHILDREN
CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful if swallowed. Avoid contact with skin, eyes, or clothing. Avoid contamination of cooking utensils and food preparation surfaces.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, drink one or two glasses of water and induce vomiting by touching the back of the throat with finger. Repeat until vomit fluid is clear. Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person. If on skin, remove contaminated clothing and wash affected area with soap and water. If irritation persists,contact a physician. If in eyes, flush eyes for at least 15 minutes with water. If irritation persists contact a physician.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Keep out of any natural body of water. Do not contaminate water by cleaning od equipment or disposal of wastes. Do not discharge unused material into natural bodies of water unless in accordance with a NPDES permit.

STORAGE AND DISPOSAL: Do not store in areas accessible to children. Do not store in places where food or feed may come in contact with the product. Keep away from direct sunlight. Unused material should be disposed of on site or approved waste disposal facility.

CONTAINER DISPOSAL: Empty container thoroughly and rinse with water. Dispose in regular trash collection.

EPA Reg. No. 59824- EPA Est. No. 59824-JP-1

Net Contents: 10 lbs; 20 lbs; or 100 lbs.

KANEBO ZEOLITE U.S.A.,INC.
350 Fifth Ave., Suite 2018
New York, N.Y. 10118

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL 25 1994

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 59824-2

(Back Panel for Bactekiller AZ - EPA FS 59824-E)

BACTEKILLER AZ
Silver-Zinc Zeolite

DIRECTIONS FOR USE
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

BLENDING AND FORMULATING INSTRUCTIONS
FOR THE LISTED MATERIALS

BACTEKILLER AZ is a silver zinc zeolite powder designed to be incorporated into various materials at various states of their manufacturing process to impart antimicrobial properties to the manufactured materials. The powder can be incorporated into the materials as an integral part of the finished products throughout their entire thickness, or as a film over the surfaces of the manufactured materials, depending on the particular method of manufacture of the finished materials and needs of the manufacturer.

Bactekiller AZ may be incorporatedinto the following materials at the specific Maximum Inhibitory Concentrations (MIC) on a dry weight basis of finished products.

APPLICATION		MIC
Plastic,Film:	(non-food use only and no water pipes)	
	polyethylene, polypropylene, polyvinyl-chloride, polyacetate, and polyester	1.50 %
Paint:	(Water base and solvent base) (not for exterior paint)	1.50 %
Paper coating:	(non food packaging paper, no food contact) (not for paper production use)	1.50 %
Adhesive:	(non food contact) plywood adhesives	2.00 %
Synthetic Fibers:	polyester, nylon, polypropylene, Acrylic, and Rayon	1.50 %
Pigments:	dyestuffs and inks	1.00 %
Textile Finishing and Manufacturing		0.75 %

For details in blending BACTEKILLER AZ with these materials refer to supplemental labeling.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUL 25 1994

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 59824-2

SUPPLEMENTAL LABELING

BACTEKILLER AZ - FS 59824-E
(Silver-Zinc Zeolite)

Claims: Bactekiller AZ is to be incorporated into the following materials at suitable stages of the manufacturing process to impart antimicrobial activity to the treated materials and thus make them bacteriostatic against odor causing bacteria.

Fibers: polyester, polypropylene, nylon, polyethylene, acrylic and rayon

applications:
Home Furnishings: mattress cover pads, sheets, blankets, quilt and pillow fiber fill, curtain and drapery, carpet and carpet underlay, upholstery, wiping cloths, towels, bags, wallcover fabrics, and cushion pads.

Apparel: interlinings, industrial uniforms, coats and aprons, sportswear, sleepwear, stockings, socks, helmets, caps and gloves.

Industrial: brush bristles, shoe linings, artificial leather, filter (non food contact), book covers, sail cloth and ropes.

Plastic Films and Molded Plastics: (non-food use only and no water pipes)
Types: polyester, polyamide, polypropylene, polyethylene, polysiloxane, polyethylene copolymer, polyvinyl alcohol, epoxy resin, phenol resin, polycarbonate, cellulose acetate, polystyrene, polyurethane, acrylic resin, methyl methacrylate, acrylonitrile butadiene styrene copolymer.

Applications: gloves, shower curtains, [redacted] cable wraps, protective covers, non-food contact foam containers, brush handles, sponges, insulators, gaskets, non-food tubing, non-food contact containers and film, furniture.

Paper coating:(not for food packaging or for food contact)
(not for paper production use)
Types: cellulosic, synthetic, speciality, reinforced.

Applications: wall paper, non-food wrap, wiping towels, book covers, corrugated paper filters.

Paint: Water based and oil based paints for interior surface.(not for exterior paint)

Adhesives:(not for adhesive for paper or containers that will come in contact with food)
Applications: adhesive for plywood manufacture, adhesive for cement tile and sealants.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL 25 1994

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 59824-2

Company Data Report

Company No.: 59824

Name: KANEBO USA, INC

Address: 693 FIFTH AVENUE, 17TH FLOOR
NEW YORK, NY 10022
USA

Contact: Phone:

Agent: N
Consortium: N
Undeliverable: N

Company Types	Active Flag
Manufacturer	Y

SUBMISSION BAR CODE # _____ REVIEWER _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 59824-E PM 31 ACTION CODE 116

DESCRIPTOR Quail-LC50 (AZ)

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION
[ ] NON-RESIDENTIAL USE ONLY
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION	EPA RECEIVE DATE	PM RECEIVE DATE
08 04 93	08 05 93	08 09 93

METHOD OF SUPPORT

[X] CITE-ALL 6-22-84
[ ] SELECTIVE
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

FORMULATORS EXEMPTION

[ ] SUBMITTED
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
TOXICOLOGY				
HED TOX.				
ENVIRON. FATE				
FISH/WILDLIFE	8/13			
OTHER _____				

STATUS _____

RESPONSE CODE 38 RESPONSE DATE JUL 13 1994

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 13 1994

Kanebo Zeolite U.S.A. Inc.
350 Fifth Ave Suite 2018
New York, NY 10118

Attention: Olivia Laird
Agent

Subject: Bactekiller AZ
EPA File Symbol No. 59824-E
Your Submission Dated August 4, 1993

The Agency has completed it review of the additional Fish and Wildlife information as submitted above. No additional Fish & Wildlife data is required at this time.

Just a reminder, as discussed with your company on several occassions, that since the testing of this product was performed with the formulated product, any change in use patterns and/or change of formulation (ie. raising the concentration or either the zinc or silver) may require additional data.

If you have any questions concerning this letter, contact V. Goncarovs at 703-305-6663.

Sincerely yours,

Marshall Swindell
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

DP Barcode : D194114
PC Code No : 072501,022501
EEB Out : FEB 16 1994

To: John Lee
Product Manager 31
Registration Division (H7505C)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 059824-E
Chemical Name : Silver Zinc Zeolite
Type Product : Microbiocide
Product Name : Bactekiller AZ
Company Name : Kanebo Zeolite USA, Inc.
Purpose : Submission of avian dietary LC50 study in support of registration.

Action Code : 116 Date Due : 12/11/93
Reviewer : H. Mansfield Date In : 08/17/93

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)	428709-01		72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

DP BARCODE: D194114

CASE: 280486 DATA PACKAGE RECORD DATE: 08/13/93
SUBMISSION: S446166 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 116 RESB NC-NON-FOOD/FEED U
CHEMICALS: 072501 Silver 0.0000%
129015 Zinc 0.0000%

ID#: 059824-E BACTEKILLER AZ (silver & zinc)
COMPANY: 059824 KANEBO ZEOLITE U.S.A., INC
PRODUCT MANAGER: 31 JOHN LEE 703-305-5675 ROOM: CM2 270
PM TEAM REVIEWER: VALDIS GONCAROVS 703-305-6663 ROOM: CM2 272
RECEIVED DATE: 08/05/93 DUE OUT DATE: 02/11/94

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 194114 EXPEDITE: Y DATE SENT: 08/13/93 DATE RET.: / /
CHEMICAL: 129015 Zinc
DP TYPE: 001 Submission Related Data Package
CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT	
DIV : EFED	08/13/93	02/17/94	ADMIN DUE DATE: 12/11/93
BRAN: EEB	08/17/93	/ /	NEGOT DATE: 12/11/93
SECT:	/ /	/ /	PROJ DATE: / /
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

review the study and itemize for the record the remaining data requirments for this product.

Previous reviewer: Heather Mansfield

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

DP BARCODE: D194114

CASE: 280486 DATA PACKAGE RECORD DATE: 08/13/93
SUBMISSION: S446166 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 116 RESB NC-NON-FOOD/FEED U
CHEMICALS: 072501 Silver 0.0000%
129015 Zinc 0.0000%

ID#: 059824-E BACTEKILLER AZ (silver & zinc)
COMPANY: 059824 KANEBO ZEOLITE U.S.A., INC
PRODUCT MANAGER: 31 JOHN LEE 703-305-5675 ROOM: CM2 270
PM TEAM REVIEWER: VALDIS GONCAROVS 703-305-6663 ROOM: CM2 272
RECEIVED DATE: 08/05/93 DUE OUT DATE: 02/11/94

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 194114 EXPEDITE: Y DATE SENT: 08/13/93 DATE RET.: / /
CHEMICAL: 129015 Zinc
DP TYPE: 001 Submission Related Data Package
CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT	
DIV : EFED	08/13/93	02/17/94	ADMIN DUE DATE: 12/11/93
BRAN: EEB	08/17/93	/ /	NEGOT DATE: 12/11/93
SECT:	/ /	/ /	PROJ DATE: / /
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

review the study and itemize for the record the remaining data requirments for this product.

Previous reviewer: Heather Mansfield

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 16 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Silver-Zinc Zeolite Data Review
DP Barcode: D194114
ID No: 059824-E

FROM: Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

2/15/94

TO: John Lee, PM 31
Antimicrobial Program Branch
Registration Division (7505C)

Background

○In 1992 EEB reviewed a *Daphnia magna* EC_{50} (MRID No. 420328-05). The study did not fulfill the guideline requirements, but did indicate that silver-zinc (AgZn) zeolite is similar in toxicity to aquatic invertebrates as silver-copper (AgCu) zeolite. On the basis of this information, EEB accepted Kanebo's contention that the chemicals have a similar aquatic toxicity and noted that AgCu aquatic toxicity data may fulfill the guideline requirements for aquatic toxicity testing with AgZn. EEB also stated that if Kanebo wanted to use AgCu avian toxicity data to fulfill the same guideline requirements for AgZn, the company must provide bridging data to indicate that the chemicals have similar toxicities to avian species.

The AgCu aquatic tests submitted did not satisfy the guideline requirements. It was also noted that estuarine/marine testing was required.

Recycled/Recyclable
Printed with Soy/Canola Ink on paper that contains at least 50% recycled fiber

○In a submission that EEB reviewed in 1993, Kanebo made label modifications which eliminated the requirement for estuarine/marine testing.

Data was also submitted that upgraded the three AgCu aquatic toxicity studies to satisfying data requirements. The studies indicating that silver copper zeolite is very highly toxic to aquatic invertebrates (EC_{50} = .60 ppm), moderately toxic to warmwater fish (LC_{50} = 3.4 ppm), and slightly toxic to coldwater fish (LC_{50} = 100 ppm) fulfill the freshwater aquatic toxicity testing of AgZn zeolite. Ag zeolite and AgZn zeolite were also shown to be very highly toxic to aquatic invertebrates (EC_{50}s = .0350 and .30 ppm, respectively).

Kanebo Zeolite USA Inc. submitted the following dietary study with AgZn zeolite for review:

Campbell, S.M. and J.B. Beavers. 1993. Silver-zinc Zeolite: A Dietary LC_{50} Study with the Northern Bobwhite. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory Study NO. 363-102. Submitted by Kanebo Zeolite, USA, Inc., New York, New York. EPA MRID No. 428709-01.

Conclusions

The variability in the measured concentrations of the active ingredients that was present in the first bobwhite LC_{50} study was not present in the silver measurements of this study. Measured concentrations of silver were between 91 and 103% of the nominal for homogeneity testing and 94 to 119% of the nominal for silver verification. Zinc measurements were not performed for this study as the typical avian feed used in dietary studies contains zinc. Not measuring the zinc probably did not affect the results of this study. It is assumed that the zinc was distributed as well as the silver.

The study is scientifically sound and meets the guideline requirements for a bobwhite LC_{50} with the formulated product. The LC_{50} of 5620 classifies silver-zinc zeolite as practically non-toxic to bobwhite quail.

The testing requirements for AgZn zeolite have been fulfilled. As AgCu and AgZn zeolite appear to be similar in toxicity to avian, fish, and aquatic invertebrate species, studies performed with AgCu zeolite may be used to fulfill the guideline requirements for AgZn zeolite as an indoor use chemical. Any change in the use pattern may necessitate further testing. It should also be noted that since testing was performed with the formulated product, raising the concentration of either zinc or silver may necessitate additional testing.

Testing for indoor use chemicals is required to provide information in case of a spill and for environmental hazards labeling. Risk assessments are not performed for indoor use chemicals.

A table displaying the status of the three zeolite compounds is attached to the review of the AgCu zeolite study (DP barcode D194114) and will not be reiterated here. If there are any questions, please contact Heather Mansfield at 305-5064.

DATA EVALUATION RECORD

1. **CHEMICAL:** Silver-zinc Zeolite.
Shaughnessey Number: 221700

2. **TEST MATERIAL:** Silver-zinc zeolite; CAS # 130328-20-0; Batch # TZ 158; % a.i.: silver 3.6% anhydrous weight basis, zinc 6.1% anhydrous weight basis; purity: anhydrous silver zinc zeolite > 99% in total anhydrous weight; a white powder.

3. **STUDY TYPE:** 71-2. Avian Dietary LC_{50} Test.
Species Tested: Bobwhite quail (*Colinus virginianus*).

4. **CITATION:** Campbell, S.M. and J.B. Beavers. 1993. Silver-zinc Zeolite: A Dietary LC50 Study with the Northern Bobwhite. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory Study No. 363-102. Submitted by Kanebo Zeolite, USA, Inc., New York, New York. EPA MRID No. 428709-01.

5. **REVIEWED BY:**

Nancy M. Gourlie, M.S.
Staff Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Nancy M. Gourlie
Date: 9/22/93

6. **APPROVED BY:**

Michael L. Whitten, M.S.
Wildlife Toxicologist
KBN Engineering and
Applied Sciences, Inc.

Signature: Michael L. Whitten
Date: 9-22-93

Henry T. Craven, M.S.
Supervisor, EEB/HED
USEPA

Signature: Heather Mansfield 1/6/94
Date: Boodyean 2 14 94

7. **CONCLUSIONS:** The study is scientifically sound and meets the requirements of an avian LC_{50} study using a formulated product. Based on nominal concentrations, the LC_{50} was greater than 5620 ppm. This classifies the test material as practically non-toxic to bobwhite quail. The NOEC was 5620 ppm.

8. **RECOMMENDATIONS:** N/A

6 hrs

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Animals:** The birds used in the study were 10-day old bobwhite quail (*Colinus virginianus*) obtained from the Wildlife International Ltd. production flock. All birds were from the same hatch, pen-reared and phenotypically indistinguishable from wild birds. The birds could not be differentiated by sex. The birds were acclimated to the facilities from the day of hatch until test initiation. Birds exhibiting abnormal behavior were not used in the test.

B. **Test System:** During acclimation and testing, birds were housed indoors in pens constructed of galvanized steel wire mesh and sheeting. Pen dimensions were 72 cm x 90 cm x 23 cm. Fluorescent lights provided 16 hours of light per day. The average temperature in the brooding compartment of the pens was 38 $\pm$ 1°C. The average ambient room temperature was 26.0 $\pm$ 1.8°C, with an average relative humidity of 42 $\pm$ 8%.

C. **Dosage:** Eight-day dietary LC_{50} test. Nominal dietary concentrations were 562, 1000, 1780, 3160, and 5620 parts per million (ppm). The dietary concentrations were not adjusted for purity of the test substance. Therefore, the dietary concentrations and the LC_{50} are reported as ppm of the test substance as received.

D. **Design:** Groups of ten birds were assigned, by indiscriminate draw, to each of four control groups and five treatment groups. All birds were fed Wildlife International Ltd.'s game bird ration. Food and water were supplied *ad libitum* during acclimation and during the test.

The test diets were prepared by mixing the test substance first into acetone and then blending into the diet with corn oil. The concentration of corn oil in the treatment and control diets was 2%. Acetone was volatilized from the diets during the mixing procedure. Diets were prepared on the day of test initiation. The birds were fed the appropriate dietary concentrations for five days, and then given untreated food during a three-day recovery period. Samples of the diets were taken to verify the test concentrations and to confirm the stability and homogeneity of the test substance in

the diets. The samples were frozen and sent to ESE Laboratories, Gainesville, Florida, for analysis. Diets were analyzed for silver and zinc by ICP, and quantitation of the test substance was based on silver concentrations due to background concentrations of zinc in the avian diet.

Observations were made at least twice daily for mortalities, signs of toxicity, and abnormal behavior. Birds were weighed individually at test initiation, on day 5, and at test termination (day 8). Group food consumption was determined for the five-day exposure period and the three-day recovery period. Consumption was measured by calculating the change in the weight of the feed presented to the birds over time.

E. **Statistics:** Due to the absence of mortality in all treatment groups, the LC_{50} was not calculated. An estimation of the LC_{50} was made by a visual inspection of the mortality data.

12. **REPORTED RESULTS:** Results of diet samples analyzed for dose verification, homogeneity, and test substance stability show that measured values were similar to nominal values (Tables 1 - 3, attached).

There were no mortalities in the control groups nor in any treatment group during the study. All birds in the control and treatment groups were normal in appearance and behavior throughout the test period.

When compared to the control groups, there was no reduction in body weight or feed consumption in any treatment group during days 0-5.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The dietary LC_{50} was greater than 5620 ppm, the highest concentration tested. The no mortality concentration was 5620 ppm. The no-observed-effect concentration was 5620 ppm.

Quality Assurance and Good Laboratory Practice statements were included in the report and analytical appendix, indicating conformance with GLP regulations as set forth in 40 CFR Part 160, with the following exceptions:

Periodic analyses of basal ration and water for background organic and inorganic concentrations were not fully conducted under Good Laboratory Practice Standards.

Test substance characterization was not audited by Wildlife International Ltd. for compliance with Good Laboratory Practice Standards. These data were reportedly the responsibility of the sponsor for separate submittal to EPA.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

A. Test Procedure: The test procedures were in accordance with Subdivision E, ASTM, and SEP guidelines except for the following deviations:

The temperature in the brooding compartment of the pens was approximately 38°C; guidelines state that the brooder temperature should be approximately 35°C.

The birds were not randomly assigned to pens. Instead, they were assigned by "indiscriminate draw."

Necropsies were not conducted. These are recommended, but not required, by guidelines.

B. Statistical Analysis: Due to the absence of mortality during the test, the LC_{50} could not be calculated. Based on nominal concentrations, the LC_{50} was greater than 5620 ppm.

C. Discussion/Results: The report stated that the birds were assigned to groups by indiscriminate draw. Strictly speaking, "indiscriminate draw" is not the same as "random" assignments. However, this method of assignment probably did not affect the results of the test.

Other deviations mentioned in paragraph 14.A (above) were relatively minor and probably did not affect the results of the test.

Using nominal concentrations, the LC_{50} was greater than 5620 ppm. The NOEC was 5620 ppm.

The study is scientifically sound and meets the requirements of an LC_{50} study using a formulated product.

D. Adequacy of the Study:

(1) Classification: Core for a formulated product.

(2) **Rationale:** The deviations noted in 14 A probably did not affect the vailidity of the study.

(3) **Repairability:** N/A.

15. **COMPLETION OF ONE-LINER:** Yes; September 13, 1993.

TABLE 1

Homogeneity of Silver-Zinc Zeolite, Measured as Total Silver, in Avian Diet

Nominal Zeolite Concentration (ppm)	Sample I.D. Number (S-363-102-)	Location Sampled In Mixing Vessel	Concentration: Measured (ppm a.i. Silver)	Concentration: Corrected[1] Zeolite (ppm)	% of nom.	Mean ($\bar{x}$) Standard Deviation (SD) Coefficient of Variation (CV)	Percent of Nominal
562	2	Top Left	19.1	530	94		
	3	Top Right	19.9	553	98		
3.690 silver = 20.2 ppm AS	4	Middle Left	20.2	561	~100	$\bar{x}$ = 538	
	5	Middle Right	20.9	580	103	SD = 32.1	95.7
	6	Bottom Left	17.9	497	88	CV = 6.0%	
	7	Bottom Right	18.3	508	90		
5620	8	Top Left	203	5640	~100		
	9	Top Right	194	5390	96		
	10	Middle Left	194	5390	96	$\bar{x}$ = 5740	
	11	Middle Right	202	5610	~100	SD = 200	97.3
	12	Bottom Left	185	5140	91	CV = 3.6%	
	13	Bottom Right	203	5640	~100		

[1] Values were corrected to reflect Silver-Zinc Zeolite concentrations based on a 3.6% silver content of the product.

TABLE 2

Verification of Silver-Zinc Zeolite, Measured as Total Silver, in Avian Diet

Nominal Zeolite Concentration (ppm)	Sample No. (S-363-102-)	Day of Study	Concentration		Percent of Nominal
			Measured (ppm a.i. Silver)	Corrected[1] Zeolite (ppm)	
0	1	0	< 0.49	< 13.6	--
1000	14	0	34.1	947	94.7
1000	15	0	38.5	1070	107
1780	16	0	75.8	2110	119
1780	17	0	58.6	1630	91.6
3160	18	0	107	2970	94.0
3160	19	0	110	3060	96.8

[1] Values were corrected to reflect Silver-Zinc Zeolite concentrations based on a 3.6% silver content of the product.

TABLE 3

Ambient Stability of Silver-Zinc Zeolite, Measured as Total Silver, in Avian Diet on Day 5

Nominal Zeolite Concentration (ppm)	Sample No. (S-363-102-)	Concentration		Percent of Nominal
		Measured (ppm a.i. Silver)	Corrected[1] Zeolite (ppm)	
0	20	< 0.50	< 13.9	--
562	21	21.0	583	103
562	22	21.1	586	104
1000	23	38.3	1060	106
1000	24	37.9	1050	105
1780	25	65.7	1830	103
1780	26	61.2	1700	96
3160	27	118	3280	104
3160	28	98.2	2730	86
5620	29	197	5470	97
5620	30	180	5000	89

[1] Values were corrected to reflect Silver-Zinc Zeolite concentrations based on a 3.6% silver content of the product.

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

KANEBO ZEOLITE USA, INC.
350 FIFTH AVE., SUITE 2018
NEW YORK, NY 10118

AUG - 9 1993

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 08/05/93. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

August 4, 1993

Mr. John H. Lee
Environmental Protection Agency
Antimicrobial Branch
Registration Division (H7505C)
401 M Street, S.W.
Washington D.C. 20460

428709-ØØ

SUBJECT: BACTEKILLER AZ
EPA FILE SYMBOL 59824-E
Response to the letter of October 26, 1992, and March 17, 1993.

Dear Mr. Lee,

In response to your letter dated October 26, 1992, and March 17, 1993, item 2 regarding avian dietary LC50 with the bobwhite quail, please find the necessary document in this administrative package for the registration of the product listed above.

The pertinent additional Dietary LC50 Study (Volume 2) has been submitted under separate volume in compliance with PR Notice of July 29, 1986.

We have encountered problems finding a space at a laboratory to proceed with this study because most of the GLP based avian test spaces in the US were completely occupied with studies for Reregistration.

We have made a sincere effort to submit additional required data and we trust that this is the last final data required to the full approval of Bactekiller AZ after more than five years from our initial submission.

We hope that you will give this your timely consideration and approve the full registration of our product.

Sincerely,

Olivia D. Laird
President
Laird's Regulatory Consultants

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

KANEBO ZEOLITE U.S.A.,INC.
350 Fifth Avenue, Suite 2018
New York, NY 10118

2. REGULATORY ACTION TO BE TAKEN

Resubmission for registration of A Me-Too Application, Additional Information requested by the EPA for BACTEKILLER AZ

Product Name: BACTEKILLER AZ

EPA File Symbol: 59824-E

3. TRANSMITTAL DATE

August 4,1993

4. LIST OF SUBMITTED INFOMATION

Volume 1. Administrative Material

42870901 Volume 2. A Dietary LC50 Study with the Northern Bobwhite

Company Official: Tsunoo Ohgawara
Vice President

Tsunoo Ohgawara

Company Name: Kanebo Zeolite U.S.A.,Inc.

Company Contact: Olivia D. Laird, Agent
Laird Regulatory Consultants
501 South Lincoln Avenue
Sterling, Virginia 20164

(703) 471-6590
phone

SUBMISSION BAR CODE #_____ REVIEWER_____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 59824-E PM 31 ACTION CODE 116

DESCRIPTOR Mutagen + Leaching (acute studies missing) (Sent to EPA in April)

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION
[ ] NON-RESIDENTIAL USE ONLY
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION	EPA RECEIVE DATE	PM RECEIVE DATE
06 23 93	06 24 93	06 25 93

PM Reid 6-30-93

METHOD OF SUPPORT

[X] CITE-ALL 6/22/88
[ ] SELECTIVE
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

FORMULATORS EXEMPTION

[ ] SUBMITTED
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
TOXICOLOGY				
HED TOX.	6/30/93	all three	studies	routed.
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER_____				

STATUS_____

JUL 25 1994

RESPONSE CODE 37 RESPONSE DATE Reg Notice

Williams-Foy
12/8/93

DP BARCODE: D192668

CASE: 280486 DATA PACKAGE RECORD DATE: 07/06/93
SUBMISSION: S443598 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 116 RESB NC-NON-FOOD/FEED U
CHEMICALS: ~~129015~~ Zinc 0.0000%
~~072501~~ ~~Silver~~ 129103 0.0000%

ID#: 059824-E BACTEKILLER AZ (silver & zinc)
COMPANY: 059824 KANEBO ZEOLITE U.S.A., INC
PRODUCT MANAGER: 31 JOHN LEE 703-305-5675 ROOM: CM2 270
PM TEAM REVIEWER: VALDIS GONCAROVS 703-305-6663 ROOM: CM2 272
RECEIVED DATE: 06/24/93 DUE OUT DATE: 12/31/93

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 192668 EXPEDITE: Y DATE SENT: 06/30/93 DATE RET.: / /
CHEMICAL: 129015 Zinc
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 10/28/93 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : HED	07/01/93	/ /
BRAN: TB-2	07/02/93	/ /
SECT: RS-4	07/02/93	/ /
REVR : SWILLIAM	07/06/93	/ /
CONTR:	/ /	/ /

VALDIS: THE CORRECT CHEMICAL CODE IS: 129103 for this compound BL. CORRECT: JBOULA

* * * DATA REVIEW INSTRUCTIONS * * *

review the requested studies

Previous reviewer: SanYvette Williams

Also identify any remaining data requirements for the new use patterns as declared on the enclosed label.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

DUE : 10/28/93.
TECH. HRS : 16

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 8 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: BACTEKILLER AZ (Silver Zinc Zeolite): Additional Data Submission In Response to Agency's Comment of 03/15/93

FROM: SanYvette Williams-Foy, D.V.M. 12/6/93
Review Section IV, Tox. Branch II (H7509C)

TO: Valdis Goncarovs/John Lee, PM 17
Registration Division

THRU: Jess Rowland, M.S., Acting Section Head 12/6/93
Section IV, Tox. Branch II (H7509C)

and

Marcia van Gemert, Ph.D., Chief 11/7/93
Toxicology Branch II
Health Effects Division (H7509C)

EPA IDENTIFICATION NUMBERS: PC Code: 129103
DP Barcode: D192668
MRID #'s: 428201-01, and
428201-02

Sponsor: Kanebo Zeolite, USA, Inc.

Action Requested: Toxicology was requested to review and address the additional information submitted for Bactekiller AZ in support of its registration.

Response: The information supplied by the registrant for each study is acceptable. Therefore, each study [MRID #: 420328-02 (leaching), and MRID#: 420328-04 (in vivo mammalian cytogenetic assay in rats [84-2])] are upgraded to Core-minimum and are acceptable for regulatory purposes.

Recycled/Recyclable
Printed with Soy/Canola Ink on paper that contains at least 50% recycled fiber

I. Background: In a letter dated March 15, 1993, the Agency cited the following deficiencies: 1. The rationale for using pH 6.5 in the leaching study [MRID#: 420328-02] was not provided. In addition the pH levels above and below pH 6.5 were not included in the report. 2. Test material stability was not present [MRID#: 420328-02] in the batch of acute studies. 3. An explanation was requested as to why slides could not be read from many of the males in the In vivo mammalian cytogenetic assay in rats [MRID#: 420328-04].

II. Review of Registrant's Response: In their response, the Registrant provided additional information/clarification to the following issues: 1. The resubmitted information [MRID#: 428201-02] stated that the rationale for using pH 6.5 was based on data from three companion studies ["Silver Zinc Zeolite - Release of Silver and Zinc Under Hydrolysis Conditions" (MRID#: 420328-06), "Silver Copper Zeolite - Leaching of Silver and Copper From Impregnated Polymers" (MRID#: 416158-18), and "Silver Copper Zeolite - Release of Silver and Copper Under Hydrolysis Conditions" (MRID#: 416158-16]. The silver-zinc zeolite hydrolysis study demonstrated that, by itself, the test material was most unstable at acidic pH (See table below). Because the hydrolysis study with silver-copper zeolite demonstrated that it was most unstable at acidic pH, the leaching study with the same test material incorporated into polymers utilized an acidic pH.

Silver Copper Zeolite Hydrolysis
Percent of Ion released after 30 days
(linear regression analysis)

pH	Silver	Zinc
pH 5	2.4%	4.0%
pH 6	0.53%	0.48%
pH 7	0.39%	1.5%

2. The resubmitted information [MRID#: 428201-01] stated that males from all dose groups, including the negative control, had extremely low mitotic indices when compared to females. Therefore, many of the slides were not analyzed.

III. Conclusion: The information supplied by the registrant for each study is acceptable. Therefore, each study [MRID #: 420328-02 (leaching), and MRID#: 420328-04 (in vivo mammalian cytogenetic assay in rats [84-2])] are upgraded to Core-minimum and are acceptable for regulatory purposes.

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

JUN 25 1993

KANEBO ZEOLITE USA, INC.
350 FIFTH AVE., SUITE 2018
NEW YORK, NY 10118

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/24/93. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

EXPERIMENT III
TABLE 6

AMES SALMONELLA/MICROSOME MUTAGENICITY ASSAY WITH SILVER COPPER ZEOLITE
INDIVIDUAL PLATE COUNT

		Number of revertants per plate											
	S-9	TA 98			TA 100	TA 1535			TA 1537				
WATER CONTROL	(-)	37	34	36	NT	8	4	15	20	15	18		
POSITIVE CONTROLS	(-)	726	679	649	NT	247	301	233	349	321	393		
TEST COMPOUND: (mg/plate)													
0.15	(-)	*****			NT	*****			*****				
0.1	(-)	*****			NT	*****			*****				
0.05	(-)	*****			NT	*****			*****				
0.03	(-)	23	23	24 T	NT	10	11	7 T	13	12	12 T		
0.015	(-)	41	35	28	NT	10	13	10	10	19	6		
0.010	(-)	35	37	40	NT	16	13	11	15	15	17		
0.005	(-)	31	41	45	NT	9	13	14	15	19	18		

NT: TA100 was not tested in this assay.
*****: Chemical was exceedingly toxic, no bacterial background lawn was evident, and the plates were not evaluated.
T: Chemical had a slight toxic effect on the bacteria, but the plates were evaluated.

POSITIVE CONTROLS(-S9)

TA 98	2-Nitrofluorene	3 ug/plate
TA 100	Sodium Azide	10 ug/plate
TA 1535	Sodium Azide	0.5 ug/plate
TA 1537	9-Aminoacridine	80 ug/plate

428201- CD CD

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER (APPLICANT)

KANEBO ZEOLITE USA, INC.
350 FIFTH AVENUE, SUITE 2018
NEW YORK, NY 10118

PLEASE SEND ALL CORRESPONDENCE TO AGENT:
OLIVIA D. LAIRD
501 SOUTH LINCOLN AVENUE
STERLING, VA 20164

Telephone: (703) 471-6590, FAX (703)471-6269

Pm 32

2. REGULATORY ACITION TO BE TAKEN

Registration of a me-too product resubmission for Bactekiller AZ

PRODUCT NAME: BACTEKILLER AZ
FILE SYMBOL: 59824-E

3. TRANSMITTAL DATE

June 23, 1993

4. LIST OF SUBMITTED STUDIES

42820101 Volume 1: Toxicity, In Vivo Mammalian Cytogenetics Assay in Rats
42820102 Volume 2: Toxicity, Leaching Study

Official: for/Tsuneo Ohgawara
Vice President

Signature

Company Name: KANEBO ZEOLITE USA, INC.

Company Contact: LAIRD'S REGULATORY CONSULTANTS
(Agent)

(703) 471-6590, FAX (703) 471-6269
(telephone)

SUBMISSION BAR CODE # _____ REVIEWER _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 59824-E PM 31 ACTION CODE _____

DESCRIPTOR tox data

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION
[ ] NON-RESIDENTIAL USE ONLY
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION			EPA RECEIVE DATE			PM RECEIVE DATE		
04	14	93	04	14	93	04	14	93

METHOD OF SUPPORT

[ ] CITE-ALL
[ ] SELECTIVE
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

FORMULATORS EXEMPTION

[ ] SUBMITTED
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
TOXICOLOGY				
HED TOX.	data needs format (one retained) 2 returned to agent only			
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER _____				

STATUS _____

RESPONSE CODE 10 RESPONSE DATE JUN 07 1993

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

427355-00

KANEBO ZEOLITE USA, INC.
350 Fifth Avenue, Suite 2018
New York, NY 10118

2. REGULATORY ACTION TO BE TAKEN

Registration of a me-too product (Product Manager 31)
Resubmission for Bactekiller AZ - EPA FS 59824-E
Response to EPA Comment Dated March 15, 1993

3. TRANSMITTAL DATE

April 14, 1993

4. LIST OF SUBMITTED STUDIES

Rejected(02)
42735501
Rejected(04)

Volume 1 - Administrative materials
Volume 2 - In Vivo Mammalian Cytogenetics Assay in Rats
Volume 3 - The Stability of the Test Material for Six Acute Toxicity Studies
Volume 4 - Leaching Study

Company Official: Tsuneo Ohgawara
Vice President

Tsuneo Ohgawara
Signature

4/14/93

Company Name: Kanebo Zeolite USA, Inc.

Company Contact: Olivia D. Laird, Agent

Laird's Regulatory Consultants
501 South Lincoln Avenue
Sterling, Virginia 20164

(703) 471-6590
phone

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

KANEBO ZEOLITE USA, INC.
350 FIFTH AVE., SUITE 2018
NEW YORK, NY 10118

JUN 07 1993

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 04/14/93. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

Rejected study [02] :

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

Rejected study [04] :

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

COMPANY: KANEBO ZEOLITE USA, INC.
350 Fifth Avenue, Suite 2018
New York, NY 10118

Product Name: BACTEKILLER AZ

Company No: 59824-E

Regulatory Action
Resubmission of additional data for a Me-Too Product

PLEASE SEND ALL CORRESPONDENCE TO AGENT

OLIVIA D. LAIRD
Laird's Regulatory Consultants
501 SOUTH LINCOLN AVENUE
STERLING, VA 20164

Telephone: (703)471-6590

VOLUME 1

ADMINISTRATIVE MATERIALS

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

KANEBO ZEOLITE USA,INC.
350 Fifth Avenue, Suite 2018
New York, NY 10118

2. REGULATORY ACTION TO BE TAKEN

Resubmission for registration of A Me-Too Application, Additional Information requested by the EPA for BACTEKILLER AZ

Product Name: BACTEKILLER AZ

EPA File Symbol: 59824-E

3. TRANSMITTAL DATE

April 14, 1993

4. LIST OF SUBMITTED STUDIES

Volume 1. Administrative Materials

Volume 2. In Vivo Mammalian Cytogenetics Assay in Rats

Volume 3. The Stability of the Test Material for Six Acute Toxicity Studies

Volume 4. Leaching Study

Company Official: Tsuneo Ohgawara *Tsuneo Ohgawara* 4/14/'93
Vice President

Company Name: Kanebo Zeolite USA.,Inc.

Company Contact: Olivia D. Laird, Agent/Submitter
Laird Regulatory Consultants
501 South Lincoln Avenue
Sterling, Virginia 20164

(703) 471-6590
phone

April 14, 1993

Mr. John H. Lee, PM 31
Environmental Protection Agency
Antimicrobial Branch
Registration Division (H7505C)
401 M Street, S.W.
Washington D.C. 20460

SUBJECT: BACTEKILLER AZ
EPA FILE SYMBOL 59824-E
Response to your letter of March 15, 1993

Dear Mr. Lee,

Enclosed please find all of the necessary additional documents in this administrative package (Volume 1) for the registration of the product listed above.

The pertinent supplemental In Vivo Mammalian Cytogenetics Assay in Rats (Volume 2), The Stability of the Test Material for Six Acute Toxicity Studies (Volume 3) and Leaching Study (Volume 4) have been submitted under separate volumes in compliance with PR Notice 86-5 of July 29, 1986. The data have been submitted to address the concerns raised in your deficiency letter of March 15, 1993.

You will find all of the required documents in order, and I trust that you will give this application your timely consideration. We are certain that the supplemental material will lay to rest the concern of each discipline.

Sincerely,

Olivia D. Laird
President
Laird's Regulatory
Consultants

LAIRD'S REGULATORY CONSULTANTS
Over 19 Years Experience and Expertise in
The Regulation of Pesticide Products

Mr. John H. Lee (PM 31)
Environmental Protection Agency
Antimicrobial Branch
Registration Division
401 M Street, SW
Washington, DC 20460

April 30, 1993

SUBJECT: Bactekiller AZ
EPA File Symbol 59824-E
Response to your letter of March 17, 1993
Withdrawl of the amendment proposal dated
December 23, 1991 (MRID No. 42173801)

Dear Mr. Lee:

In response to your letter regarding the switch in th e zinc content in our formulation from 6.5 + 0.7% to 9.0 + 4%. In order to eliminate the requirement for submission of new data we have made the decision to withdraw our amendmant proposal of MRID No. 42173801 of December 23rd, 1991.

Per our telephone conversation of April 29th, we have enclosed a revised CSF and five copies of the revised label declaring 6.5% unformatted per our discussion.

Thank you for your very timely response to the submission.

Sincerely,

Olivia D. Laird
President
Agent for Kanebo Zeolite

37 6-29-93

Olivia D Laird ♦ 501 S Lincoln Ave, Sterling Park, VA 22170 ♦ 703/471-6590 ♦ 703/471-6269 (fax)

SUBMISSION BAR CODE # _____ REVIEWER _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 59824-E PM 31 ACTION CODE 116

DESCRIPTOR more labels. (6.1902n)

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION
[ ] NON-RESIDENTIAL USE ONLY
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION			EPA RECEIVE DATE			PM RECEIVE DATE		
02	12	93	02	12	93	03	08	93

METHOD OF SUPPORT

[ ] CITE-ALL
[ ] SELECTIVE
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

FORMULATORS EXEMPTION

[ ] SUBMITTED
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
TOXICOLOGY				
HED TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER _____				

STATUS _____

_____

RESPONSE CODE 38 RESPONSE DATE MAR 17 1993

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 17 1993

Kanebo Zeolite U.S.A. Inc.
350 Fifth Ave Suiter 2018
New York, NY 10118

Attention: Olivia Laird
Agent

Subject: Bactekiller AZ
EPA File Symbol No. 59824-E
Your Submission Dated February 12, 1993

The review of the submission has raised several questions which require to be addressed.

1. Your last chemistry package (MRID # 42173801), your CSF dated 12-27-91 and your cover letter of December 23, 1991 all indicate that you were amending your chemistry of this product to reflect an increase of zinc from 6% to 9%.

   After a review of the above information, our letter of April 30, 1992 instructed you to revise the label declaration to read 9%.

   Your current label of 2-12-93 submitted indicates 6%.

   If you want to go back to 6%, then the Agency will require a new CSF for our review and a statment that you are withdrawing the amendment change.

   Please clarify your intensions.

2. Our letter of October 26, 1992 also indicated that we require a response from you regarding the data requirement: Avian Dietary (Quail) for this silver-zinc product. Please refer to the Fish & Wildlife review previously sent to you and respond accordingly for this product.

   Note: The remaining data requirements are dependent upon the response you recently submitted under the File Symbol 59824-R.

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

3. A cursory review of the label follows.

   a. Since you have decided to delete outdoor uses, the use pattern: "Exterior surfaces for paints" must also be deleted.

   b. The term: "Self-sanitized" is inappropriate for this type of product. The highest claim permitted would be: "bacteriostatic against odor causing bacteria".

4. Just a reminder that after a review of the above requested information, additional data and/or information may be required to support your application.

5. The Agency reserves full label review at this time.

This letter does not constitute registration and the product may not be lawfully marketed until all the required information has been submitted for review and found acceptable.

If you have any questions concerning this letter, contact V. Goncarovs at 703-305-6663.

Sincerely,

John H. Lee
Product Manager 31
Antimicrobial Program Branch
Registration Division (H7505C)

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

COMPANY: KANEBO ZEOLITE U.S.A.,INC.
350 Fifth Avenue, Suite 2018
New York, NY 10118

Product Name: BACTEKILLER AZ

Company No: 59824-E

Regulatory Action
Resubmission of label for a
Me-Too Product

PLEASE SEND ALL CORRESPONDENCE TO AGENT:

OLIVIA D. LAIRD
LAIRD'S REGULATORY CONSULTANTS
501 SOUTH LINCOLN AVENUE
STERLING, VA 20164

Telephone: (703) 471-6590

VOLUME 1

ADMINISTRATIVE MATERIAL

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

KANEBO ZEOLITE U.S.A.,INC.
350 Fifth Avenue, Suite 2018
New York, NY 10118

2. REGULATORY ACTION TO BE TAKEN

Resubmission of label for registration of A Me-Too Application.
Label revision indicated by the EPA for BACTEKILLER AZ

Product Name: BACTEKILLER AZ

EPA File Symbol: 59824-E

3. TRANSMITTAL DATE

February 12, 1993

4. LIST OF SUBMITTED INFOMATION

Volume 1. Administrative Material

Company Official: Tsunoo Ohgawara Tsuneo Ohgawara
Vice President

Company Name: Kanebo Zeolite U.S.A.,Inc. Feb/11/'93

Company Contact: Olivia D. Laird, Agent
Laird Regulatory Consultants
501 South Lincoln Avenue
Sterling, Virginia 20164

(703) 471-6590
phone

Mr. John H. Lee
Environmental Protection Agency
Antimicrobial Branch
Registration Division (H7505C)
401 M Street, S.W.
Washington D.C. 20460

February 12, 1993

SUBJECT: BACTEKILLER AZ
EPA FILE SYMBOL 59824-E
Response to the letter of October 26, 1992

Dear Mr. Lee,

Enclosed herewith please find the necessary labeling revision per your comments in your letter of October 26, 1992, eliminating the water treatment and paper production uses along with clarifying the intended paper coating uses for our Bactekiller products.

We have also rectified the ingredient statement on the label per your indication about zinc to coincide with the test material submitted as Appendix C of Product Chemistry (MRID # 420328-01).
You will find the required labeling revisions in order and I trust that you will give this application your timely consideration.

Sincerely,

Olivia D. Laird
President
Laird's Regulatory Consultants

(Front Panel Label for BACTEKILLER AZ-EPA FS 59824-E)

BACTEKILLER AZ
Silver-Zinc Zeolite

BACTEKILLER AZ is a antimicrobial powder for commercial and industrial use designed to be incorporated into various materials during varying stages of the manufacturing process to impart antimicrobial activity to the manufactured materials. For more details of the various materials refer to the supplemental labeling for uses of Bactekiller AZ.

Active Ingredients	
Silver* as elemental	3.5%
Zinc* as elemental	6.1%
Inert Ingredients	90.4%

*from silver-zinc sodium alumino silicate complex

KEEP OUT OF REACH OF CHILDREN
CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful if swallowed. Avoid contact with skin, eyes, or clothing. Avoid contamination of cooking utensils and food preparation surfaces.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, drink one or two glasses of water and induce vomiting by touching the back of the throat with finger. Repeat until vomit fluid is clear. Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person. If on skin, remove contaminated clothing and wash affected area with soap and water. If irritation persists, contact a physician. If in eyes, flush eyes for at least 15 minutes with water. If irritation persists contact a physician.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Keep out of any natural body of water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge unused material into natural bodies of water unless in accordance with a NPDES permit.

STORAGE AND DISPOSAL: Do not store in areas accessible to children. Do not store in places where food or feed may come in contact with the product. Keep away from direct sunlight. Unused material should be disposed of on site or an approved waste disposal facility.

CONTAINER DISPOSAL: Empty container thoroughly and rinse with water. Dispose in regular trash collection.

EPA Reg. No. 59824-

EPA Est. No. 59824-JP-1

Net Contents: 10 lbs; 20 lbs; or 100 lbs.

KANEBO ZEOLITE U.S.A., INC.
350 Fifth Ave., Suite 2018
New York, N. Y. 10118

(Back Panel for Bactekiller AZ -EPA FS 59824-E)

BACTEKILLER AZ
Silver-Zinc Zeolite

DIRECTIONS FOR USE
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

BLENDING AND FORMULATING INSTRUCTIONS
FOR THE LISTED MATERIALS

BACTEKILLER AZ is a silver zinc zeolite powder designed to be incorporated into various materials at various states of their manufacturing process to impart antimicrobial properties to the manufactured materials. The powder can be incorporated into the materials as an integral part of the finished products throughout their entire thickness, or as a film over the surfaces of the manufactured materials, depending on the particular method of manufacture of the finished materials and needs of the manufacturer.

Bactekiller AZ may be incorporated into the following materials at the specified Maximum Inhibitory Concentrations (MIC) on a dry weight basis of finished products.

APPLICATION	MIC
Plastic Film: (non-food use only and no water pipes):	
Polyethylene, polypropylene, polyvinyl chloride, polyacetate, and polyester	1.50%
Paint (Water base and solvent base)	1.50%
Paper coating (non food packaging paper, no food contact) (not for paper production use)	1.50%
Adhesive (non food contact): plywood adhesives	2.00%
Synthetic Fibers: Polyester, Nylon, Polypropylene, Acrylic, and Rayon	1.50%
Pigments: dyestuffs and inks	1.00%
Textile Finishing and Manufacturing	0.75%

For details in blending BACTEKILLER A with these materials refer to supplemental labeling.

SUPPLEMENTAL LABELING

BACTEKILLER AZ - FS 59824-E
(Silver-Zinc Zeolite)

Claims: Bactekiller AZ is to be incorporated into the following materials at suitable stages of the manufacturing process to impart antimicrobial activity to the treated materials, and thus make them self sanitized to suppress the growth of bacteria and mold responsible for unpleasant odors and discoloration of the treated materials.

Fibers: Polyester, polypropylene, nylon, polyethylene, acrylic, rayon

applications:
home furnishings: mattress cover pads, sheets, blankets, quilt and pillow fiber fill, curtain and drapery, carpet and carpet underlay, upholstery, wiping cloths, towels, bags, wallcover fabrics, cushion pads

apparel: interlinings, industrial uniforms, coats and aprons, sportswear, sleepwear, stockings, socks, helmets, caps, gloves.

Industrial: brush bristles, shoe linings, artificial leather, filter (non food contact), book covers, sail cloth, ropes.

Plastic Films and Molded Plastics: (non-food use only and no water pipes):

types: polyester, polyamide, polypropylene, polyethylene, polysiloxane, polyethylene copolymer, polyvinyl alcohol, epoxy resin, phenol resin, polycarbonate, cellulose acetate, polystyrene, polyurethane, acrylic resin, methyl methacrylate, acrylonitrile butadiene styrene copolymer.

Applications: gloves, shower curtains, air ducts, cable wraps, protective covers, non-food contact foam containers, brush handles, sponges, insulators, gaskets, non-food tubing, non-food contact containers and film, furniture.

Paper coating (not for food packaging or for food contact):
(not for paper production use)

types: cellulosic, synthetic, specialty, reinforced

applications: wallpaper, non-food wrap, wiping towels, book covers, corrugated paper filters.

Paint: water based, oil based paints; for interior and exterior surfaces

Adhesives (not for adhesives for paper or containers that will come in contact with food):

Applications: adhesive for plywood manufacture, adhesive for cement tile and sealants

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 23 1992

Mrs. Olivia Laird, President
Laird's Regulatory Consultants
501 S. Lincoln Avenue
Sterling Park, VA 22170

Dear Mrs. Laird:

This responds to your letter that was received on July 14, 1992 regarding whether or not Kanebo's non woven cuff, of Collagen fiber, containing bactekiller AC powder would require EPA registration or notification.

> The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, except that the term "pesticide" shall not include any article that is a "new animal drug" within the meaning of section 201(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(w)), that has been determined by the Secretary of Health and Human Service not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section 201(x) of such Act (21 U.S.C. 321(x)) bearing or containing a new animal drug.

Based on the submitted information, the collagen cuff containing bactekiller AC powder does not require EPA registration under FIFRA, since this material is implanted into the human body and is eventually absorbed by the human body.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								97

It appears that the product would be subject to the laws enforced by the Department of Health and Human Services. It is suggested that you contact that Agency in regard to this product's label.

If you have any questions concerning this letter, do not hesitate to contact me.

Sincerely,

John H. Lee
Product Manager 31
Antimicrobial Program Branch
Registration Division H7505C

59824-A
59824-E
59824-G

Kanebo ZEOLITE U.S.A., INC.
350 FIFTH AVENUE, SUITE 2018, NEW YORK, N.Y. 10118, U.S.A
PHONE 212-244-1506, FAX 212-563-4064

March 30, 1992

Our marketing people anticipate that following EPA/FIFRA antimicrobial registration of Bactekiller AC powder within the label(Note-1) we will be approached by a potential customer in the medical field whose product is an antimicrobial collagen cuff* regulated by the 510 K(FDA medical device).

In anticipation of this occurance, we would like to inquire whether the EPA will require any documentation in support of 510 K(FDA) regulated end use(cuff) beyond** that already contained in our current EPA submission.

We would also like to inquire:
Is it necessary to notify the EPA of an FDA-approved product containing Kanebo's Bactekiller AC powder?
If so, who is responsible for notification -- Kanebo or its customer?

* Nonwoven cuff of collagen fiber incorporated with 3.0 % Bactekiller powder and used with percutaneous vascular catheter for infection control pourpose.

** Summary of differences between the two antimicrobial submissions.

Terms	EPA/FIFRA	510K/FDA medical device
1. Application	Pile carpet	Cathetel cuff
2. Antimicrobial part	Pile fiber	Nonwoven cuff fiber
3. Fiber matrix	PET staple fiber	Collagen fiber
4. Incorporation level	1.5 %	3.0 %
5. Claim	Note-1	Note-2

Note-1
Bactekiller AC is incorporated into the following materials at suitable stages of the manufacturing process to impart antimicrobial activity to the treated materials suppressing the growth of bacteria and mold responsible for unpleasant odors,discolorration and making the treated materials self-sanitized.(Submission as an antimicrobial powder)

Note-2
An antimicrobial self-sanitized cuff which is imparted antimicrobial activity to suppress the growth of bacteria and mold responsible for disease.(Submission as a cuff)

Sincerely,

Tsuneo Ohgawara
TSUNEO OHGAWARA
VICE PRESIDENT

Kanebo

LAIRD'S REGULATORY CONSULTANTS
Over 19 Years Experience and Expertise in
The Regulation of Pesticide Products

Ms. Juanita Wills, Branch Chief
Environmental Protection Agency
Antimicrobial Branch, (H7505C)
Registration Division
401 M Street, SW
Washington, DC 20460

April 9, 1992

RECEIVED
JUN 14, 1992
ANTIMICROBIAL BRANCH

SUBJECT: Bactekiller AC
EPA REG. NO. 59824-R
Inquiry on efficacy data requirements because or its use in 510 K (Medical Device) approved by FDA

Dear Ms. Wills:

On behalf of my client, Kanebo Zeolite U.S.A, Inc., I delivered a copy of the attached sheet to Mr. Goncarovs of PM Team 31, on April 6, 1992, in hopes of a decision as to whether or not the production and commercialization of antimicrobial self-sanitized cuff for infection control (510K approved medical device) which is regulated by the FDA requires approval of the antimicrobial powder as a manufacturing use product by the EPA because of its impregnation with the Bactekiller powder. Please note the levels of activity which are presented on the label. This medical cuff contains Bactekiller AC which is presently pending registration with EPA as a manufacturing use antimicrobial powder.

Mr. Goncarovs informed me that you instructed your people to forward such issues/items (Antimicrobial Medical Device) to you for a determination. Please review, or have the attached page reviewed (dated March 30, 1992) and advise me of the efficacy data requirements if any. We have three Bactekiller products submitted as manufacturing use products which have been pending since 1988. We would like to know now if additional data (efficacy data) are required to our current EPA submission in connection with the cuff. We don't want to wait until we are at the point of registration only to be told that efficacy data are required. If efficacy is required only by Kanebo's customers we need to know that also.

Thank you for your prompt response to to this letter.

Sincerely,

Olivia D. Laird
President

LA RD'S REGULATORY CONSU ANTS
Over 19 Years Experience and Expertise in
The Regulation of Pesticide Products

RECEIVED
JUL 14 1992
ANTIMICROBIAL BRANCH

TO MS JUANITA WILLS

PENDING ACTIONS IN THE ANTIMICROBIAL BRANCH

FILE SYMBOL/ REG. NUMBER	DATE OF APPLICATION	PM	GENERAL INFORMATION CONCERNING SUBMISSION
65862-R	3/11/92	32	Routine Chlorine Gas application
46043-I	1/14/92	32	Me-too Trichloro-s-triazinetrione
46043-T	1/14/92	32	Me-too Trichloro-s-triazinetrione
46043-T	1/14/92	32	Additional Brand Name
5389-6	4/10/92	32	A letter in response to EPA letter for a low percentage of Trichloro for which we requested expedite on the basis that if data are still required after consideration of all of the facts we would like to know as soon as possible.
57427-3	10/14/91	32	Calcium Hypochlorite approval of Egg-shell sanitizing use which is already listed in the standard, need for USDA's approval.
64492-R 64492-ENNNU	9/19/91 12/18/91	32 32	Sodium Hypochlorite, I have Spoken to Travaglini Several times about these but have received no results.
59824-R 59824-E 59824-G	6/22/88 " "	31 31 31	elemental Silver and elemental Copper which should have been handled from the beginning as a me-too chemical. This has been documentented in an EPA memo dated March 25, 1991. All of the data had already been generated for these product but all reviews have not been completed. I don't understand why we cannot be given temporary registrations for each of these products since a gross error has been made and the data is in house
59824-R	4/09/92	31	This letter, a copy of which is attached for your convenience. It was sent to your attention and I understand thet you gave Mr. Lee instructions to respond to it, to date I've not received a response. I did talk to the head of your

JUN 19 1992

Kanebo Zeolite USA, Inc.
350 Fifth Avenue, Suite 2018
New York, NY 10118

Attention: Tsuneo Ohgawara
Vice President

Gentlemen:

Subject: Bactekiller AZ
EPA File Symbol 59824-E
Your Submission Dated May 11, 1992

In reference to your question regarding reregistration, all companies who currently hold active registered products containing the chemicals:

Silver
Zinc

have been notified to participate in the reregistration process. However, all pending applications who contain the chemicals are asked at a minimum to submit Phase 2 & Phase 3 responses in order for companies to be made aware that when and if registration is issued additional responsibilities such as data may be imposed.

Enclosed please find a copy of the reregistration process. Your Agent is fully aware of this process and we suggest you contact her for any additional questions regarding this matter.

In respect to the label submitted, we require a full label for our review, not just one panel. Partial labels just add confusion and delays processing.

This letter does not constitute registration and the product may not be lawfully marketed until it is registered.

64659:I:WP50:V.G.:WP31-5:KEVRIC:06/05/92:07/04/92:dd

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70)

OFFICIAL FILE COPY

If you have any questions concerning this letter, please contact V. Goncarovs at (703) 305-6663.

Sincerely yours,

John H. Lee
Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number: 167702

Section I

1. Company/Product Number: 59824-E
2. EPA Product Manager: Mr. John H. Lee
   PM#: 31
3. Proposed Classification: [X] None [ ] Restricted
4. Company/Product (Name): Bactekiller AZ (Silver-zinc zeolite)
5. Name and Address of Applicant *(Include ZIP Code)*:
   KANEBO ZEOLITE U.S.A.,INC.
   350 Fifth Ave., Suite 2018
   New York, N.Y. 10118
   [ ] *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
   EPA Reg. No. 59824-E
   Product Name Bactekiller AZ

Section II

[ ] *Amendment - Explain below*
[X] Resubmission in response to Agency letter dated 4/30,'92
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[X] "Me Too" Application.
[ ] Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Revised label of ingredient statement in responce to Agency letter dated 4/30,'92.

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[X] Yes*	[ ] Yes	[ ] Yes	[X] Metal
[ ] No	[X] No	[X] No	[ ] Plastic
	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	[ ] Glass
			[ ] Paper
			[ ] Other (Specify) _____

* ***Certification must be submitted.***

3. Location of Net Contents Information: [X] Label [ ] Container
4. Size(s) of Retail Container: 18 liter can
5. Location of Label Directions: [X] On Label [ ] On Labeling accompanying product
6. Manner In Which Label Is Affixed To Product: [ ] Lithograph [X] Paper glued [ ] Stenciled [ ] Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Ms. Olivia D. Laird	PRESIDENT Laird's Reg.Consultants	(703) 471-6590

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Tsuneo Ohgawara
3. Title: Vice President Kanebo Zeolite U.S.A.,Inc.
4. Typed Name: TSUNEO OHGAWARA
5. Date: May 11, 1992

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PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your **Company Number**, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the **Product Number**.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

(Front Panel Label for BACTEKILLER AZ-EPA FS 59824-E)

BACTEKILLER AZ
Silver-Zinc Zeolite

BACTEKILLER AZ is a antimicrobial powder for commercial and industrial use designed to be incorporated into various materials during varying stages of the manufacturing process to impart antimicrobial activity to the manufactured materials. For more details of the various materials refer to the supplemental labeling for uses of Bactekiller AZ.

Active Ingredients	
Silver* as elemental	3.5%
Zinc* as elemental	9.0%
Inert Ingredients	87.5%

*from silver-zinc sodium alumino silicate complex

KEEP OUT OF REACH OF CHILDREN
CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful if swallowed. Avoid contact with skin, eyes, or clothing. Avoid contamination of cooking utensils and food preparation surfaces.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, drink one or two glasses of water and induce vomiting by touching the back of the throat with finger. Repeat until vomit fluid is clear. Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person. If on skin, remove contaminated clothing and wash affected area with soap and water. If irritation persists, contact a physician. If in eyes, flush eyes for at least 15 minutes with water. If irritation persists contact a physician.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Keep out of any natural body of water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge unused material into natural bodies of water unless in accordance with a NPDES permit.

STORAGE AND DISPOSAL: Do not store in areas accessible to children. Do not store in places where food or feed may come in contact with the product. Keep away from direct sunlight. Unused material should be disposed of on site or an approved waste disposal facility.

CONTAINER DISPOSAL: Empty container thoroughly and rinse with water. Dispose in regular trash collection.

EPA Reg. No. 59824-

EPA Est. No. 59824-JP-1

Net Contents: 10 lbs; 20 lbs; or 100 lbs.

KANEBO ZEOLITE U.S.A., INC.
350 Fifth Ave., Suite 2018
New York, N. Y. 10118

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EPA Reg. No. 59824-

EPA Est. No. 59824-SP-1

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Kanebo

Kanebo ZEOLITE U.S.A., INC.

350 FIFTH AVENUE, SUITE 2018, NEW YORK, N.Y. 10118, U.S.A.
PHONE 212-244-1506, FAX 212-563-4064

Office of Pesticide Programs
401 M D Street, S.W.
Washington, D.C. 20460

Att: Mr. John H. Lee
Product Manager(31)
Registration Division(H7505 C)

May 11, 1992

Dear Mr. Lee

Subject: Bactekiller AZ
EPA File Symbol 59824-E
Revised label of ingredient statement

We have revised the label to comply with the item 1 of your letter dated April 30, 1992 and 5 copies of the label are attached here with.

We slso noticed in your letter the statement "--- this product will now also be subject to reregistration requirements." I am aware that we must be reregistered at an appointed time when a call-in is issued and after the products have been registered. But please let me know what the "NOW"means.

We hope that you will give it timely consideration and approve the registratuion of our product.

Yours sincerely,

Tsuneo Ohgawara

TSUNEO OHGAWARA
Vice president
Kanebo Zeolite U.S.A., inc.

59824-R
59824-E
59824-G

Kanebo ZEOLITE U.S.A., INC.
350 FIFTH AVENUE, SUITE 2018, NEW YORK, N.Y. 10118, U.S.A
PHONE 212-244-1506, FAX 212-563-4064

March 30, 1992

Our marketing people anticipate that following EPA/FIFRA anti-microbial registration of Bactekiller AC powder within the label(Note-1) we will be approached by a potential customer in the medical field whose product is an antimicrobial collagen cuff* regulated by the 510 K(FDA medical device).

In anticipation of this occurance, we would like to inquire whether the EPA will require any documentation in support of 510 K(FDA) regulated end use(cuff) beyond** that already contained in our current EPA submission.

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If so, who is responsible for notification -- Kanebo or its customer?

* Nonwoven cuff of collagen fiber incorporated with 3.0 % Bactekiller powder and used with percutaneous vascular catheter for infection control pourpose.

** Summary of differences between the two antimicrobial submissions.

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5. Claim	Note-1	Note-2

Note-1
Bactekiller AC is incorporated into the following materials at suitable stages of the manufacturing process to impart antimicrobial activity to the treated materials suppressing the growth of bacteria and mold responsible for unpleasant odors,discolorration and making the treated materials self-sanitized.(Submission as an antimicrobial powder)

Note-2
An antimicrobial self-sanitized cuff which is imparted antimicrobial activity to suppress the growth of bacteria and mold responsible for disease.(Submission as a cuff)

Sincerely,

Tsuneo Ohgawara
TSUNEO OHGAWARA
VICE PRESIDENT

Kanebo

Record Number _____

Reference Number _____

Input Date _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 59824-E PM _____ |8| Action Code 116

|10| Descriptor (Amend/Resubmisions only) Revised data package

|5| Intrastate Call-in ☐ (Y) Yes ☐ (N) No

|15| Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person ☐ (R) Non-residential Use Only ☐ (N) Not-Applicable

|20| Registration Type:

☐ (1) Conditional ☐ (2) Unconditional

|25| Proposed Classification:

☐ (R) Restricted ☐ (G) General

|30| Final Classification:

☐ (R) Restricted ☐ (N) Not Classified

|35| Date on Application: 01 21 92 (MO DAY YR)

|04| EPA Received Date: 01 22 92 (MO DAY YR)

|40| Date Received by PM 01 24 92 (MO DAY YR)

|80| Method of Support:

☐ (1) Cite-All ☐ (6) Owner Submission

☐ (4) Not Applicable ☐ (7) Total Submission

☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
RD					
PM					
PL				38	4/13/92
CH					
EF					

|108| Status: _____

|115| FINAL ACTION Response Code _____

|120| Response 04 30 92 (MO DAY YR)

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

DP BARCODE: D173512

CASE: 280486 DATA PACKAGE RECORD DATE: 01/24/92
SUBMISSION: S410258 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 116 RESB NC-NON-FOOD/FEED U
CHEMICALS: 072501 Silver 0.0000%

ID#: 059824-E
COMPANY: 059824 KANEBO ZEOLITE U.S.A., INC
PRODUCT MANAGER: 31 JOHN LEE 703-305-5675 ROOM: CM2 258
PM TEAM REVIEWER: VALDIS GONCAROVS 703-305-6663 ROOM: CM2 260
RECEIVED DATE: 01/22/92 DUE OUT DATE: 07/30/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 173512 EXPEDITE: Y DATE SENT: 01/24/92 DATE RET.: / /
CHEMICAL: 072501 Silver
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 05/23/92 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : RD	/ /	/ /
BRAN: RSB	/ /	/ /
SECT: PCRS	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

review the package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

Kanebo **ZEOLITE U.S.A., INC.**

B3

TRANSMITTAL DOCUMENT 421738-ΦΦ

1. Name and address of submitter (applicant)

   KANEBO ZEOLITE U.S.A.,INC.

   350 Fifth Ave.,Suite 2018
   New York, N.Y. 10118

2. Proposed Regulatory Action
   Amendment to revise the third page of the transmittal letter in the administrative Volume (1), and pages 4 & 5 CA of the Confidential Attachment section in the Chemistry volume (2) submitted September 20, 1991

3. Transmittal Date: **JANUARY 21, 1992**

4. List of Submitted Amendment.

   Volume 1 : Administrative Materials

   421738Φ1 Volume 2 : Chemistry Data (amendment to Confidential attachment section)

5. Company official: Tsuneo Ohgawara Tsuneo Ohgawara
   Vice President
   Kanebo Zeolite U.S.A.,Inc.

6. Company contact: Olivia D. Laird
   Federal Regulatory Consultants, Inc.
   Consultant for Kanebo Zeolite U.S.A.,Inc.

   Tel. (703) 471-6590 FAX (703) 471-6269

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

JAN 23 1992

KANEBO, LTD
P.O. BOX 125
OSAKA 530, JAPAN,

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 01/22/92. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Kanebo

Kanebo, LTD.
OSAKA EKIMAE DAINI BUILDING
2-2, UMEDA 1-CHOME, KITA-KU, OSAKA 530, JAPAN
TELEX J63327 TELEFAX 06-348-5154

Kanebo Zeolite U.S.A., Inc.
350 Fifth Avenue
Suite 2018
New York, N.Y. 10118

Att: Mr. Kunio Kameda
President

August 17th, 1990

This is to transfer the rights of the following three (3) product applications which were submitted to the EPA for registration under the following file symbols:

Bactekiller AC - Silver Copper Zeolite - EPA File Symbol 59824-R
Bactekiller AZ - Silver Zinc Zeolite - EPA File Symbol 59824-E
Bactekiller A - Silver Zeolite - EPA File Symbol 59824-G

Kanebo Zeolite U.S.A., Inc. of New York is the sole owner of these three products and is to be listed as the registrant of these products when the EPA Registration Notice is issued.

Kanebo, Ltd. of Japan relinquishes all rights to these applications and hereby transfers the right to Kanebo Zeolite U.S.A., Inc. of New York since Kanebo Zeolite U.S.A., Inc. is financially responsible for all data generated in support of these applications.

Yours sincerely,

Iwao Murakami

Iwao Murakami
General Manager
Polyester Staple

Kanebo

Kanebo ZEOLITE U.S.A., INC.
350 FIFTH AVENUE, SUITE 2018, NEW YORK, N.Y. 10118, U.S.A.
PHONE 212-244-1506, FAX 212-563-4064

Office of Pesticide Programs
401 M Street, S.W.
Washington, D.C. 20460

ATT: Ms. Anne Lindsay, Director
Registration Division (H-7504C) 6/17/1991

Dear Ms. Lindsay,

In June 1988 Kanebo Ltd. of Japan submitted through their agent, Federal Regulatory Consultants, Inc. three (3) applications for registration of three products, which have been assigned the following synbols:

Bactekiller AC - Silver Copper Zeolite - EPA File Symbol: 59824 - R
Bactekiller AZ - Silver Zinc Zeolite - EPA File Symbol: 59824 - E
Bactekiller A - Silver Zeolite - EPA File Symbol: 59824 - G

At the time these applications were filed the registrant was designated as Kanebo Ltd.,

Osaka Ekimae Daini Building
2-2 Umeda 1-Chome, Kita-Ku
Osaka 530, Japan
TELEFAX: 06-348-5154

Since that time Kanebo Ltd. has transferred the rights to the Applications to Kanebo Zeolite U.S.A., Inc of New York, who has been solely financially responsible for generating the required data for registration of these products.

Please refer to the enclosed letter from Kanebo Ltd., of Japan transferring the rights to Kanebo Zeolite U.S.A., Inc of New York as sole owner.

This letter is a request for your office to have the records changed to reflect the change in company name and address from,

Kanebo Ltd.
Osaka Ekimae Daini Building
2-2 Umeda, 1-Chome, Kita-Ku,
Osaka 530, Japan
TELEFAX: 06-348-5154

To

Kanebo Zeolite U.S.A., Inc.
350 Fifth Avenue
Suite 2018
New York, N.Y. 10118

We would like to have this change made before the products are registered.

Yours sincerely,

Kunio Kameda
President
Kanebo Zeolite U.S.A., Inc.

Kanebo ZEOLITE U.S.A., INC.
350 FIFTH AVENUE, SUITE 2018, NEW YORK, N.Y. 10118, U.S.A.
PHONE 212-244-1506, FAX 212-563-4064

VOLUME 1

ADMINISTRATIVE MATERIALS FOR

KANEBO ZEOLITE U.S.A., INC.

BACTEKILLER AZ

(SILVER ZINC ZEOLITE)

FILE SYMBOL 59824-E

RESUBMISSION

Attention : Mr. John Lee, PM 31

Table of Contents

1) Transmittal Document

2) Letter appointing FRC, Inc. as agent for KANEBO ZEOLITE U.S.A., INC.

3) Cover Letter to Mr. John Lee, PM 31

4) Letter for transferring the rights to the Applications from Kanebo Ltd. to Kanebo Zeolite U.S.A.,Inc.

5) Letter requesting a change in submitter's name and address

6) Letter to Mr. Walter Francis, summarizing results of our of our meeting of August 2, 1991

7) Revised labeling for 59824-E

8) Volume 2: Chemistry Data

Kanebo

Kanebo ZEOLITE U.S.A., INC.
350 FIFTH AVENUE, SUITE 2018, NEW YORK, N.Y. 10118, U.S.A.
PHONE 212-244-1506, FAX 212-563-4064

Ms. Anne Lindsay, Director
Registration Division (H7504C)
Office of Pesticide Programs, EPA
401 M St., S. W.
Washington, D. C. 20460

Dear Ms. Lindsay:

By this letter, I hereby authorize Mrs. Olivia D. Laird or Mr. Arturo E. Castillo doing business as FEDERAL REGULATORY CONSULTANTS, INC. at the following addresses:

Mrs. Olivia D. Laird	Mr. Arturo E. Castillo
501 South Lincoln Ave.	2801 Barberry Lane
Sterling Park, VA 22170	Bowie, MD 20715
Tel. (703) 471-6590	Tel. (301) 464-2569
Fax (703) 471-6269	Fax (301) 464-0057

to deal with the Environmental Protection Agency in all matters pursuant to the registration of our Zeolite products.

This authorization is effective as of this date and will remain in effect until further notice.

Yours sincerely,

Kunio Kameda

Kunio Kameda, President

Kanebo ZEOLITE U.S.A., INC.
350 FIFTH AVENUE, SUITE 2016, NEW YORK, N.Y. 10118, U.S.A.
PHONE 212-244-1506, FAX 212-563-4064

Office of Pesticide Programs
401 M. Street, S.W.
Washington, D.C. 20460

September 20, 1991

ATT: Mr. John Lee
Product Manager 31 (H-7504)
Registration Division

Dear Mr.Lee

(1) Resubmission of Bactekiller AZ.

After our initial submission to E.P.A. on June 22, 1988, Silver zinc zeolite (Bactekiller AZ,Chemical formula : App.B,Vol 2.) it was checked by the Agency under the E.P.A. file symbol = 59824-E, as an antimicrobial manufacturing use powder.

On May 31, 1989 submitter Kanebo Ltd. in Japan received your notification requesting additional data.

On March 21, 1989 Kanebo Ltd. established an affiliate company Kanebo Zeolite U.S.A.,Inc. for the future production and commercialization of Silver zinc zeolite in the United States and authorized the company to deal with the E.P.A. submission matters in place of Kanebo Ltd.

In order to satisfy your requirements, we sent a representative production sample (Chemical formula: App.C,Vol 2.)of Silver zinc zeolite to the GLP qualified Life Sciences Laboratories of Arthur D.Little,Inc. in Cambridge MA,and proceeded to complete the Toxicology studies, Environmental fate and Product chemistry studies .

Finally today, 26 months after your letter, we have completed the necessary additional data based on GLP guidelines and your advices during our meeting on June 13, 1989 and on August 2, 1991.

Note: We have found the same Silver zinc zeolite has a significant capacity to absorb amines and mercaptans on its porous surface in an anhydrous state, and Kanebo Zeolite U.S.A., Inc. has already submitted the same substance to the E.P.A. as a deodorant under the trade name of Livefresh AZ.

On November 15, 1998 the same Silver zinc zeolite was approved as a mixture in PMN (Case number = P90-62).

(2) Ingredients of Bactekiller AZ.

Silver zinc zeolite is manufactured by mixing zeolite, silver ions and zinc ions in water within PH 4 to 5 and separating the resultant particles by filtration (Manufacturing: App.C,Vol 2.)

September 20, 1991

Mr. Walter C. Francis, Deputy Br. Chief

Antimicrobial Program Branch

Registration Division (H7504C)

Office of Pesticide Programs, EPA

401 M St., S.W.

Washington D.C. 20460

Dear Mr. Francis :

Subject : KANEBO ZEOLITE U.S.A.,INC.
(1) Bactekiller AC - EPA FS 59824-R
(2) Bactekiller AZ - EPA FS 59824-E
(3) Bactekiller A - EPA FS 59824-G

The officials of Kanebo Zeolite U.S.A.,Inc. and I thank you and the reviewers who met with us on August 2, 1991 to discuss the applications for the three products listed above. This letter summarizes our discussions and actions we are taking based upon your guidance concerning those applications :

1. The Agency will consider the pending applications for the three products as new uses for old chemicals, under the assigned file symbols.

   a. We have already submitted revised labels with an ingredient statement showing the active ingredients for #1 (59824-R) Silver and Copper, with each active keyed and a keyed sub-statement "from silver-copper sodium alumino silicate complex." Also, the labels have been revised to accommodate the comments from the Agency's letter of June 20, 1991 for that product.

   b. You concurred with our proposal that the zinc in product #2 (59824-E) will be treated as an inert ingredient, and that the application will be considered as a separate registration application under the existing file symbol 59824-E. The enclosed revised label reflects this change, listing silver with an asterisk as sole active ingredient, with a keyed substatement "from silver-zinc sodium alumino silicate complex."

   c. At the meeting Ms. Anna Skapars, the chemist, indicated that zinc will be considered as inert, but that it may turn out to be a new inert ingredient. We accept this, but we believe that we have submitted information with appropriate regulatory citations to show that zinc has been approved for use in cosmetics, medicines (skin ointments), and food contact packaging without any concerns for potential adverse effects.

We maintain that at the concentration present in #2 (59824-E), zinc should pose no concerns to the EPA for potential adverse effects from use of Kanebo's product for impregnating fabrics and textiles that will come in contact with human skin. Therefore, it should be approved as an inert ingredient in the product in question without the need for submitting any additional toxicological data. We have already included Arthur D. Little's summary of the published toxicological profile for zinc as part of the records for these applications. We feel that the information also supports our position that zinc should be approved as an inert ingredient without any additional data.

d. Similarly, we are enclosing a revised label for product #3, (59824-G),with an ingredient statement showing silver keyed as sole active ingredient with a keyed substatement "from silver sodium alumino silicate complex."

e. We believe that Ms. Skapars concurred with us, that the same label revisions prescribed in the Agency's letter of June 20, 1991 for #1 (59824-R) would be applicable for #2 (59824-E) and #3 (59824-G). Therefore, we have revised the labels to comply with those comments as applicable for the latter two products. In particular, we alert you that we have revised the labeling for all three products to non-food contact paper and adhesives as prescribed in the EPA June 20, 1991 letter, until such time as Kanebo succeed in getting FDA approval for the use of the three products for manufacturing packaging for food.

2. Chemistry : The GL Series 63 explanatory comments which we resubmitted with our letter of July 15, 1991 for #1 (59824-R), are also applicable to #2 (59824-E), and #3 (59824-G). Therefore, with this letter we are resubmitting those comments as separate attachments for each of the two latter products.

3. Toxicological Issues :

a. Under separate volumes, we are submitting a set of acute toxicity data for #2 (59824-E), and #3 (59824-G). The data will support our position that all three products are substantially the same with respect to signal word and human hazard precautionary labeling.

b. We submit to you that the complete package of toxicological data previously submitted for #1 (59824-R), plus some leaching studies, will suffice to support the new uses related to treated fabrics or textiles that will come in contact with human skin, as proposed for all three products. At the meeting the EPA toxicologist, Ms. Sunnyvette Williams, indicated that the teratology study would be acceptable provided Arthur D. Little gave her positive control teratology data for #1 (59824-R), to complete the record. By cover letter of August 20, 1991 Dr. Marquis of Arthur D. Little, Inc. sent this information directly to the attention of Ms. Williams. This should complete the teratology data.

4. Environmental Fate Considerations : The Environmental Fate Branch was not represented at the meeting. It was our impression that at the time of the meeting that the Environmental Fate data submitted a year ago had not yet been assigned for review. We would hope that by now this part of our previous submission is under conduction.
A GL 163-1 Leaching Study (MRID # 41615818) was included as part of the data. At the meeting, Ms. Williams indicated that the leaching study had been assigned to her for review. We will be very grateful to the Agency if the leaching study can be reviewed because it will show very low leaching and thus support the use of Kanebo's product #1 (59824) for treating fabrics or textiles (under wear is not included) which will come in contact with human skin.
Also, in the current submission we are including a Leaching study and Hydrolysis Study for #2 (59824-E), and Leaching metal comparision study for #3 (59824-G).
The same small amount of silver ion of 3.5 % is keyed in zeolite for the three products, therefore leaching silver levels are substantially the same .
For most applications the antimicrobials are not intended for use in its free state, but will be incorporated at low levels in the matrix of plastic polymers.

5. Wildlife and Aquatic Toxicology :

a. Mr. Les Stuart representing his branch indicated that there was some mix-up in assignment of the data for review. We left the meeting with the impression that the data had not yet been assigned, or had only recently been assigned, for review. We indicated at the meeting that we would appreciate a decision as soon as possible. Nevertheless, it is important to note that Mr. Stuart advised us that since these products will henceforth be treated as old chemicals, these data may not have been required for the indoor uses proposed for the three products, since those uses would not pose any significant potential adverse effects to fish or other organisms in public waters.
In this regard, we emphasize that for most applications, Kanebo's products are not intended for use in their free powder states, but will be incorporated at low levels in the matrix of plastic polymers.
If the toxicological issues are resolved and the products can be registered minus a decision on the fish and wildlife studies, Kanebo is willing to delete the proposed uses for the products to treat water against slime producing micro-organisms in recirculating waters, pending review of the data.

b. With these resubmissions we are including a daphnia study for #2 (59824-E), the silver zinc zeolite powder, and another for #3 (59824-G), the silver zeolite powder.
Both studies for powders will show that the products are substantially similar to #1 (59824-R), the silver copper zeolite product, with respect to potential adverse effects to daphnids.

These comments conclude our assessment of the meeting, and we trust that they will also serve to coordinate our current resubmissions for #2 (59824-E) and #3 (59824-G).
The three products are submitted under the same uses and the same incorporation levels. Actual selection of the three should be done after preliminary compatibility test with the customer's resin,residual polymerization catalyst in the customer's resin and other additives in the resin in order to have an acceptable whiteness of the final polymer products.

These are the only three products that KANEBO ZEOLITE U.S.A.,INC can depend on for its survival in the U.S. market and the survival of the firm depends on the registration of the products with the EPA as antimicrobial agents.

Since March 21, 1989, when KANEBO ZEOLITE U.S.A.,INC. was established, the company has been very diligent in its efforts to satisfy the requirements for registration of its three products at a considerable expenditure of time and funds.

Again, we would like to reiterate our plea for the Agency to expedite the registrations of the three products. We hope that our plea for a timely decision will be given the consideration we believe it justly deserves, given the history and circumstances associated with these applications.

Sincerely,

AE Castillo

Arturo E. Castillo
Agent for KANEBO

(1) Bactekiller AC - EPA FS 59824-R
(2) Bactekiller AZ - EPA FS 59824-E
(3) Bactekiller A - EPA FS 59824-G

PLEASE NOTE: In our meeting with the Deputy Branch Chief of the Antimicrobial Program Branch, it was established that since all three products listed above are substantially similar in the uses proposed for registration and in their physical chemical properties, the comments/revisions issued by the EPA for #1 (59824-R) are equally applicable for #2 and #3. Therefore, the following information applies to all three products, and is being submitted at this time as supplements to already submitted chemistry data, MRID Nos.408 42701 for 59824-R, 408 42801 for 59824-E, 408 42901 for 59824-G.

1. As part of the administrative volume our resubmission of July 15, 1991 we included a revised label for #1 to comply with the partial review received from the product manager. The revised label contains the revised ingredient statement so that the product can be considered as an old chemical (new use). With this resubmission we are including the same attachment (with minor changes) for placement in the files for #2 (59824-E), and #3 (59824-G).

2. Explanatory comments why certain items of GL Series 63 do not apply to Kanebo's products.

63-6: Boiling Point doe not apply for these products because they are ceramic powders; according to the guideline footnotes this item only applies to liquids and gases, not to solids. The chemistry addendum submitted as volume 2 for each of the products #1, #2, and #3 clarify this in more detail.

63-9: Vapor Pressure: all three products are stable solid ceramic powders resistant to high temperatures, they are not a volatile materials that give off vapors at ordinary temperatures. Refer to volume 2, chemistry addendum for each of the three products.

63-10 (Dissociation Constant): All three products are solids which do not dissolve in water or other solvents, and therefore this requirement does not apply. Refer to volume 2, chemistry addendum for each of the products.

63-11: Octanol/Water Partition Coefficient applies to chemicals which disperse differentially in water and octanol depending on partial solubility or separation into the two solvents. It applies mainly to organic non polar chemicals. All three of Kanebo's products are ceramic solid powders which are neither soluble nor

dispersible in octanol or water. Therefore this requirement does not apply. Refer to chemistry addendum for each product.

63-14 (Oxidizing/Reducing Action): All three products are very stable inorganic solid materials. They do not dissolve in water; they are not classified as oxidizing or reducing agents. Refer to chemistry addendum for each of the three products.

63-15 (Flammability): These products are solid stable materials resistant to high temperatures. They will not ignite at ordinary temperatures. Refer to chemistry addendum for more detailed explanation.

63-16 (Explodability): These products are very stable solid materials consisting primarily of zeolite, a naturally occurring mineral. They do not have any explosive properties even at high temperatures. Refer to chemistry addendum.

63-18 (Viscosity): The products are neither liquids nor viscous materials (semi-liquids); being solids they do not have any viscous properties. therefore viscosity does not apply. Refer to chemistry addendum for more details.

63-19 (Miscibility): According to the 40 CFR 158.120 footnote #14 miscibility is required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents. Kanebo's products are solids, not miscible with liquids.

63-20 (Corrosion Characteristics): All three products are very stable solids, and do not have any corrosive properties. They are not soluble in water or other common solvents, and are not considered as oxidizing agents. For more details refer to the chemistry data for each product.

3. Food Packaging Use: Kanebo is in the process of filing petitions with the Food and Drug Administration (FDA) for approval of its products for use in adhesives and paper for use in food packaging materials and containers that will come in contact with food. Pending such approval, Kanebo has revised the labels for all three products, and is submitting such labels with this package, restricting the products for use in paper that will not be used for food contact packaging or direct contact food containers, and to adhesives to be used in building materials only, such as plywood, tile cement and sealants.

4. Miscellaneous Labeling Revisions: We have revised the labels for all three products to comply with the partial review comments relating to other aspects of the label for all three products, to the extent that those comments apply to all three

products. The revised labels are being resubmitted for 59824-E, and 59824-G as part of the administrative volume for those products. The revised label for 59824-R was submitted to the product manager on July 15, 1991.

LABELING

PLEASE NOTE: The revised label EPA FS 1519824-E, show the mode of inclusion of Bactekiller AZ in the finished materials and final concentrations of the product in the various impregnated materials. This information is included in the Administrative Materials (Volume 1) for the Product Manager's consideration, and as part of the non-confidential portion of the Chemistry Data (Volume 2) for the chemistry reviewer's convenience.

Record Number _____

Reference Number _____

Input Date _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 59824-E PM _____ |8| Action Code 116

|10| Descriptor (Amend/Resubmisions only) inc. Zn conc. 6.5% → 9%.

|5| Intrastate Call-in ☐ (Y) Yes ☐ (N) No

|15| Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person ☐ (R) Non-residential Use Only ☐ (N) Not-Applicable

|20| Registration Type:

☐ (1) Conditional ☐ (2) Unconditional

|25| Proposed Classification:

☐ (R) Restricted ☐ (G) General

|30| Final Classification:

☐ (R) Restricted ☐ (N) Not Classified

|35| Date on Application: 12 23 91 (MO DAY YR)

|04| EPA Received Date: 12 30 91 (MO DAY YR)

|40| Date Received by PM 12 30 91 (MO DAY YR)

|80| Method of Support:

☐ (1) Cite-All ☐ (6) Owner Submission

☐ (4) Not Applicable ☐ (7) Total Submission

☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
RD					
PM					
PL				(28)	4/17/92
CH					
EF					

|108| Status: _____

|115| FINAL ACTION Response Code _____

|120| Response 4 30 92 (MO DAY YR)

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

Kanebo

Kanebo ZEOLITE U.S.A., INC.

350 FIFTH AVENUE, SUITE 2018, NEW YORK, N.Y. 10118, U.S.A.
PHONE 212-244-1506, FAX 212-563-4064

Office of Pesticide Programs
401 M D Street, S. W.
Washington, D.C. 20460

Att: Mr. John Lee
Product Manager 31 (H-7504)
Registration Division

December 23, 1991

Dear Mr. Lee

RE: Amendment of zinc content (inert ingredient) range in Bactekiller AZ-EPA FS 59824-E.
Resubmission of September 20, 1991.

In our resubmission of Bactekiller AZ dated September 20, 1991, we have proposed the zinc content in zeolite as 6.5 ± 0.7 % without including sufficient information about recent status of the color stability of the product.

Here we would like to amend the zinc content range in Bactekiller AZ from 6.5 ± 0.7 % to 9.0 ± 4.0 % by weight anhydrous basis in order to have enough color stability of the product.

Antimicrobial efficacy of Bactekiller AZ(Silver zinc zeolite) is derived from the silver ion content. (Table 1).

Zinc ions are linked together with silver ions in zeolite in order to improve the white color stability of Silver zeolite at elevated temperature. (>200°C).

In our applications, Bactekiller AZ is incorporated into various type of thermoplastic polymers which have different melting temperatures.

After extrusion, white color stability of the polymer product is realized by masking effect of zinc to the silver in zeolite matrix.

Our extrusion temperature varies from 150°C to 320°C depending on the polymer type.

Therefore we would like to have wider range for zinc in Bactekiller AZ and we enclose here with the following amended pages.

Page 7 of 25 in Volume 1.
Page 40 of 43 and Page 41 of 43 in Volume 2. (MRID=42032801)
Amended parts are marked by short underlines.
Also find enclosed herewith a confidential statement of the ranges of ingredients to address this change.

We hope that you will give it timely consideration and approve the registration with this amendment.

Yours sincerely,

Kunio Kameda

Kunio Kameda
President
Kanebo Zeolite U.S.A.,Inc.

Table 1: Antimicrobial Efficacy of Metal ion in zeolite

(MINIMUM INHIBITORY CONCENTRATION ppm)

Metal-Zeolite	Metal %	Microbial Species: Escherichia Coli	Pseudomonas aeruginosa	Staphylococcus aureus	Aspergillus niger
Silver-zeo	0.58	>4000	>40000	>4000	>40000
	1.21	1000	1000	1000	10000
	1.69	500	500	500	500
	2.79	250	250	500	500
	3.24	250	125	500	500
	3.75	125	125	250	250
	11.00	125	125	250	500
Zinc-zeo	6.42	>4000	>4000	>4000	>4000
	11.00	>4000	>4000	>4000	>4000
	14.57	>4000	>4000	>4000	>4000
Silver zinc -zeo	3.51 Ag+ 3.02 Zn	250	250	500	500
	3.19 Ag+ 6.11 Zn	250	250	500	500
	3.18 Ag+ 8.02 Zn	500	500	1000	500

Kanebo ZEOLITE U.S.A. INC.

TRANSMITTAL DOCUMENT

1. Name and address of submitter (applicant)

KANEBO ZEOLITE U.S.A.,INC.

350 Fifth Ave.,Suite 2018
New York, N.Y. 10118

2. Proposed Regulatory Action

Amendment of zinc (inert ingredient) content range in the resubmission for Bactekiller AZ-EPA FS 59824-E

3. Transmittal Date: December 23, 1991

4. List of Submitted Amendment.

Volume 1 : Amended page 7 of 25 (Resubmission dated September 20, 1991)

Volume 2 : Amended pages; Page 40 of 43 and Page 41 of 43 (Resubmission dated September 20, 1991 MRID = 4203208)

5. Company official: Tsuneo Ohgawara Tsuneo Ohgawara

Vice President
Kanebo Zeolite U.S.A.,Inc.

6. Company contact: Olivia D. Laird
Federal Regulatory Consultants, Inc.
Consultant for Kanebo Zeolite U.S.A.,Inc.

Tel. (703) 471-6590 FAX (703) 471-6269

Pages 135 - 140 *Access to FIFRA Registration Data is restricted under FIFRA section 10(g)*

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

JAN 14 1992

KANEBO, LTD
P.O. BOX 125
OSAKA 530, JAPAN,

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 12/30/91. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected study [01] :

It is not acceptable to send in only replacement pages or inadvertently omitted pages for a study previously submitted. A complete replacement version of the study, which meets all of the requirements of PR Notice 86-5, should be submitted. On the title page of the replacement study, identify the previously submitted study by EPA accession or MRID number. If these EPA numbers are unknown to you, call EPA at (703) 557-3240 for assistance in identifying the appropriate number(s). In the transmittal of the replacement study, explain fully both the relationship of the newly submitted replacement study to the original study, and the specific differences between the two versions. This will allow our reviewers to tell quickly whether or not the resubmission will significantly impact a review already underway or completed.

Kanebo ZEOLITE U.S.A., INC.

TRANSMITTAL DOCUMENT

1. Name and address of submitter (applicant)

KANEBO ZEOLITE U.S.A.,INC.

350 Fifth Ave.,Suite 2018
New York, N.Y. 10118

2. Proposed Regulatory Action

Amendment of zinc (inert ingredient) content range in the resubmission for Bactekiller AZ-EPA FS 59824-E

3. Transmittal Date: December 23, 1991

4. List of Submitted Amendment.

Volume 1 : Amended page 7 of 25 (Resubmission dated September 20, 1991)

Volume 2 : Amended pages; Page 40 of 43 and Page 41 of 43 (Resubmission dated September 20, 1991 MRID = 4203208) Reject (01)

5. Company official: Tsuneo Ohgawara Tsuneo Ohgawara

Vice President
Kanebo Zeolite U.S.A.,Inc.

6. Company contact: Olivia D. Laird
Federal Regulatory Consultants, Inc.
Consultant for Kanebo Zeolite U.S.A.,Inc.

Tel. (703) 471-6590 FAX (703) 471-6269

from Y-Gonzalez

DP BARCODE: D172950

CASE: 280486 DATA PACKAGE RECORD DATE: 01/08/92
SUBMISSION: S409421 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 116 RESB NC-NON-FOOD/FEED U
CHEMICALS: 072501 Silver 0.0000%

ID#: 059824-E
COMPANY: 059824 KANEBO ZEOLITE U.S.A., INC
PRODUCT MANAGER: 31 JOHN LEE 703-305-5675 ROOM: CM2 258
PM TEAM REVIEWER: VALDIS GONCAROVS 703-305-6663 ROOM: CM2 260
RECEIVED DATE: 12/30/91 DUE OUT DATE: 07/07/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 172950 EXPEDITE: Y DATE SENT: 01/08/92 DATE RET.: / /
CHEMICAL: 072501 Silver
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 05/07/92 CSF: Y LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : RD	/ /	/ /
BRAN: RSB	/ /	/ /
SECT: PCRS	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

review the new csf, increasing ZN to 9 %.

IS THIS STILL AN INERT OR IS ZINC REALLY AN ACTIVE.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

Return to Customer

5392.

J25-1249

Kanebo

Kanebo ZEOLITE U.S.A., INC.

350 FIFTH AVENUE, SUITE 2018, NEW YORK, N.Y. 10118, U.S.A.
PHONE 212-244-1506, FAX 212-563-4064

RECEIVED
OCT 26 1990
SUBSTANCE SERVICE

Chemical Abstract Services
Registry Services Dept.
P.O. Box 3012
Columbus, Ohio 43210

ATT: Ms. Roberta Fiete October 25, 1990

Dear Ms. Fiete:

Per your conversation today with our consultant, Mr. Art Castillo, we are herewith transmitting by Federal Express our patents for modified Zeolites containing certain metal ions to give them antimicrobial properties.

Kanebo Zeolite, has modified the well established Zeolite (CAS No. 1318-02-1) by exchanging some of the sodium ions to produce three products described below. It should be noted that the crystalline structure of the original Zeolite has not been altered. A copy of that structure is attached.

(1) BACTEKILLER AC CAS Registry Number: 130328-19-7*
Contains 3.5% +/- 0.5% Silver and 6.1% +/- 0.7% Copper by weight in its anhydrous state.

(2) BACTEKILLER AZ CAS Registry Number: 130328-20-0*
Contains 3.5% +/- 0.5% Silver and 6.5% +/- 0.7% Zinc in its anhydrous state.

(3) BACTEKILLER A CAS Registry Number: 130328-18-6*
Contains 3.5% +/- 0.5% Silver in its anhydrous state.

We have filed applications for registration for the three products in question, as bacteriostatic agents, to comply with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), administered by the Environmental Protection Agency (EPA). However, the EPA will not process the applications until we obtain CAS numbers assigned by your agency.

PARCEL EXPRESS

CAS REGISTRY NUMBERS WITH ASTERISKS

CAS Registry Numbers appended with an asterisk represent substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCB). These UVCB substances are not well-defined, and do not have unique structural diagrams or specific molecular formulas; thus, in the CAS Registry database these substances receive only a CA Name (i.e., no structural diagram, no molecular formula) and a special code (CTS or CRS) which identifies them as poorly-defined substances.

Whenever numbers for these substances are cited, as for example in the CA Registry Handbook-Number Section or in Inventory publications, they are clearly tagged (an asterisk appended to the Registry Number). These Registry Numbers are not included in the routine CA abstracting and indexing services and cannot be used to search the CA File available on CAS Online through STN International. To search the CA File for these substances, the Index Name or terms derived from the name(s) should be used to locate literature references.

Chemical Abstracts Service A DIVISION OF THE AMERICAN CHEMICAL SOCIETY

2540 Olentangy River Road
P.O. Box 3012
Columbus, Ohio 43210
Phone: 614-447-3600

WUI TELEX: 6842086
TWX: 810-482-1608
Cable: CHEMABS
TELEFAX: 614-447-3713

November 9, 1990

Chemical Abstracts Service (CAS)
CAS Registry Services
2540 Olentangy River Road
P.O. Box 3343
Columbus, OH 43210

Kanebo Zeolite U.S.A., Incorporated
ATTN: Mr. Kunio Kameda
350 Fifth Avenue
Suite 2018
New York, NY 10118

Dear Mr. Kameda,

Thank you for your CAS Registry Services request of October 25, 1990. The CAS Registry Numbers for your three substances are enclosed.

Your check number 1528 in the amount of $21.00 for the technical processing of your order has been received.

If you have any questions, please contact me at (614)-447-3600, extension 2308.

Sincerely,

Debby Van Hoose

Debby VanHoose
CAS Registry Services

Enclosure(s): Form 1
Form 4
Form 20
Form 27

cc: E. M. Shanbrom
File 62-1036

DSV:dsv, /ul6e/dsv62/Files/1036/6731D (UNIX16)

Record Number _____

Reference Number _____

Input Date _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 59824-E PM ____ |8| Action Code 116

|10| Descriptor (Amend/Resubmisions only) Should be 9.090 7m

|5| Intrastate Call-in ☐ (Y) Yes ☐ (N) No

|15| Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person ☐ (R) Non-residential Use Only ☐ (N) Not-Applicable

|20| Registration Type:

☐ (1) Conditional ☐ (2) Unconditional

|25| Proposed Classification: |30| Final Classification:

☐ (R) Restricted ☐ (R) Restricted

☐ (G) General ☐ (N) Not Classified

|35| Date on Application: 09 20 91 (MO DAY YR)

|04| EPA Received Date: 09 25 91 (MO DAY YR)

|40| Date Received by PM 10 02 91 (MO DAY YR)

|80| Method of Support:

☐ (1) Cite-All ☐ (6) Owner Submission

☐ (4) Not Applicable ☐ (7) Total Submission

☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
RD					
PM	MAR 15 1993				
PL					
CH	OCT 26 1992 Heather Manfield				
ABS	APR 30 1992				

HED-TOX 10-17
EF - 10-17
EE - 10-17
Chem 10-17

|108| Status: _____

|115| FINAL ACTION Response Code _____

|120| Response ___ MO DAY YR

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

DP BARCODE: D169928

CASE: 280486 DATA PACKAGE RECORD DATE: 08/05/93
SUBMISSION: S405144 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 116 RESB NC-NON-FOOD/FEED U
CHEMICALS: 072501 Silver 0.0000%
129015 Zinc 0.0000%

ID#: 059824-E BACTEKILLER AZ (silver & zinc)
COMPANY: 059824 KANEBO ZEOLITE U.S.A., INC
PRODUCT MANAGER: 31 JOHN LEE 703-305-5675 ROOM: CM2 270
PM TEAM REVIEWER: VALDIS GONCAROVS 703-305-6663 ROOM: CM2 272
RECEIVED DATE: 09/25/91 DUE OUT DATE: 04/02/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 169928 EXPEDITE: Y DATE SENT: 10/04/91 DATE RET.: / /
CHEMICAL: Unknown
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	10/17/91	08/24/93
BRAN: EFGB	10/18/91	/ /
SECT: CRS3	12/18/91	/ /
REVR : STERMES	12/18/91	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 02/01/92
NEGOT DATE: / /
PROJ DATE: 07/30/93

* * * DATA REVIEW INSTRUCTIONS * * *

review the data and label and cover

NOte : Cooling water uses, etc adequate data on file?
also identify any additional data for this product.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
169923	TB-2/RS-4	10/04/91	02/01/92	Y	Y	Y
169929	EEB/RS2	10/04/91	02/01/92	Y	Y	Y
169930	RSB/PCRS	10/04/91	12/04/91	Y	Y	Y

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 13 1994

Kanebo Zeolite U.S.A. Inc.
350 Fifth Ave Suite 2018
New York, NY 10118

Attention: Olivia Laird
Agent

Subject: Bactekiller AZ
EPA File Symbol No. 59824-E
Your Submission Dated September 20, 1991
(Environmental Fate only)

The review of the submission package (Environmental Fate data) has been completed and the attached review and the DER is enclosed for your review. In summary, one data package was reviewed.

1. The study (MRID # 42032806) which is not a conventional hydrolysis study but a release from matrix study is incomplete. The information requested in the DER and the summary review will be required to be addressed.

2. A special leach study from treated proudcts must also be conducted with this product. Refer to the DER and the summary review and submit the requested information to complete this data requirement. Note: do not use the guideline no. 163-1. Please use Guideline No. 168-SS-1 Special study when you resubmit the requested information.

Just a reminder that after a review of the above requested information, additional data and/or information may be required to support your registration.

If you have any questions concerning this letter, contact V. Goncarovs at 703-305-6663.

Sincerely yours,

Marshall Swindell
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

APR 30 1992

Kanebo Zeolite U.S.A., Inc.
350 Fifth Avenue, Suite 2018
New York, NY 10118

Attention: Olivia Laird
Agent

Gentlemen:

Subject: Bactekiller AZ
EPA File Symbol 59824-E
Your Submissions Dated September 20, December 23, 1991, and January 21, 1992

The Agency has completed a partial review of the above submission. Note that this letter only addresses the chemistry issue at this time.

1. A product chemistry data package review is now completed and no additional chemistry data is required at this time.

   Note: Based upon a review of the information submitted, zinc will be required to be declared as an active. Therefore, revise your ingredient statement on the label to read as follows:

   Active Ingredients
   Silver* as elemental 3.5%
   Zinc* as elemental 9.0%
   Inert Ingredients 87.5%
   *from silver-zinc sodium alumino silicate complex

2. The other three departments:

   - Toxicology

   - Environmental Fate

   - Fish and Wildlife

64611:I:V.G.:WP31-05:KEVRIC:04/14/92:05/14/92:aw:wo:dd
R:64608:V.G.:WP31-05:KEVRIC:04/17/92:05/16/92:dd

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

have yet to complete their reviews. When their reviews are completed, you will be notified of their recommendations/ conclusions.

3. Just a reminder that since this product label will now declare two old chemicals as actives:

   - silver

   - zinc

   then this product will now also be subject to reregistration requirements. Initially Phase 2 and Phase 3 responses will be required to be submitted to the Reregistration Division.

4. Just a reminder that after a review of the above information, additional data may be required to support your application.

5. The Agency reserves full label review at this time.

6. This letter does not constitute registration and the product may not be lawfully marketed until it is registered.

If you have any questions concerning this letter, please contact V. Goncarovs at (703) 305-6663.

Sincerely yours,

John H. Lee
Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 15 1993

Kanebo Zeolite U.S.A. Inc.
350 Fifth Ave Suite 2018
New York, NY 10118

Attention: Olivia Laird
Agent

Subject: Bactekiller AZ
EPA File Symbol No. 59824-E
Your Submission Dated September 20, 1991
(Toxicology only)

The review of the submission package (Toxicity data) has been completed and the following comments are outlined below.

1. The study "In vivo mammalian cytogenetics assay in rats" is incomplete. Please provide explanation and clarification (on an individual animal basis) as to why slides could not be read from many of the males, particularly those of the 5000 mg/kg dosage group sacrificed at 18 hours.

2. The six acute toxicity studies are incomplete. The stability of the test material was not included in the study.

3. The leaching study is incomplete. The rationale for using pH 6.5 was not provided. In addition, the pH levels above and below the pH 6.5 were not included in the report. Note: The guideline no. 163-1 is inappropriate for this type of study. That guideline line number is reserved for Environmental Fate data requirements. No guideline number is available for this type of leaching study under section 158.340 (Toxicology).

4. It has been noted for the record in this file, that the remaining toxicological concerns for this product are also dependent upon the toxicity review for the other pending application: "BACTEKILLER AC (EPA FILE 59824-R)".

5. Note that any data submitted must conform to PR Notice 86-5 (formatting)

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

6. Just a reminder that after a review of the above requested information, additional data and/or information may be required to support your product.

7. The Agency reserves full label review at this time.

This letter does not constitute registration and the product may not be lawfully marketed until all the required information has been submitted for review and found acceptable.

If you have any questions concerning this letter, contact V. Goncarovs at 703-305-6663.

Sincerely,

John H. Lee
Product Manager 31
Antimicrobial Program Branch
Registration Division (H7505C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 26 1992

Kanebo Zeolite U.S.A. Inc.
350 Fifth Ave Suiter 2018
New York, NY 10118

Attention: Olivia Laird
Agent

Subject: Bactekiller AZ
EPA File Symbol No. 59824-E
Your Submission Dated September 20, 1991
(Fish & Wildlife only)

The review of the submission package (Fish & Wildlife data) has been completed and the attached review and the DERS are enclosed for your review.

Note for your records that the Toxicology department and Environmental Fate Department has yet to complete their review of data submitted for the above date.

Just a reminder that after a review of the above requested information, additional data and/or information may be required to support your application.

The Agency reserves full label review at this time.

This letter does not constitute registration and the product may not be lawfully marketed until all the required information has been submitted for review and found acceptable.

If you have any questions concerning this letter, contact V. Goncarovs at 703-305-6663.

Sincerely,

John H. Lee
Product Manager 31
Antimicrobial Program Branch
Registration Division (H7505C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

*U.S. Government Printing Office: 1992 — 620-856/40672

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

OCT - 2 1991

KANEBO, LTD
P.O. BOX 125
OSAKA 530, JAPAN,

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 09/25/91. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

TRANSMITTAL DOCUMENT

420328-00

1. Name and address of submitter (applicant)

KANEBO ZEOLITE U.S.A., INC.

FEDERAL REGULATORY
CONSULTANTS, INC.
2801 BARBERRY LANE
BOWIE, MD 20715

2. ~~Proposed Registration, Resub~~

Registration of Me-Too Product (Product Manager 31)
Resubmission for Bactekiller AZ - EPA FS 59824-E

3. Transmittal Date: September 20, 1991

4. List of Submitted Studies

Volume 1: Administrative Materials for Mr. Lee, PM 31

Volume 2: Chemistry Data; 40 CFR Section 158.120
Supplement to MRID # 408 42801
GL Nos. 61-1, 61-2; 62-3, 63-17 (Storage Stability)
Explanatory Comments why GL Nos. 63-6, -9, -10, -11, -14, -15,-16, -18, -19 and -20 do not apply to all three of Knaebo's products.

42032801

Volume 3: Acute Toxicity Data (81-1,81-2,81-3,81-4,81-5,81-6,)
ADL Summary of Toxicity Data (6 Volumes)

42032802

Volume 4: Mutagenicity Study (GL# 84-2)

42032803

Volume 5: In vivo chromosome aberation assay (GL 84-2)

42032804

Volume 6: Daphnid Study, Sub. Div. E (GL 72-2)

42032805

Volume 7: Hydrolysis Study (GL# 161-1)

42032806

Volume 8: Leaching Study (GL# 163-1)

42032807

Cmpany Official: Tsuneo Ohgawara

Arturo E. Castillo
for Tsuneo Ohgawara

Company Name: KANEBO ZEOLITE U.S.A., INC.

Company Contact: OLIVIA D. LAIRD OR ARTURO E. CASTILLO
Consultants/Sole Agents for
Kanebo Zeolite U.S.A., Inc.

Tel. (301) 464-2569 FAX (301) 464-0057

DP BARCODE: D169930

CASE: 280486 DATA PACKAGE RECORD DATE: 10/17/91
SUBMISSION: S BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 116 RESB NC-NON-FOOD/FEED U
CHEMICALS: ** UNKNOWN **
ID#: 059824-E
COMPANY: 059824 KANEBO ZEOLITE U.S.A., INC
PRODUCT MANAGER: 31 JOHN LEE 703-557-3675 ROOM: CM2 258
PM TEAM REVIEWER: VALDIS GONCAROVS 703-557-3663 ROOM: CM2 260
RECEIVED DATE: 09/25/91 DUE OUT DATE: 04/02/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 169930 EXPEDITE: Y DATE SENT: 10/04/91 DATE RET.: / /
CHEMICAL: Unknown
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 12/04/91 CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : RD	/ /	/ /
BRAN: RSB	/ /	/ /
SECT: PCRS	/ /	/ /
REVR : Anna Skapars	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

review the package and label and data

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
169923	TB-2/RS-4	10/04/91	02/01/92	Y	Y	Y
169928	EFGB	10/04/91	02/01/92	Y	Y	Y
169929	EEB	10/04/91	02/01/92	Y	Y	Y

PRODUCT CHEMISTRY Review
RSB

EPA Reg. No. or File Symbol 59824-E

Date Division Received 9-25-91

Products Manager No. 31 (Lee)

Product Name Bactekiller AZ

Company Name Kanebo Zeolite U.S.A., Inc.

100.0 Commencs:

a. The label for this product should declare:
Active Ingredients
Silver * as elemental 3.5%
Zinc * as elemental 9.0%
Inert Ingredients 87.5%
* from silver-zinc sodium alumino silicate complex

b. Enclosed product chemistry data is in compliance with data requirements in 40 CFR part 158.150 through 158.190. It includes 12 months storage and stability data at ambient storage conditions and data is acceptable.

c. Submit revised label and revise ingredient statement.

The container sizes are 8 10.0 lbs or above so pesticide & container & contamination statements should be as per PR 83-3 use Ind/Ag language on 83-3
Fill out 8570-1 form completely
Anna Skapars
3-17-92

The limits ~~st~~ for silver or zinc ~~st~~ ~~st~~ should be as per 40 CFR or ~~data~~ 5 batch analyses of zeolite will be required. The limits are very wide doesn't confirm to std limits

3/18/92

Pages 159 - 163 *Access to FIFRA Registration Data is restricted under FIFRA section 10(g)*

BB

Table of Contents

1) Transmittal Document

2) Letter appointing FRC, Inc. as agent for KANEBO ZEOLITE U.S.A., INC.

3) Cover Letter to Mr. John Lee, PM 31

4) Letter for transferring the rights to the Applications from Kanebo Ltd. to Kanebo Zeolite U.S.A.,Inc.

5) Letter requesting a change in submitter's name and address

6) Letter to Mr. Walter Francis, summarizing results of our of our meeting of August 2, 1991

7) Revised labeling for 59824-E

8) Toxicology Summary from Arthur D. Little, Inc.

Please Note: As part of this resubmission we have submitted the following data under separate volumes, in accordance with PR Notice 86-5:

9) Volume 2: Chemistry Data

10) Volume 3: Acute Toxicity Data (81-1, 2, 3, 4, 5, and 6)
Toxicology Summary from Arthur D. Little, Inc.

11) Volume 4: Mutagenicity Study (GL# 84-2)

12) Volume 5: In vivo chromosome aberation assay (GL 84-2)

13) Volume 6: Daphnid Study (GL # 72-2)

14) Volume 7: Hydrolysis Study (GL# 161-1)

15) Volume 8: Leaching Study (GL# 163-1)

D169929
DPBARCODE (RECORD)

SHAUGHNESSY NO

REVIEW NO.

EEB REVIEW

DATE IN: 10-28-91 OUT: SEP 21 1992

CASE # : 280486 REREG CASE #:
SUBMISSION # : S405144 LIST A, B, C, D
ID # : 059824-E

DATE OF SUBMISSION 09-25-91

DATE RECEIVED BY EFED 10-24-91

SRRD/RD REQUESTED COMPLETION DATE 02-01-92

EEB ESTIMATED COMPLETION DATE 02-01-92

SRRD/RD **ACTION** CODE/TYPE OF REVIEW 116 - Resubmission

MRID #(S)

DP TYPE 001 - Submission Related Data Package

PRODUCT MANAGER, NO. J. Lee (31)

PRODUCT NAME(S) Bactekiller AZ

TYPE PRODUCT F R I N H D Antimicrobial

COMPANY NAME Kanebo Zeolite USA, Inc.

SUBMISSION PURPOSE Review data, label, and cover letter

INCLUDE USE(S)

COMMON CHEMICAL NAME Silver-zinc Zeolite

DP BARCODE: D169929

CASE: 280486 DATA PACKAGE RECORD DATE: 10/17/91
SUBMISSION: S405144 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 116 RESB NC-NON-FOOD/FEED U
CHEMICALS: ** UNKNOWN ** SILVER ZINC ZEOLITE
ID#: 059824-E
COMPANY: 059824 KANEBO ZEOLITE U.S.A., INC
PRODUCT MANAGER: 31 JOHN LEE 703-557-3675 ROOM: CM2 258
PM TEAM REVIEWER: VALDIS GONCAROVS 703-557-3663 ROOM: CM2 260
RECEIVED DATE: 09/25/91 DUE OUT DATE: 04/02/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 169929 EXPEDITE: Y DATE SENT: 10/04/91 DATE RET.: / /
CHEMICAL: Unknown
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 02/01/92 CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	10/24/91	09/14/92
BRAN: EEB	10/28/91	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

review the data, label and cover letter

Note: Added Cooling water any additional data requirements

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
169923	TB-2/RS-4	10/04/91	02/01/92	Y	Y	Y
169928	EFGB	10/04/91	02/01/92	Y	Y	Y
169930	RSB/PCRS	10/04/91	12/04/91	Y	Y	Y

92-07 EFGWB# Sylvia

DP BARCODE: D169929

CASE: 280486 DATA PACKAGE RECORD DATE: 10/17/91
SUBMISSION: S 405144 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 116 RESB NC-NON-FOOD/FEED U
CHEMICALS: ** UNKNOWN ** Silver zinc zeolite
ID#: 059824-E
COMPANY: 059824 KANEBO ZEOLITE U.S.A., INC
PRODUCT MANAGER: 31 JOHN LEE 703-557-3675 ROOM: CM2 258
PM TEAM REVIEWER: VALDIS GONCAROVS 703-~~557-3663~~ 305 6663 ROOM: CM2 260
RECEIVED DATE: 09/25/91 DUE OUT DATE: 04/02/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 169929 EXPEDITE: Y DATE SENT: 10/04/91 DATE RET.: / /
CHEMICAL: Unknown
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 02/01/92 CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	10/24/91	09/21/92
BRAN: EEB	10/28/91	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

review the data, label and cover letter

Note: Added Cooling water any additional data requirements

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
169923	TB-2/RS-4	10/04/91	02/01/92	Y	Y	Y
169928	EFGB	10/04/91	02/01/92	Y	Y	Y
169930	RSB/PCRS	10/04/91	12/04/91	Y	Y	Y

221700 AS
129057 AS Cu
hydrolysis 420328-05

Sylvia
Richard Mahler

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Silver-Zinc Zeolite
DP Barcode: D169929
ID No: 59824-E

FROM: Douglas J. Urban, Acting Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C) 9/16/92

TO: John Lee, PM 31
Antimicrobial Program Branch
Registration Division (H7505C)

According to Kanebo Zeolite USA's label for silver-zinc zeolite, the chemical may be used in the following manufacturing processes: fibers (indoor nonfood); plastic films and molded plastics (indoor nonfood); paper (aquatic nonfood industrial); paint (indoor nonfood); adhesives (indoor nonfood); and water treatment (aquatic nonfood industrial).

EEB requires four tests to support the registration of chemicals with indoor nonfood uses: 71-1(a) avian acute oral, preferably with the bobwhite quail; 71-2(a) avian dietary, preferably with the bobwhite quail; 72-1(c) fish acute toxicity, preferably with the rainbow trout; 72-2(a) aquatic invertebrate toxicity, preferably with *Daphnia magna.* Three additional tests, estuarine/marine acute studies, are currently required to support uses in once-through cooling towers, oil recovery drilling muds/packer fluids, secondary oil injection waters and pulp and paper mills. Because of silver-zinc zeolite's paper processing uses and because the label does not specify the water treatment uses (leaving it uncertain as to whether or not the chemical may be used in once-through cooling towers, etc.) 72-3(a) fish acute toxicity, preferably with the sheepshead minnow; 72-3(b) mollusc acute toxicity, preferably with *Crassostrea virginica*, and 72-3(c) shrimp acute toxicity, preferably with the mysid shrimp are required.

Recycled/Recyclable
Printed on paper that contains at least 75% recycled fiber

Kanebo submitted one study with the end use product of 4± 1% silver and 6± 1% zinc to support the registration of silver-zinc zeolite-- 72-2, *Daphnia magna* EC_{50} {MRID No. 420328-05}. This study was submitted to demonstrate that the toxicity of silver-zinc zeolite is comparable to that of silver-copper zeolite (for which 5 studies had been submitted, including a daphnia study) and silver zeolite (for which one daphnia study had been submitted. The *Daphnia magna* study did not fulfill guideline requirements, largely because the actual amount of silver present was not detected. Further, the results that were obtained indicate that the concentrations of both of the metals were much less than desired. This may either be due to the inherently low solubility of these metals or to insufficient detection methods. The study does, however, indicate that silver-zinc zeolite is very highly toxic to aquatic invertebrates and has a similar toxicity to aquatic invertebrates as both silver zeolite and silver-copper zeolite. EEB will accept Kanebo's contention that the chemicals have a similar aquatic toxicity and allow that aquatic testing with silver-copper zeolite with 4±1% silver and 6±1% copper be used to satisfy the data requirements for silver-zinc zeolite with 4±1% silver and 6±1% zinc. Because Kanebo tested the end-use products, if the concentration of the metals in silver-zinc zeolite are raised, additional testing may be required.

Before EEB can accept the silver-copper zeolite testing for fulfilling avian toxicity requirements, the same sort of bridging data that was submitted for aquatic toxicity testing is necessary. Kanebo should conduct an avian dietary LC_{50} with silver-zinc zeolite, preferably with the bobwhite quail to determine if its avian toxicity is similar to that of silver-copper zeolite. If the toxicity is similar, than an avian acute oral LD_{50} with silver-copper zeolite may be used to satisfy the data requirements for silver-zinc zeolite.

There is a possible discrepancy between the concentration of zinc in the test substance and on the label. The label indicates that there is 9% zinc in silver-zinc zeolite while the CSOF indicates that there is 6.5% zinc. This discrepancy must be resolved with Kanebo. If the value is 9%, then the toxicity values for silver-zinc zeolite should be adjusted accordingly.

In summary, the current data requirements for silver-zinc zeolite are:

1. Guideline 71-2(a), the avian dietary performed with the bobwhite quail should be performed with silver-zinc zeolite to provide bridging data for birds between silver-zinc zeolite and silver-copper zeolite.

2. Guideline 71-1(a), the avian acute oral toxicity, may be

performed with silver-copper zeolite if the avian dietary tests demonstrate a similar toxicity.

3. Guidelines 72-1(c) and 72-2(a), aquatic toxicity testing with the rainbow trout (preferred) or bluegill sunfish and *Daphnia magna* should be repeated with silver-copper zeolite. The original tests did not satisfy guideline requirements because the concentration of the metals in the test solutions indicate that the concentrations of the metals were much less than desired. Testing with silver-copper zeolite can fulfill the guideline requirements for silver-zinc zeolite.

4. Estuarine/marine testing may be performed with silver-copper zeolite to satisfy the requirements for silver-zinc zeolite: 72-3(a) fish acute toxicity, preferably with the sheepshead minnow; 72-3(b) mollusc acute toxicity, preferably with *Crassostrea virginica*; and 72-3(c) shrimp acute toxicity, preferably with the mysid shrimp.

5. Kanebo should rectify the discrepancy between the 9% zinc reported on the label and the ~6% zinc reported on the CSOF and used for testing purposes.

Kanebo mentioned that it would be "willing to delete the proposed uses for the products to treat water against slime producing microorganisms in recirculating waters, pending review of the data." EEB points out that even if Kanebo submits a label that specifies that the allowable water treatment uses of silver-zinc zeolite are such that the chemical may not be used in once through cooling towers (or drilling muds/packer fluids or secondary oil recovery injection waters), the company still must delete the paper production use in order to be exempt from performing the estuarine/marine testing. Kanebo would then only need to submit the results of the chemical analysis from the two avian dietary studies, perform an avian dietary LC_{50} with silver-zinc zeolite (to provide bridging data), perform an avian oral LD_{50} with silver-copper zeolite (if the bridging data demonstrates that silver-copper and silver-zinc zeolite are similar in toxicity to birds), and repeat the acute aquatic studies with the rainbow trout and *Daphnia magna* using silver-copper zeolite in order to satisfy the data requirements for silver-zinc zeolite.

The attached data table reiterates the current status of the data requirements for silver-zinc (and silver and silver-copper) zeolite. If there are any questions, please contact Heather Mansfield (305-5064).

Date: 6/22/92
Case Nos: 280485,6, & 7
Chemical Nos: 129057, not available, & 221700

PHASE IV
DATA REQUIREMENTS FOR
ECOLOGICAL EFFECTS BRANCH:
SILVER ZEOLITE
SILVER-COPPER ZEOLITE
& SILVER-ZINC ZEOLITE

Data Requirements	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation (MRID, date study was reviewed)	Must Additional Data Be Submitted under FIFRA3(c)(2)(B)?
6 Basic Studies in Bold					
71-1(a) Acute Avian Oral, Quail	TEP[3]	F,M		----------	
	Silver		No		Yes[4]
	Silver-copper		No		Yes
	Silver-zinc		No		Yes[5]
71-1(b) Acute Avian Oral, Quail/Duck	TGAI	----------	No	----------	No
71-2(a) Acute Avian Diet, Quail	TEP[3]	F,M			
	Silver		No		Yes[6]
	Silver-copper		No	416158-11, 9/27/91	Yes[7]
	Silver-zinc		No		Yes[8]
71-2(b) Acute Avian Diet, Duck	TEP[3]	F,M			
	Silver		No		No[9]
	Silver-copper		No	416158-12, 9/27/91	Yes[7]
	Silver-zinc		No		No[9]
71-3 Wild Mammal Toxicity	----	----------	No	----------	No
71-4(a) Avian Reproduction, Quail	----	----------	No	----------	No
71-4(b) Avian Reproduction, Duck	----	----------	No	----------	No
71-5(a) Simulated Terrestrial Field Study	----	----------	No	----------	No
71-5(b) Actual Terrestrial Field Study	----	----------	No	----------	No
72-1(a) Acute Fish Toxicity Bluegill	TEP[3]	F,M			
	Silver		No		No[10]
	Silver-copper		No	416158-13, 9/2/92	No[10]
	Silver-zinc		No		No[10]
72-1(b) Acute Fish Toxicity Bluegill	(TGAI)	----------	No	----------	No

* In Bibliographic Citation column indicates study may be upgradeable

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ECOLOGICAL EFFECTS BRANCH:
SILVER ZEOLITE
SILVER-COPPER ZEOLITE
& SILVER-ZINC ZEOLITE

Data Requirements	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation (MRID, date study was reviewed)	Must Additional Data Be Submitted under FIFRA3(c)(2)(B)?
72-1(c) Acute Fish Toxicity Rainbow Trout	TEP[3]	F,M			
	Silver		No		Yes[11]
	Silver-copper		No	416158-14, 9/2/92	Yes[11]
	Silver-zinc		No		Yes[11]
72-1(d) Acute Fish Toxicity Rainbow Trout	(TGAI)	----------	No	----------	No
72-2(a) Acute Aquatic Invertebrate Toxicity	TEP[3]	F,M			
	Silver		Yes	420327-03, 6/24/92	No
	Silver-copper		No	416158-15, 9/2/92	Yes[12]
	Silver-zinc		No	420328-05, 6/24/92	Yes[12]
72-2(b) Acute Aquatic Invertebrate Toxicity	(TGAI)	----------	No	----------	No
72-3(a) Acute Estu/Mari Tox Fish	TGAI	----------	No	----------	No
72-3(b) Acute Estu/Mari Tox Mollusk	TGAI	----------	No	----------	No
72-3(c) Acute Estu.Mari Tox Shrimp	TGAI	----------	No	----------	No

* In Bibliographic Citation column indicates study may be upgradeable

Date: 6/22/92
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DATA REQUIREMENTS FOR
ECOLOGICAL EFFECTS BRANCH:
SILVER ZEOLITE
SILVER-COPPER ZEOLITE
& SILVER-ZINC ZEOLITE

Data Requirements	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation (MRID, date study was reviewed)	Must Additional Data Be Submitted under FIFRA3(c)(2)(B)?
72-3(d) Acute Estu/Mari Tox Fish	TEP[3]	F,M		----------	
	Silver		No		Yes[13]
	Silver-copper		No		Yes[13]
	Silver-zinc		No		Yes[13]
72-3(e) Acute Estu/Mari Tox Mollusk	TEP[3]	F,M		----------	
	Silver		No		Yes[13]
	Silver-copper		No		Yes[13]
	Silver-zinc		No		Yes[13]
72-3(f) Acute Estu/Mari Tox Shrimp	TEP[3]	F,M		----------	
	Silver		No		Yes[13]
	Silver-copper		No		Yes[13]
	Silver-zinc		No		Yes[13]
72-4(a) Early Life-Stage Fish	----	----------	No	----------	No
72-4(b) Live-Cycle Aquatic Invertebrate	----	----------	No	----------	No
72-5 Life-Cycle Fish	----	----------	No	----------	No
72-6 Aquatic Org. Accumulation	----	----------	No	----------	No
72-7(a) Simulated Aquatic Field Study	----	----------	No	----------	No
72-7(b) Actual Aquatic Field Study	----	----------	No	----------	No
122-1(a) Seed Germ./Seedling Emerg.	----	----------	No	----------	No
122-1(b) Vegetative Vigor	----	----------	No	----------	No
122-2 Aquatic Plant Growth	----	----------	No	----------	No
123-1(a) Seed Germ./Seedling Emerg.	----	----------	No	----------	No
123-1(b) Vegetative Vigor	----	----------	No	----------	No
123-2 Aquatic Plant Growth	----	----------	No	----------	No
124-1 Terrestrial Field Study	----	----------	No	----------	No

* In Bibliographic Citation column indicates study may be *upgradeable*

Date: 6/22/92
Case Nos: 280485,6, & 7
Chemical Nos: 129057, not available, & 221700

PHASE IV
DATA REQUIREMENTS FOR
ECOLOGICAL EFFECTS BRANCH:
SILVER ZEOLITE
SILVER-COPPER ZEOLITE
& SILVER-ZINC ZEOLITE

Data Requirements	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation (MRID, date study was reviewed)	Must Additional Data Be Submitted under FIFRA3(c)(2)(B)?
124-2 Aquatic Field Study	----	----------	No	----------	No
123-3 Honey Bee Acute Contact	----	----------	No	----------	No
141-2 Honey Bee Residue on Foliage	----	----------	No	----------	No
141-5 Field Test for Pollinators	----	----------	No	----------	No

* In Bibliographic Citation column indicates study may be upgradeable

1. Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product

2. Use Patterns: A = Terrestrial Food Crop; B = Terrestrial Feed Crop; C = Terrestrial Non-Food Crop; D = Aquatic Food Crop; E = Aquatic Non-Food Outdoor; F = Aquatic Non-Food Industrial; G = Aquatic Non-Food Residential; H = Greenhouse Food Crop; I = Greenhouse Non-Food Crop; J = Forestry; K = Outdoor Residential; L = Indoor Food; M = Indoor Non-Food; N = Indoor Medical; O = Indoor Residential; Z = Use Group for Site 00000

3. As the registrant has chosen to conduct toxicity testing with the TEPs, any change in the formulations may require additional testing. The following test concentrations were employed: silver zeolite, 4 $\pm$ 1% silver; silver-copper zeolite, 4 $\pm$ 1% silver and 6 $\pm$ 1% copper; and silver-zinc zeolite, 4 $\pm$ 1% silver and 6 $\pm$ 1% zinc. There is a discrepancy between the concentration of zinc in the test substance and on the label. The label indicates that there is 9% zinc in silver-zinc zeolite while the CSOF indicates that there is 6.5% zinc. This discrepancy must be resolved by Kanebo. If the value is 9%, then the toxicity values for silver-zinc zeolite testing should be adjusted accordingly.

4. An avian oral toxicity test is required. A test conducted with silver-copper zeolite may be used to satisfy this guideline requirement as the two chemicals have the same percentage of silver. If the amount of silver should be increased, additional testing may be required as the registrant has decided to test with the end-use product, not the TGAI.

5. The avian LD_{50}, with the preferred species the bobwhite quail, is outstanding. The registrant may use data from silver-copper zeolite testing to satisfy guideline requirement if an avian dietary LC with silver-zinc zeolite indicates that the compounds have a similar avian toxicity.

6. Data from the avian dietary LC_{50} performed with silver-copper zeolite may be used to satisfy this data requirement as the both zeolite chemicals contain the same percentage of silver. The results of the feed analysis are still needed in order for the silver-copper zeolite study to be classified as "core."

7. The chemical analysis of the feed should be submitted.

8. This test should be performed with silver-zinc zeolite to provide bridging data on avian toxicity. If this avian dietary study demonstrates that silver-zinc zeolite and silver-copper zeolite are similar in their toxicity to birds, the LD_{50} data from silver-copper zeolite may be used to satisfy the avian LD_{50} requirement for silver-zinc zeolite.

9. Only one avian LC_{50} is required to support the registration of indoor nonfood and aquatic nonfood industrial use chemicals. The bobwhite quail is the preferred species.

10. Only one aquatic LC_{50} is required to support the registration of a indoor nonfood or aquatic nonfood industrial use chemical. The rainbow trout is the preferred species.

11. Data from silver-copper zeolite may be used to satisfy the aquatic guideline requirements for silver zeolite and silver-zinc zeolite. The rainbow trout study should be repeated to accurately assess the actual concentration of silver and copper that is present.

12. The silver-copper and silver-zinc zeolite aquatic invertebrate studies do not fulfill guideline requirements, largely because the actual amount of each metal was not always detectable. Also, the results of the analysis for silver, zinc, and copper in the test solutions indicate that the concentrations of the metals were much less than desired. The silver (which does satisfy guideline requirements), silver-copper, and silver-zinc zeolite studies indicate that the zeolite chemicals are very highly toxic to aquatic invertebrates and that they all have a similar toxicity to aquatic invertebrates. Therefore, daphnia testing need only be repeated with silver-copper zeolite and the data may be used to fulfill the guideline requirements for silver-zinc zeolite. Because Kanebo tested the end-use products, if the concentration of any of the metals are increased, additional testing may be required.

13. Because the uses of the zeolite chemicals include paper production and because the labels allow water treatment without limiting the type (so that the chemical may not be used in once through cooling towers (or drilling muds/packer fluids or secondary oil recovery injection waters)), acute estuarine/marine testing is required. Testing performed with silver-copper zeolite may be used to satisfy the estuarine/marine fish, shrimp, and oyster tests for silver zeolite and silver-zinc zeolite.

* In Bibliographic Citation column indicates study may be upgradeable

DATA EVALUATION RECORD

1. **CHEMICAL:** Silver-Zinc Zeolite./Sh. No. Not available

2. **TEST MATERIAL:** Silver-Zinc Zeolite, 99%: 4 ±1% silver, 6±1% zinc; a white powder.

3. **STUDY TYPE:** 48 hour flow through EC_{50} with *Daphnia magna*

4. **CITATION:** Ward, T.J. and R.L. Boeri. 1991. Acute Flow-Through Toxicity of Silver-Zinc Zeolite to the *Daphnia magna.* EnviroSystems Study No. 90184-ADL. Prepared by EnviroSystems Division, Resource Analysts, Inc., Hampton, NH. Submitted by Kanebo Zeolite USA, Inc. EPA MRID No. 420328-05.

5. **REVIEWED BY:**

Heather N. Mansfield, Zoologist
Ecological Effects Branch
Environmental Fate and Effects Division

Signature: Heather Mansfield
Date: 6/24/92

6. **APPROVED BY:**

Allen Vaughan, Acting Head, Section 2
Ecological Effects Branch
Environmental Fate and Effects Division

Signature: Allen W. Vaughan
Date: 9.15-92

7. **CONCLUSIONS:** This study is scientifically sound, but may not be used for assessing the environmental impact of silver-zinc zeolite largely because silver levels often were not detected. Both silver and zinc levels were far below the nominal concentrations. Based on nominal concentrations, the EC_{50} for silver-zinc zeolite was 0.44 ppm and the NOEC was estimated to be 0.30 ppm. These toxicity values characterize silver-zinc zeolite as very highly toxic to daphnids.

8. **RECOMMENDATIONS:** This study should be repeated to more accurately assess the actual concentrations of silver and zinc present in the test solutions.

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Animals:** *Daphnia magna* (less than 24 hours old) that were reared in-house.

B. **Test System:** An intermittent-flow proportional diluter delivered test solution or control water to individual 19.6-L glass aquaria (20x40x25cm) containing 15 L of test solution. All parts of the diluter in contact with the test solutions were made of glass or Teflon®. The volume of each aquarium was replaced an average of 8.1 times every 24 hours. The daphnids were housed in

cages (glass cylinders with Nitex® screening) suspended in the test aquaria which were randomly positioned in a temperature-controlled water bath set at 20 ±1°C. The system was maintained on a 16:8 (light:dark) photoperiod under cool-white fluorescent light with an intensity of 12 $\mu Es^{-1} m^{-2}$.

The test dilution water was well water collected in Hampton, NH. Water was adjusted to a hardness of 160 mg as $CaCO_3$ and stored in polyethylene tanks where it was aerated.

C. Dosage: Five nominal concentrations (0.075, 0.125, 0.20, 0.30, and 0.50 mg/L) and a dilution water control were used.

D. Design: Twenty daphnids were randomly distributed among two replicates of each treatment. Daphnids were not fed and the test containers were not aerated.

Observations of mortality and sublethal responses were recorded initially and every 24 hours. Dead organisms were removed from the containers when observed. The temperature, dissolved oxygen (D.O.), conductivity, and pH were measured daily in each test chamber containing live daphnids. The temperature in one vessel was recorded continuously during the study.

Silver and zinc concentrations were measured using graphite furnace AA methods. Samples were collected at 0 and 48 hours.

E. Statistics: Median lethal (LC_{50}) and effective (EC_{50}) concentrations were calculated by the probit method using nominal concentrations of test material. The no-observed-effect concentration (NOEC) was the test concentration that allowed at least 90% survival of exposed test organisms and does not cause sublethal effects.

12. REPORTED RESULTS: During the test, conductivity, ranged between 770 and 820 μmho/cm. The pH ranged between 7.9 and 8.2. Temperatures ranged between 19.8 and 20.7°C. Dissolved oxygen ranged from 8.8 to 9.5 mg/L (99-103% of saturation).

A light brown insoluble material was observed in test vessels with .30 and .50 ppm silver-zinc zeolite throughout the test, and at .125 and .20 ppm silver-zinc zeolite at 24 and 48 hours. Measured concentrations of silver were generally only slightly above the detection limit (0.0002 mg/L) and were not in agreement with nominal values (Table 2, attached). The measured values ranged from 14 to 26% of nominal concentrations.

No control deaths occurred.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

The EC_{50} values were calculated with nominal values of silver-zinc zeolite are presented in Table 4 (attached). The 48-hour EC_{50} was 0.44 based on nominal concentration of total product. The 48-hour NOEC was estimated to be .30 ppm.

A Quality Assurance and a GLP statement were included in the report.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

A. Test Procedure: The test procedures were generally in accordance with guidelines, but deviated from the SEP as follows:

- The test material was not identified by lot or batch number.
- A 30-minute dawn and dusk simulation was not used.
- The amount of time between test solution preparation and daphnid addition was not stated.
- The amount of silver and zinc in solution could not be accurately assessed.
- Nominal concentrations were employed in calculations although this was a flow-through test.

B. Statistical Analysis: The study author's conclusions (concerning the nominal concentrations) were confirmed by the probit method using EPA's Toxanal program.

C. Discussion/Results: The authors stated that two replications of each concentration were conducted. Because the cages were inside of one aquarium, these duplications were not true replicates.

Reporting an EC_{50} based on nominal concentrations is not acceptable since this is a flow-through test.

The measurement technique needs to be improved to more accurately assess the amount of metal present in the solution.

The EC_{50} for silver-zinc zeolite was 0.44 ppm and the NOEC was estimated to be 0.30 mg/L (both values are based on the nominal concentration of total product). Silver-zinc zeolite is considered to be very highly toxic to aquatic invertebrates.

D. Adequacy of the Study:

(1) Supplemental for silver-zinc zeolite

(2) Rationale: The results of the analysis for both silver and zinc in the test solutions indicate that the concentrations of the metals were much less than desired. Silver levels were often not detected. This may be due to insufficient detection methods.

(3) Repairability: No

15. COMPLETION OF ONE-LINER FOR STUDY: Yes, 6-18-92.

Table 2. Measured concentrations of test substance during toxicity test with Silver-Zinc Zeolite

Nominal Concentration (mg/L)		Measured Concentration of Total Metal (mg/L)		
Zeolite	Metal	0 hour	48 hour	Mean
Silver				
0 (control)		ND	ND	ND
0.075	0.003	0.00028	ND	<0.00028
0.125	0.005	0.00049	ND	<0.00049
0.20	0.008	0.0011	ND	<0.0011
0.30	0.012	0.0019	0.00058	0.0012
0.50	0.020	0.0037	0.00056	0.0021
Zinc				
0 (control)		0.006	0.004	0.005
0.075	0.004	0.003	0.002	0.002
0.125	0.008	0.007	0.003	0.005
0.20	0.012	0.006	0.004	0.005
0.30	0.018	0.008	0.003	0.006
0.50	0.030	0.016	0.003	0.010

Note: ND = none detected (less than the detection limit of 0.0002 mg/L). All concentrations were determined using graphite furnace AA methods.

Table 3. Survival data from toxicity test with Silver-Zinc Zeolite

Nominal Concentration of Zeolite (mg/L)	rep.	Number Alive			Number Affected		
		0hr	24hr	48hr	0hr	24hr	48hr
0.00	1	10	10	10	0	0	0
(control)	2	10	10	10	0	0	0
0.075	1	10	10	10	0	0	0
	2	10	10	10	0	0	0
0.125	1	10	10	10	0	0	0
	2	10	10	10	0	0	0
0.20	1	10	10	10	0	0	0
	2	10	10	10	0	0	0
0.30	1	10	10	10	0	0	0
	2	10	10	9	0	0	0
0.50	1	10	10	6	0	0	2
	2	10	6	2	0	0	0

Note: Affected daphnids were immobilized

Table 4. Median lethal concentrations (LC50s) and median effective concentrations (EC50s) from toxicity test with Silver-Zinc Zeolite

Exposure period	LC50/ EC50	95 percent confidence limit	Calculation method
Nominal Concentration of Silver-Zinc Zeolite			
24 hour LC50	>0.50 mg/L	--	--
48 hour LC50	0.47 mg/L	0.41 - 0.56 mg/L	Probit
24 hour EC50	>0.50 mg/L	--	--
48 hour EC50	0.44 mg/L	0.39 - 0.51 mg/L	Probit
Measured Concentration of Total Silver			
24 hour LC50 48 hour LC50	Values can not be calculated		--
24 hour EC50 48 hour EC50	Values can not be calculated		--
Measured Concentration of Total Zinc			
24 hour LC50 48 hour LC50	Values can not be calculated		--
24 hour EC50 48 hour EC50	Values can not be calculated		--

silver-zinc zeolite ~~LC50~~ DAPHNIA EC50

****

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
.5	20	14	70	5.765915
.3	20	1	5	2.002716E-03
.2	20	0	0	9.536742E-05
.125	20	0	0	9.536742E-05
.075	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .3 AND +INFINITY CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .4346973

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
1	.1836774	.4346973	.3896139	.5108619

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	.2369813	1	.9998238

SLOPE = 9.832878

95 PERCENT CONFIDENCE LIMITS = 5.046163 AND 14.61959

LC50 = .4420366

95 PERCENT CONFIDENCE LIMITS = .3901122 AND .5080909

LC10 = .3283218

95 PERCENT CONFIDENCE LIMITS = .2422501 AND .3752499

312193 735 S. Williams Silver-Zinc Zeolite 2-0211 10/22/91

DP BARCODE: D169923

CASE: 280486 DATA PACKAGE RECORD DATE: 10/22/91
SUBMISSION: S BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 116 RESB NC-NON-FOOD/FEED U
CHEMICALS: 072501 Silver 0.0000%

ID#: 059824-E
COMPANY: 059824 KANEBO ZEOLITE U.S.A., INC
PRODUCT MANAGER: 31 JOHN LEE 703-557-3675 ROOM: CM2 258
PM TEAM REVIEWER: VALDIS GONCAROVS 703-557-3663 ROOM: CM2 260
RECEIVED DATE: 09/25/91 DUE OUT DATE: 04/02/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 169923 EXPEDITE: Y DATE SENT: 10/04/91 DATE RET.: / /
CHEMICAL: Unknown
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 02/01/92 CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : HED	/ /	/ /
BRAN: TB-2	/ /	/ /
SECT: RS-4	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

for doyle/williams

since your dept just reviewed a similar submisison and in light of meeting with registrant, could this submission be done in a shorter period of time.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
169928	EFGB	10/04/91	02/01/92	Y	Y	Y
169929	EEB	10/04/91	02/01/92	Y	Y	Y
169930	RSB/PCRS	10/04/91	12/04/91	Y	Y	Y

APPENDIX A

40 CFR PART 158 DATA SUBMITTED AUGUST 30, 1990 TO THE EPA FOR BACTEKILLER AC (SILVER-COPPER ZEOLITE) - FILE SYMBOL 59824-R
Data were deveoped by Arthur D. Little, Inc., Life Sciences Laboratories, 30 Memorial Drive, Cabridge, MA 02140

MRID No.	GL # AND TITLE OF STUDY	
41615801	**Product Chemistry (40 CFR 158.120; 61; 62; 63)**	
	Toxiological Data (40 CFR 158.135)	
41615802	81-1	Acute Oral Toxicity
41615803	81-2	Acute Dermal Toxicity
41615804	81-3	Acute Inhalation
41638501	81-4	Primary Eye Irritation
41615805	81-5	Primary Dermal Irritation
41615806	**81-6**	**Guiney Pig Sensitization**
41615807	**82-3**	**90-Day Subchronic Dermal Toxicity (Rats)**
41638502	**83-3**	**Teratogenicity (Rats)**
	Series 84:	**Mutagenicity**
41615808	84-2(a)	Mutagenicity Assay (Ames/Salmonella)
41615809	84-2(b)	In Vitro Chromosomal Aberration
41615810	84-2(c)	In Vivo Chromosomal Aberration
	Data on Wildlife & Aquatic Organisms (40 CFR 158.145)	
41615811	71-2(a)	Dietary LC_{50} (Mallard Duck)
41615812	71-2(b)	Dietary LC_{50} (Bobwhite Quail)
41615813	72-1(a)	Acute Fish Toxicity (Bluegill)
41615814	72-1(b)	Acute Fish Toxicity (Trout)
41615815	72-2	Acute Invertebrate Toxicity (Daphnia)
	Environmental Fate Data (40 CFR 158.130)	
41615816	2161-1	Hydrolysis Study
41615817	161-2	Photolysis Study
41615818	163-1	Leaching Study

Kanebo ZEOLITE U.S.A., INC.

BB

TRANSMITTAL DOCUMENT 421738-ΦΦ

1. Name and address of submitter (applicant)

KANEBO ZEOLITE U.S.A.,INC.

350 Fifth Ave.,Suite 2018
New York, N.Y. 10118

2. Proposed Regulatory Action
Amendment to revise the third page of the transmittal letter in the administrative Volume (1), and pages 4 & 5 CA of the Confidential Attachment section in the Chemistry volume (2) submitted September 20, 1991

3. Transmittal Date: JANUARY 21, 1992

4. List of Submitted Amendment.

Volume 1 : Administrative Materials

421738Φ1 Volume 2 : Chemistry Data (amendment to Confidential attachment section)

5. Company official: Tsuneo Ohgawara Tsuneo Ohgawara

Vice President
Kanebo Zeolite U.S.A.,Inc.

6. Company contact: Olivia D. Laird
Federal Regulatory Consultants, Inc.
Consultant for Kanebo Zeolite U.S.A., Inc.

Tel. (703) 471-6590 FAX (703) 471-6269

In this process, silver ions and zinc ions are deposited on the crystalline surfaces of dispersed zeolite.

Just in the same way, zeolite has been used as an agent in detergents to capture heavy metals such as silver, copper, zinc, calcium and magnesium from hard water.

Thus, Silver zinc zeolite has the chemical name of sodium silver zinc aluminosilicate where the ion exchangeable sodium ions in zeolite are partly substituted with silver ions and zinc ions in an aqueous dispersion of zeolite.

Based on the ion exchange characteristics of zeolite, silver ions and zinc ions firmly stored in zeolite carrier gradually leach out in water phase when in contact with water.

Antimicrobial efficacy of Silver zinc zeolite is derived from the silver ions. Zinc ions are linked together with silver ions in order to improve the white color stability of Silver zeolite at elevated temperature(>200°C).

(3) Regulatory background of the three ingredients.

Zeolite, silver and zinc have the following regulatory background.

a) Zeolite as a direct food additive.

Zeolite has been listed in 21 CFR part 182 subpart c as an anticaking agent (182.2727 Sodium alumino silicate) and widely used as a direct food additive not exceeding 2 % by weight.

b) Silver in drinking water.

Silver ion is currently permitted in drinking water at levels not exceeding 50 ppb for silver (40 CFR 141).

c) Silver fluoride as an antimicrobial slimicide.

Irradiated silver fluoride is currently permitted to use as an antimicrobial slimicide in the process water of paper production.

The limit of addition to process water is not to exceed 0.024 lbs (calculated as silver fluoride) per ton of paper produced (21 CFR part 121.2505).

This limit is calculated to be 192 ppb as silver fluoride or 126 ppb as silver in the water.

d) Silver acetate as a smoking deterrent

RESPATON or TABMINT which is an antismoking lozenge or chewing gum containing silver acetate 6.00 mg, ammonium chloride 10.00 mg, cocarboxylase 0.025 mg and excipient +390 mg (consist of sugar, gum base, corn syrup, glycerin and flavors) has been used extensively in European and Scandinavian countries for years.

The formula has been marketed for years in the United States in lozenge form under the trade name of Fumex.

Six month oral toxicity study in wister rats and in rhesus monkeys at the maximum daily dose of 3000 mg/kg (Ag=46.5 mg/kg), Silver retention studies in mice at the maximum dose of 1000 mg/kg (Ag=15.5 mg/kg) and Teratogenicity study in rats have been reported with no silver related adverse effect.

e) Silver nitrate as a slimicide.

Silver nitrate is permitted as a slimicide in the manufacturing of paper and paper board that contact food in 21 CFR 176.300.

f) Zinc in drinking water.

Zinc ion is currently permitted in drinking water at levels not to exceed 5000 ppb for zinc. (40 CFR 143)

g) Zinc compound as nutrients.

Zinc chloride (182-8985), zinc sulfate (182-8997), zinc stearate (182-8994), zinc gluconate (182-8988) and zinc oxide (182-8991) are each permitted for use as nutrients in 21 CFR 182.

h) Zinc compounds as stabilizers.

Zinc orthophosphate and zinc resinate are permitted as stabilizers not to exceed 50,000 ppb zinc as a migrant in finished foods in 21 CFR 181.29.

i) Zinc nitrate in adhesives.

Zinc nitrate is permitted as a constituent of adhesive intended for use in packaging food in 21 CFR 175.105.

(4) Relationship with Silver copper zeolite (Bactekiller AC)

In August 30, 1990 Silver copper zeolite (blue powder) was submitted to the E.P.A. under file symbol = 59824-R by us where copper ions are linked to zeolite in place of zinc of this submission material.

We have three antimicrobial zeolites and Chmical Abstract Service, a division of American Chemical Society gave the following CAS numbers for our three substances as belonging to the same chemical group.

1. Bactekiller AC (Silver copper zeolite):
   CAS = 130328-19-7*
   Contains 3.5 ± 0.5 % Silver and 6.1 ± 0.7 % Copper by weight in its anhydrous state.
2. Bactekiller AZ (Silver zinc zeolite):
   CAS = 130328-20-0*
   Contains 3.5 ± 0.5 % Silver and 9.0 ± 4.0 % by weight in its anhydrous state.
3. Bactekiller A:
   CAS = 130328-18-6*
   Contains 3.5 ± 0.5 % Silver by weight in its anhydrous state.

We have already resubmitted Silver copper zeolite with extensive subchronic study data and we believe that it is not necessary to repeat all of the same subchronic studies for this Silver zinc resubmission because of the following reasons.

1. Both have the same silver content of 3.5 ± 0.5 %.
2. Same content level of zinc (9.0 ± 4.0 %) in place of copper (6.1 ± 0.7 %)
3. Same production process and condition.
4. Similar low level of metal ion leaching. (Leaching study data comparision : Appendix G)
5. Zinc is recognized less toxic than copper: (Acute toxicology studies, Daphnia LC 50 data mutagenicity test result data comparision for both substances and the maximum permitted level comparision in drinking water)

(5) Japanese market information.

Each of our three powders is recognized as a mixture of already permitted zeolite, silver, zinc or copper and approved to use as an additive in polymers.

Various kinds of antimicrobial self sanitized polymer products have been commercialized by incorporation of Bactekiller powders.

Especially, Silver zinc zeolite is white and widely compatible with most of polymers or their polymerization catalysts.

Polymer products such as film, tube, and plate incorporated with Silver zinc zeolite show low level of silver and zinc leaching which comply with the Japanese Food and Sanitation Law.

The sales operation in food contact area until 4,1990 are summarized as the following.

Products	Sales since	Polymer type	Bactekiller AZ %	Used Kg	Regulation
Chopping board	Oct. '88	PE	1.0	3550	No.370-30
Glove	Feb. '90	PE	1.0	130	No.370-30

* Ministry of Health and Welfare Notice No.370-30 (1959)

(6) Application in this submission.

Silver zinc zeolite is a non-soluble, non-vaporizable fine ceramic powder and has the capacity to inhibit the growth of simple organisms such as bacteria and fungi but not of higher organisms such as insects, ticks or fleas.

We would like to market Silver zinc zeolite to sell to our customers in the United States.

Our application methods are defined as the following:

1. Incorporation with polymers.
2. Incorporation with surface coating or bonding resins.
3. Powder or granule for water treatment.

Our applications are based on the general use patterns in 40 CFR 158, App A:

12. Commercial and Industrial Uses.
13. Domestic and Human Uses.

(7) Resubmission.

We have also included for your information the toxicological summary from Arthur D. Little,Inc. which confirms the general safety characteristics of our product.

We have made a sincere effort to provide you with all the necessary information and test data and hope that you will give it timely consideration and approve the registration of our product.

Yours sincerly,

Kunio Kameda

Kunio Kameda
President
Kanebo Zeolite U.S.A.,Inc.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM:

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Review of Toxicology Studies on Silver Zinc Zeolite for Registration as a New Chemical/ Non-Food Use

TOX. CHEM. NO.: 129057 **Caswell NO.:** 735

CASE NO.: 280486 **DP CODE:** D169923

FROM: SanYvette Williams, D.V.M. SLW 2/23/93
Review Section IV, Tox. Branch II (H7509C)

TO: Valdis Goncarovs/John Lee, PM 17
Registration Division

THRU: Elizabeth Doyle, Ph.D. E.A. Doyle 2/23/93
Section IV, Tox. Branch II (H7509C)

and

Marcia van Gemert, Ph.D., Chief E.A.D. for 2/23/93
Toxicology Branch II
Health Effects Division (H7509C)

Registrant: Kanebo Zeolite, USA, Inc.

Action Requested:

Toxicology was requested to review the studies submitted for registration of Silver Zinc Zeolite.

Toxicology Branch II has completed the review of all toxicology studies submitted by the Registrant on Silver Zinc Zeolite. The Data Evaluation Report for each study is appended and conclusions of study findings are as follows:

1. *In vivo* mammalian cytogenetics assay in Sprague-Dawley rats (84-2(b)). Accession No.: 420328-04

The administration of Silver Zinc Zeolite by oral gavage did not

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induce chromosomal aberration of male or female rats following oral gavage at doses of 500, 1500 or 5000 mg/kg, and sacrifice times of 6, 18 or 24 hours after treatment.

Classification: Not Acceptable, but upgradeable to acceptable provided adequate explanation and clarification is given (on an individual animal basis) as to why slides could not be read from many of the males, particularly those of the 5000 mg/kg dosage group sacrificed at 18 hours.

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2. Ames/*Salmonella* gene mutation assay (84-2(a)). Accession No: 420328-03

Silver Zinc Zeolite did not induce mutations in *Salmonella typhimurium* in the presence and absence of a metabolic activation system, it was determined that this substance was not mutagenic to TA98, TA100, TA1535 or TA1537 strains of *Salmonella typhimurium* at the concentrations tested (0.003 to 0.15 mg/plate with activation; 0.0005 to 0.015 mg/plate without activation.

Classification: This study satisfies requirements according to guidelines for a mutagenicity study #84-2(a) and is classified Acceptable.

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3. Acute oral toxicity in rats (81-1). Accession No.: 420328-02

Based on results of this study, the LD50 for Silver Zinc Zeolite seems to be greater than 5 g/kg in male and female rats. It is considered to be very low in toxicity (Tox. Category IV).

CLASSIFICATION: Core - Supplementary. This study may be upgraded upon submission of the stability of the test material.

---

4. Acute dermal toxicity in rabbit (81-2). Accession No.: 416158-03

Based on results of this study, the acute dermal LD50 toxicity for Silver Zinc Zeolite is considered to be greater than 5 g/kg (Tox. Category III).

CLASSIFICATION: Core-Supplementary. This study may be upgraded upon submission of the stability of the test material.

---

5. Acute Inhalation Study in Rats (81-3). Accession No.: 420328-02

The results of this study indicate that the acute inhalation LC50 for Sprague-Dawley rats exposed to the highest attainable concentration of Silver Zinc Zeolite by whole body exposure is

greater than 1.43 mg/liter. [Tox. Category III]

CLASSIFICATION: Core-Supplementary. This study may be upgraded upon submission of the stability of the test material.

---

6. Primary Eye Irritation in Rabbits (81-4) Accession No: 420328-02

Based on the no rinse group mean irritation scores, Silver Zinc Zeolite is considered to be a slight to irritant to the ocular tissue of the rabbit. The maximum mean total score, calculated according to the Draize method for grading ocular effects, was 16.0. The score was calculated 48 hours postinstillation.

CLASSIFICATION: Core-Supplementary. This study may be upgraded upon submission of the stability of the test material.

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7. Primary Dermal Irritation in Rabbit (81-5) Accession No: 420328-02

Based on results of this study, Silver Zinc Zeolite, after a 0.5 g dose was applied to the skin for four hours, was regarded as a slight skin irritant with a Primary Irritation Index = 0.13. (Toxicity Category IV)

CLASSIFICATION: Core-Supplementary. This study may be upgraded upon submission of the stability of the test material.

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8. Guinea Pig Sensitization (#81-6). Accession No: 420328-02

Based on results of this study, a 60% suspension (in 0.5% Carboxymethyl cellulose) of Silver Zinc Zeolite was a non-sensitizing agent in guinea pigs when the Buehler technique is employed.

CLASSIFICATION: Core-Supplementary. This study may be upgraded upon submission of the stability of the test material.

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9. Leaching (#163-1). Accession No.: 420328-02

The concentrations of silver in the leachates generated in this study are below U.S.EPA drinking water guideline (50 ug/L) for silver. Taking into account the total zinc concentrations which included the background levels, the total zinc concentration was well below the recommended guideline for zinc in drinking water (500 ug/L).

This rationale for using pH 6.5 was not given. Information on

leaching at pH levels above and below pH 6.5 should have been included.

CLASSIFICATION: Core-Supplementary, but upgradeable upon submission of additional pH information.

Reviewed by: SanYvette Williams, D.V.M. 12/22/92
Section IV, Tox. Branch II (H7509C)
Secondary Reviewer: Elizabeth Doyle, Ph.D. E.A. Doyle 2/16/93
Section IV, Tox. Branch II (H7509C)

DATA EVALUATION REPORT

STUDY TYPE: Leaching (#163-1)

TOX. CHEM. NO.: 129057

TEST COMPOUND: Silver Zinc Zeolite

ACCESSION NO.: 420328-07

ADL REFERENCE NO.: 66365-20

TITLE OF REPORT: Silver Zinc Zeolite: Leaching of Silver and Zinc From Impregnated Polymers

AUTHOR: James N. Kyranos, Ph.D.

DATE: May 31, 1991

SPONSOR: Kanebo Zeolite USA, Inc.

PERFORMING LAB: Arthur D. Little, Inc.; Acorn Park, Cambridge, MA 02140

CONCLUSION: The concentrations of silver in the leachates generated in this study are below U.S.EPA drinking water guideline (50 ug/L) for silver. Taking into account the total zinc concentrations which included the background levels, the total zinc concentration was well below the recommended guideline for zinc in drinking water (500 ug/L).

This rationale for using pH 6.5 was not given. Information on leaching at pH levels above and below pH 6.5 should have been included.

CLASSIFICATION: This study (#163-1) is classified Supplementary, but it can be upgraded upon submission of additional pH information.

COMPLIANCE: A GLP statement was included on page 3 of study.
A Quality Assurance Statement was included on page 4 of the study.
A No Data Confidentiality Claim was included on page 2 of the study.
There was no Flagging statement included.

BACKGROUND: This study was performed "to determine the quantity of soluble silver and zinc released into an aqueous medium from polymeric materials impregnated with silver zinc zeolite".

A. MATERIALS:

Test material: Silver zinc zeolite contained 3.6% silver and 6.1% zinc on a dry weight basis. Zeolite was incorporated into two polymer matrices listed below:

Material PE -- Polyester Non-woven Fabric
Polyethylene terephthalate staple fiber incorporated with silver zinc Zeolite at 1.5% by weight (anhydrous) by mixer kneading. Non-woven production: carding and needle punching.

Material PP -- Polypropylene plate
Polypropylene plate of polypropylene incorporated silver zinc zeolite at 1.5% by weight by extruder kneading. Plate preparation by injection molding.

Negative controls: Consisted of vials containing 30 mL leaching medium (ASTM Type I water), nichrome wire, and glass beads, but no polymeric material test coupons.

Positive controls: Same as negative controls along with a small volume of a standard solution containing silver and zinc ions to give an initial concentration of 10 ppb (ug/L) of silver and 25 ppb (ug/L) of zinc.

Test Exposure System:
This system was designed to allow control of light, temperature and agitation of the test vial's contents. The test was conducted inside a black exposure chamber that had air vents permanently shielded and the top in place except when samples were removed. Temperature was controlled by a circulating water bath set at 25 $\pm$ 0.1°C. The content of each vial was mechanically agitated using a magnetic stir plate.

B. STUDY DESIGN:

Test coupons of non-woven polyester were cut as 1.5 cm x 1.5 cm ($\pm$ 0.1 cm) squares. The coupons were individually weighed and then strung in groups of three onto nichrome wire with glass bead spacers.

Test coupons of the polypropylene plate material were cut (1.5 cm x 1.5 cm) into squares, weighed and then strung into groups of three onto nichrome wire with glass bead spacers.

The coupon assemblies were placed into individual 40-mL glass vials. The leaching medium (30 mL ASTM Type I water) was added to each vial. The initial pH of the medium in each vial was measured and recorded using narrow-range pH paper.

After the vials were placed in the constant temperature water bath, taken as time zero (t_0), samples were withdrawn at intervals of 2, 4, 8, 16, 24 and 30 days ($\pm$1 hour), after time zero, for subsequent chemical analysis. The pH was again measured, then a measured quantity of concentrated nitric acid was added to bring the pH below 2. The vials were then stored in the dark in a 4 °C refrigerator before analysis.

Chemical analysis and data reduction:
Graphite Furnace Atomic Absorption Spectroscopy (GFAA) was used to analyze samples of the leachate, negative and positive controls. An external calibration curve based on appropriate standards was generated to help in quantification. Leachate samples were diluted to bring instrumentation response within the documented linear range of the analysis when necessary.

Calibration curves and calculated sample concentrations were based on the average height of the GFAA peak for two sequential analyses of each sample or diluted sample.

C. RESULTS:

Results of leaching tests for negative controls (Table 1 appended):
According to protocol, the data quality objective for the negative controls should be <5X the Level of Quantification (LOQ) for silver and <1X LOQ for zinc. After the calibration standards were measured, the analytical LOQ was determined to be 0.30 ppb for silver and 20 ppb for zinc. Therefore, all negative controls in this study had concentrations below the LOQ.

Results of leaching tests for positive controls (Table 2 appended):
The analysis of positive controls, which were spiked with 10 ppb (ug/L) silver and 25 ppb (ug/L) zinc, show that the percent of silver recovered met the protocol objective of 70-120%. The results for zinc do not meet the quality objective of the protocol. The author cites two reasons for this: 1) the relatively large background zinc concentration might not have been adequately represented by the daily blank samples, and 2) it may be related to the analytical procedure. Other possibilities include the improper preparation of the spiking solution, and/or improperly cleaned glassware.

Results of tests for polyester fabric material (Tables 4-5 appended):
The pH of the solution was constant throughout the study, except

for day 30. Although it was lower on this day, it did not appear to have an effect on the results. For each day sampling, the results for silver determination (Table 4) indicate that the Data Quality Objective of ± 20% RPD/RSD were met. Two of the duplicate samples were lower than expected and were considered outliers.

(Note: $$\text{RPD (5)} = 100 \times \frac{\text{Difference between high and low value}}{\text{Mean of the values}}$$

$$\text{RSD (\%)} = 100 \times \frac{\text{Standard Deviation (n-1 basis)}}{\text{Mean of the values}}$$

The corresponding results for leaching of zinc were considerably higher than expected when compared to the silver results. This was indicative of a large zinc background that should be proven as such.

Results of Leaching Tests for Polypropylene Plate Material (Tables 7 and 8 appended) :
The results of the silver leachate data suggest that the silver concentration is maintained at an average concentration of 0.0038 ug/g (35 ng/cm^2) throughout the study.

The results of the zinc leachate data show that there is a higher amount of zinc being leached than expected. The Author attributed the large amount zinc levels to background interferences. Unless there is proof of this, it has to be assumed that the zinc levels are legitimate.

Discussion\Conclusion:

-The results of this study show that over a 30 day period, a clear trend is shown in regard to the leachability of silver from silver zinc zeolite impregnated polymers. Silver leached at a relatively constant rate throughout the study at 0.0038 ug/g (0.0035 ng/cm^2) of polymeric material.

-Initially (Day 0-4), the amount of silver leached from the polyester fabric was 0.48 ug/mg polymeric material. After the fourth day, it had reached an average concentration of 2.30 ug/g.

-The Author states that there was uncertainty about the concentration of zinc released from each polymeric material due to the high background interference. However, the actual background level cannot be confirmed.

-The concentrations silver in the leachates generated in this study are below U.S.EPA drinking water guideline requirements (50 ug/L) for silver. Taking into account the total zinc concentrations which included the background levels, the total zinc concentration

was well below the recommended guideline for zinc in drinking water (500 ug/L).

This rationale for using pH 6.5 was not given. Information on leaching at pH levels above and below pH 6.5 should have been included. This study (#163-1) is classified Supplementary, but it can be upgraded upon submission of this information.

Table 1 - Results for Leaching Study Negative Control (Blank) Samples

SAMPLE	INITIAL pH	TEST DAY	TEST DATE	FINAL pH	ANALYSIS DATE	SILVER (ppb)	ANALYSIS DATE	ZINC (ppb)
BL-0	6.5	0	4/1/91	6.5	4/3/91	ND	4/9/91	8.9
BL-2	6.5	2	4/3/91	6.5	4/3/91	ND	4/9/91	17.3
BL-4	6.5	4	4/5/91	6.5	4/9/91	ND	4/9/91	95.9
BL-8	6.5	8	4/9/91	6.5	4/9/91	ND	4/9/91	95.2
BL-16	6.5	16	4/17/91	6.5	4/22/91	ND	4/29/91	7.7
BL-24	6.5	24	4/25/91	6.5	4/26/91	ND	4/29/91	14.6
BL-30	6.5	30	5/1/91	5.3	5/15/91	ND	5/15/91	12.9

LOQ <5X for <100

ND - Not Detected (sample response in laboratory blank range) NC s/b < 5X LOQ

Ag LOQ = .30 ppb
.5
1.50

Zn LOQ = 20 ppb
.5
100

Table 2 - Results for Analysis of Leaching Study Positive Control (Spike) Samples

SAMPLE	INITIAL pH	TEST DAY	TEST DATE	FINAL pH	ANALYSIS DATE	DILUT FACTOR	SILVER (ppb)	ZINC (ppb)**	PERCENT RECOVERY SILVER %	PERCENT RECOVERY ZINC %
SP-0-AG	6.5	0	4/1/91	6.5	4/3/91		9.9		99	
SP-0-AG	6.5	0	4/1/91	6.5	4/3/91	1:4	13.0		130	
SP-2-AG	6.5	2	4/3/91	6.5	4/3/91		8.2		82	
SP-2-AG	6.5	2	4/3/91	6.5	4/3/91	1:4	10.0		100	
SP-4-AG	6.5	4	4/5/91	6.5	4/9/91		9.4		94	
SP-4-AG	6.5	4	4/5/91	6.5	4/9/91	1:4	10.3		103	
SP-8-AG	6.5	8	4/9/91	6.5	4/9/91		10.5		105	
SP-8-AG	6.5	8	4/9/91	6.5	4/9/91	1:4	12.1		121	
SP-16-AG	6.5	16	4/17/91	6.5	4/22/91		7.9		79	
SP-16-AG	6.5	16	4/17/91	6.5	4/22/91	1:4	9.0		90	
SP-24-AG	6.5	24	4/25/91	6.5	4/26/91		8.8		88	
SP-24-AG	6.5	24	4/25/91	6.5	4/26/91	1:4	10.3		103	
SP-30-AG	6.5	30	5/1/91	5.3	5/15/91		7.9		79	
SP-30-AG	6.5	30	5/1/91	5.3	5/15/91	1:4	11.6		116	
SP-0-ZN	6.5	0	4/1/91	6.5	4/3/91			56.5		226
SP-2-ZN	6.5	2	4/3/91	6.5	4/3/91			47.5		190
SP-4-ZN	6.5	4	4/5/91	6.5	4/9/91			67.3		270
SP-8-ZN	6.5	8	4/9/91	6.5	4/9/91			70.8		284
SP-16-ZN	6.5	16	4/17/91	6.5	4/29/91			53.4		214
SP-24-ZN	6.5	24	4/25/91	6.5	4/29/91			48.5		194
SP-30-ZN	6.5	30	5/1/91	5.3	5/15/91			56.5		226

** - Corrected for blank concentration on corresponding day

Table 4 - Silver Concentration Data for Polyester Fabric Leachates

					SILVER					
SAMPLE	TEST DAY	ANALYSIS DATE	DILUTION	SOL'N CONC (ppb)	AMNT RELSED (ug/g)	AVERAGE (ug/g)	RPD/RSD	AMNT RELSED (ng/cm2)	AVERAGE (ng/cm2)	RPD/RSD
PE-0A	0	4/3/91		1.81	0.48			2.53		
						0.48	2		2.52	0.8
PE-0B	0	4/3/91		1.73	0.47			2.51		
PE-2A	2	4/3/91		4.36	1.06			6.09		
PE-2A	2	4/3/91	1:2	4.44	1.08			6.20		
						1.14	8		6.26	5
PE-2B	2	4/3/91		4.67	1.14			6.07		
PE-2B	2	4/3/91	1:2	5.14	1.26			6.68		
PE-4A	4	4/9/91		7.01	2.01			9.79		
PE-4A	4	4/9/91	1:4	6.49	1.86			9.06		
						1.96	6		9.60	6
PE-4B	4	4/9/91		7.15	2.10			10.34		
PE-4B	4	4/9/91	1:4	6.37	1.87			9.21		
PE-8A	8	4/9/91		9.01	2.15			12.58		
PE-8A	8	4/9/91	1:4	9.93	2.37			13.87		
						2.34	6		12.76	6
PE-8B	8	4/9/91		8.92	2.46			12.46		
PE-8B	8	4/9/91	1:4	8.67	2.39			12.11		

* - Outlier not used in calculation of average

DQO ±20% RPD/RSD

Table 4 - Silver Concentration Data for Polyester Fabric Leachates (Continued)

SAMPLE	TEST DAY	ANALYSIS DATE	DILUTION	SOL'N CONC (ppb)	SILVER AMNT RELSED (ug/g)	AVERAGE (ug/g)	RPD/RSD	AMNT RELSED (ng/cm2)	AVERAGE (ng/cm2)	RPD/RSD
PE-16A	16	4/22/91		8.09	2.07			11.72		
PE-16A	16	4/22/91	1:4	9.02	2.31			13.07		
						2.20	7		12.31	7
PE-16B	16	4/22/91		7.85	2.04			11.38		
PE-16B	16	4/22/91	1:4	9.02	2.36			13.07		
PE-24A	24	4/26/91		4.67	1.17*			6.77*		
PE-24A	24	4/26/91	1:2	4.39	1.10*			6.36*		
PE-24B	24	4/26/91		8.87	2.48			12.85		
PE-24B	24	4/26/91	1:4	9.64	2.69	2.59	8	13.97	13.41	8
PE-30A	30	5/15/91		2.91	0.69*			4.01*		
PE-30A	30	5/15/91	1:4	3.25	0.76*			4.48*		
PE-30B	30	5/15/91		7.43	2.05			10.77		
PE-30B	30	5/15/91	1:4	9.10	2.51	2.29	20	13.19	11.98	20

* - Outlier not used in calculation of average

Table 5 - Zinc Concentration Data for Polyester Fabric Leachates

ZINC

SAMPLE	TEST DAY	ANALYSIS DATE	DILUTION	SOL'N CONC (ppb)
PE-0A	0	4/9/91		12.4
PE-0B	0	4/9/91		9.9
PE-2A	2	4/9/91		11.0
PE-2B	2	4/9/91		31.6
PE-4A	4	4/9/91		101.8
PE-4B	4	4/9/91		80.4
PE-8A	8	4/9/91		104.3
PE-8B	8	4/9/91		99.7
PE-16A	16	4/29/91		49.4
PE-16B	16	4/29/91		49.4
PE-24A	24	4/29/91		62.1
PE-24B	24	4/29/91		60.1
PE-30A	30	5/15/91		62.2
PE-30B	30	5/15/91		68.5

Table 7 - Silver Concentration Data for Polypropylene Plate Leachates

SAMPLE	TEST DAY	ANALYSIS DATE	DILUTION	SOL'N CONC (ppb)	SILVER AMNT RELSED (ug/g)	SILVER AVERAGE (ug/g)	SILVER RPD/RSD	SILVER AMNT RELSED (ng/cm2)	SILVER AVERAGE (ng/cm2)	SILVER RPD/RSD
PP-0A	0	4/3/91		0.60	0.010*			0.94		
PP-0A	0	4/9/91		0.31	0.0051			0.49		
						0.0052	12		0.48	12
PP-0B	0	4/3/91		0.35	0.0058			0.54		
PP-0B	0	4/9/91		0.28	0.0046			0.43		
PP-2A	2	4/3/91		0.36	0.0060			0.56		
						0.0056	16		0.52	17
PP-2B	2	4/3/91		0.31	0.0051			0.47		
PP-4A	4	4/9/91		0.15	0.0024			0.23		
						0.0020	45		0.19	47
PP-4B	4	4/9/91		0.090	0.0015			0.14		
PP-8A	8	4/9/91		0.090	0.0015			0.14		
						0.0014	14		0.13	15
PP-8B	8	4/9/91		0.076	0.0013			0.12		
PP-16A	16	4/22/91		0.25	0.0040			0.37		
						0.0029	79		0.27	78
PP-16B	16	4/22/91		0.10	0.0017			0.16		
PP-24A	24	4/26/91		0.27	0.0045			0.41		
PP-24A	24	4/26/91		0.15	0.0025	0.0035	57	0.23	0.33	55
PP-24B	24	4/26/91		0.037	0.00062*			0.057*		
PP-30A	30	5/15/91		0.46	0.00076			0.071		
						0.0059	174		0.54	172
PP-30B	30	5/15/91		0.65	0.011			1.00		

* - Outlier not used in calculation of average

Table 8 - Zinc Concentration Data for Polypropylene Plate Leachates

ZINC

SAMPLE	TEST DAY	ANALYSIS DATE	DILUTION	SOL'N CONC (ppb)
PP-0A	0	4/9/91		11.0
PP-0B	0	4/9/91		9.6
PP-2A	2	4/9/91		117.6
PP-2B	2	4/9/91		97.6
PP-4A	4	4/9/91		99.7
PP-4B	4	4/9/91		101.5
PP-8A	8	4/9/91		120.1
PP-8B	8	4/9/91		138.7
PP-16A	16	4/29/91		19.7
PP-16B	16	4/29/91		23.9
PP-24A	24	4/29/91		18.4
PP-24B	24	4/29/91		27.3
PP-30A	30	5/15/91		20.2
PP-30B	30	5/15/91		16.8

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EPA Reviewer: Byron T. Backus, Ph.D.
Section II, Toxicology Branch II
HED (H7509C)
Byron T. Backus
2/8/93

DATA EVALUATION REPORT

CHEMICAL: Silver Zinc Zeolite (AgZn Zeolite) TOX. CHEM. NO.: N/A

STUDY TYPE: In vivo chromosome aberration assay in Sprague-Dawley rats

MRID NUMBER: 420328-04

SYNONYMS/CAS NO.: N/A

SPONSOR: Kanebo Zeolite USA, Inc.
New York, NY 10118

TESTING FACILITY: Arthur D. Little, Inc.
30 Memorial Drive
Cambridge, MA 02142

TITLE OF REPORT: Silver Zinc Zeolite-In vivo Chromosomal Aberration Assay in Sprague-Dawley Rats

AUTHOR(S): Kenneth S. Loveday

STUDY NUMBER(S): ADL 66365-00

REPORT ISSUED: May 13, 1991

CONCLUSION(S): Under the conditions of this study, Silver Zinc Zeolite did not induce chromosomal aberrations in bone marrow cells of male or female Sprague-Dawley rats following oral gavage at doses of 500, 1500 or 5000 mg/kg, and sacrifice times of 6, 18 or 24 hours after treatment.

CLASSIFICATION: Not Acceptable. The classification of this study is upgradeable to acceptable provided adequate explanation and clarification is given (on an individual animal basis) as to why slides could not be read from many of the males, particularly those of the 5000 mg/kg dosage group sacrificed at 18 hours.

A. Materials:

1. Test Material:
   Name: Silver Zinc Zeolite (AgZn Zeolite)
   Description: Solid, Powder
   Color: White
   Lot #: not given, received on June 13, 1989
   Purity: 99%, Ag (3.1%), Zn (6.1%), as supplied by sponsor
   Contaminants: not reported
   Solubility: Not soluble, suspended in 0.5% carboxymethyl cellulose (CMC) in deionized water

2. Controls:
   Negative: 0.5% CMC by oral gavage in deionized water (Sigma Chemical Company, lot number 114F-0414)

   Positive: Cyclophosphamide (30 mg/kg by oral gavage in deionized water) (Sigma Chemical Company, lot number 114F-0393)

3. Test compound:
   Volume of test substance administered: variable - volume of a 50, 150 or 500 mg/ml stock suspension required to give a dose of 500, 1500 or 5000 mg/kg (3.2 ml for heaviest rat)

   Route of administration: oral gavage

   Dose levels used: 500, 1500, 5000 mg/kg

4. Test animal:
   a. Species: Rat Strain: Sprague-Dawley Age: 8 - 10 wks
      Weight: male 235-320 g female 171-249 g
      Source: Taconic (Germantown, NY)

   b. No. animals used per dose: 5 + 1 males 5 + 1 females

   c. Properly maintained?
      YES

B. TEST PERFORMANCE

1. Treatment and Sampling times:
   a. Test compound
      Dosing: X once ___ twice (24 hr apart)
      ___ other (describe):

      Sampling (after last dose): X 6 hr ___ 12 hr X 24 hr
      ___ 48 hr ___ 72 hr (mark all that are appropriate)
      X other (describe): 18 hr

b. Negative and/or vehicle control

Dosing: _X_ once ___ twice (24 hr apart)
___ other (describe):

Sampling (after last dose): _X_ 6 hr ___ 12 hr _X_ 24 hr
___ 48 hr ___ 72 hr (mark all that are appropriate)
_X_ other (describe): 18 hr

c. Positive control

Dosing: _X_ once ___ twice (24 hr apart)
___ other (describe):

Sampling (after last dose): ___ 6 hr ___ 12 hr _X_ 24 hr
___ 48 hr ___ 72 hr (mark all that are appropriate)
___ other (describe):

2. Tissues and Cells Examined:

_X_ bone marrow ___ other (list):

3. Details of Slide Preparation:

Bone marrow cells were centrifuged, collected and resuspended in hypotonic buffer solution for 20 minutes at 37°C, then fixed 3 - 4 times in absolute methanol:glacial acetic acid (3:1) solution by centrifugation and resuspension. Drops of the concentrated cell suspension were placed on clean moist glass slides, air dried at least 24 hours and stained with 5% Giemsa for 5-8 minutes at room temperature.

4. Preliminary Cytotoxicity Assay:

No toxicity was observed in Sprague-Dawley rats following oral exposure to 5000 mg/kg of AgZn zeolite.

5. Cytogenetic Assay:

Six independent assays were done, three in females and three in males with sacrifice times as given above. In addition, a negative control group was run with all assays and a positive control group was included in the two 24-hour assays.

Structural chromosomal damage was evaluated in bone marrow cells arrested at the first metaphase following treatment with the test agent. Metaphase arrest was induced by injecting the rats with 1.5 mg/kg colchicine about 2 - 2.5 hours before sacrifice. Rats were killed by CO_2 asphyxiation and bone marrow cells collected from the femur(s) by flushing the cavity with 37°C hypotonic buffer solution (0.03 M KCl, 0.01 M sodium citrate) using a hypodermic needle and a syringe.

The percent mitotic index (MI) on an individual animal basis was calculated by counting the number of metaphase cells in at least 500 cells. %MI = (# metaphase cells observed / total # cells observed) x 100.

Cells were analyzed for chromatid and chromosome breaks, chromatid and chromosome gaps, interstitial deletions, double minute chromosomes, dicentrics, ring chromosomes, triradials, quadriradials, complex rearrangements, cells with at least one pulverized chromosome and cells with greater than 10 aberrations.

The total number of aberrations, the number of aberrations per cell, the number of cells with aberrations, and the percent of cells with aberrations were calculated twice, once including gaps in the calculations and once not including gaps. Normally, gaps are not included in calculating chromosomal aberrations. AgZn Zeolite did not induce an increase in chromosomal aberrations in either male or female rats as tested in this study either with or without gaps included in the calculation. No toxicity was observed during the study.

6. Reviewer's Discussion/conclusions:

The study followed the pertinent federal guidelines for conducting an in vivo chromosomal aberration assay in rat bone marrow cells (however, as discussed in the next paragraph, the number of male rats actually analyzed falls short, in many cases, of the desired five animals). The results were consistently negative in both male and female rats at all tested concentrations and sampling times. The authors of the study state that the number of chromosomal breaks and gaps were too low in both the control and test animals to evaluate using a quantitative statistical method; therefore, "the frequency of cells with chromosomal damage from the negative control groups were pooled from male and female animals to provide a range of values." Frequencies of aberrant cells from animals exposed to AgZn zeolite were compared to this range.

The authors state that six animals were dosed per test group (13 test groups per sex) and that 50 metaphase cells from each of five animals were analyzed for chromosomal aberrations where possible. This was possible in 11 of the 13 female groups but in only five of the 13 male groups (see attached tables 7 and 14). Three rats were analyzed in six of the male groups and only one rat in the 18-hour 5000 mg/kg group. The authors do not comment on this difference. Reasons given for not analyzing a slide included poor quality metaphase cells or low mitotic index. Why this appears to be predominantly a problem with males is not discussed. No toxicity was observed as a result of AgZn zeolite exposure although two male rats died as a result of gavage errors, one from the six-hour group and one from the 18-hour group. The rat from the 18-hour group was replaced with an extra rat. Therefore, the difference was not a smaller number of male rats to analyze.

Results from positive and negative controls were as expected. Summary tables of results for male and female rats are attached.

In conclusion, this study will meet the requirements for an in vivo cytogenetics assay in rats if an explanation is given for the smaller number of male rats analyzed.

7. Was the test performed under GLPs (is a quality assurance statement present)?
YES

8. CBI appendix attached?
NO

APPENDIX

Silver Zinc Zeolite - In vivo Chromosome Aberration Assay in Sprague-Dawley Rats

Evaluation of Silver Zinc Zeolite in the In Vivo Chromosomal Aberration Assay

Arthur D Little

Table 7
Summary of Chromosomal Aberration Analysis Data -- Male Rats
6- , 18- and 24-hour Dose Groups

Dose Time (hr)	Treatment		Total # Animals Analyzed	Total # Cells Analyzed		Gaps Excluded: Total # Aberr.	Gaps Excluded: Mean Aberr. / Cell	Gaps Excluded: Total # Cells Aberr.	Gaps Excluded: % Cells Aberr.	Gaps Included: Total # Aberr.	Gaps Included: Mean Aberr. / Cell	Gaps Included: Total # Cells Aberr.	Gaps Included: % Cells Aberr.
6	0.5% Carboxymethyl cellulose		5	250		0	0.000	0	0.0	0	0.000	0	0.0
	Silver zinc zeolite	500 mg/kg	3	250		2	0.008	2	0.8	2	0.008	2	0.8
		1500	5	250		2	0.008	2	0.8	3	0.012	2	0.8
		5000	3	250		0	0.000	0	0.0	0	0.000	0	0.0
18	0.5% Carboxymethyl cellulose		3	250		0	0.000	0	0.0	1	0.004	1	0.4
	Silver zinc zeolite	500 mg/kg	3	250		1	0.004	1	0.4	10	0.040	9	3.6
		1500	5	250		0	0.000	0	0.0	6	0.024	4	1.6
		5000	1	210		0	0.000	0	0.0	0	0.000	1	0.5
24	Cyclophosphamide	30 mg/kg	5	250	*	271	1.084	85	34.0	290	1.160	91	36.4
	0.5% Carboxymethyl cellulose		3	250		2	0.008	2	0.8	4	0.016	4	1.6
	Silver zinc zeolite	500 mg/kg	5	275		1	0.004	1	0.4	1	0.004	1	0.4
		1500	3	250		3	0.012	3	1.2	8	0.032	8	3.2
		5000	4	250		1	0.004	1	0.4	4	0.016	3	1.2

* : Data shows pulverized cells and/or damaged cells with more than ten chromosome aberrations per cell.

Evaluation of Silver Zinc Zeolite in the In Vivo Chromosomal Aberration Assay

Arthur D Little

Table 14
Summary of Chromosomal Aberration Analysis Data -- Female Rats
6-, 18- and 24-hour Dose Groups

Dose Time (hr)	Treatment		Total # Animals Analyzed	Total # Cells Analyzed		Gaps Excluded: Total # Aberr.	Gaps Excluded: Mean Aberr. / Cell	Gaps Excluded: Total # Cells Aberr.	Gaps Excluded: % Cells Aberr.	Gaps Included: Total # Aberr.	Gaps Included: Mean Aberr. / Cell	Gaps Included: Total # Cells Aberr.	Gaps Included: % Cells Aberr.
6	0.5% Carboxymethyl cellulose		5	250		4	0.016	2	0.8	8	0.032	8	3.2
	Silver zinc zeolite	500 mg/kg	5	250		3	0.012	3	1.2	7	0.028	6	2.4
		1500	5	250		2	0.008	2	0.8	9	0.036	8	3.2
		5000	5	250		1	0.004	1	0.4	3	0.012	3	1.2
18	0.5% Carboxymethyl cellulose		5	250		0	0.000	0	0.0	0	0.000	0	0.0
	Silver zinc zeolite	500 mg/kg	5	250		1	0.004	1	0.4	2	0.008	2	0.8
		1500	5	250		1	0.004	1	0.4	2	0.008	2	0.8
		5000	5	250		0	0.000	0	0.0	3	0.012	3	1.2
24	Cyclophosphamide	30 mg/kg	5	250	*	140	0.560	72	28.8	161	0.644	82	32.8
	0.5% Carboxymethyl cellulose		4	250		2	0.008	2	0.8	8	0.032	7	2.8
	Silver zinc zeolite	500 mg/kg	5	250		2	0.008	2	0.8	11	0.044	8	3.2
		1500	4	250		3	0.012	3	1.2	10	0.040	9	3.6
		5000	5	250		2	0.008	2	0.8	7	0.028	7	2.8

* : Data shows pulverized cells and/or damaged cells with more than ten chromosome aberrations per cell.

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HED (H7509C)
Byron T. Backus
2/8/93

DATA EVALUATION REPORT

CHEMICAL: Silver Zinc Zeolite

TOX. CHEM. NO.: N/A

STUDY TYPE: Ames/Salmonella gene mutation assay

ACCESSION OR MRID NUMBER: 420328-03

SYNONYMS/CAS NO.: N/A

SPONSOR: Kanebo Zeolite USA, Inc.
New York, NY 10118

TESTING FACILITY: Arthur D. Little, Inc.
30 Memorial Drive
Cambridge, MA 02142

TITLE OF REPORT: Silver Zinc Zeolite Ames/Salmonella mutagenesis assay

AUTHORS(S): Kenneth S. Loveday

STUDY NUMBER(S): ADL 65460-02

REPORT ISSUED: August 22, 1990

CONCLUSIONS(S): AgZn Zeolite did not induce mutations in Salmonella typhymurium strains TA98, TA100, TA1535 or TA1537 when tested at doses of 0.003 - 0.15 mg/plate with activation or at doses of 0.0005 - 0.015 mg/plate without activation.

CLASSIFICATION: Acceptable

A. Materials:

1. Test Material:

Name: Silver Zinc Zeolite (AgZn Zeolite)
Description: Solid, Powder
Color: White
Lot #: 62990
Purity: 99%
Contaminants: not reported
Solubility: Not soluble, suspended in sterile water

2. Controls:

Negative: Deionized water
Positive:

with activation:

TA98	2-anthramine (0.5 µg/plate in 100 µl/plate)
TA100	2-anthramine (1.0 µg/plate in 100 µl/plate)
TA1535	2-anthramine (2.0 µg/plate in 100 µl/plate)
TA1537	2-anthramine (3.0 µg/plate in 100 µl/plate)

without activation:

TA98	2-nitrofluorene (3.0 µg/plate in 100 µl/plate)
TA100	sodium Azide (10.0 µg/plate in 100 µl/plate)
TA1535	sodium Azide (0.5 µg/plate in 100 µl/plate)
TA1537	9-aminoacridine (80.0 µg/plate in 100 µl/plate)

3. Activation: S9 derived from

_X_ Aroclor 1254	_X_ induced	_X_ rat	_X_ liver
___ phenobarbital	___ non-induced	___ mouse	___ lung
___ none		___ hamster	___ other
___ other		___ other	

S9 microsome fraction from Aroclor 1254 induced male Sprague-Dawley rats (Microbiological Associates).

S9 mix per 10 ml:

0.4M $MgCl_2$/1.65 M KCl	0.2 ml
1 M Glucose-6-Phosphate	0.05 ml
0.1M NADP	0.4 ml
0.2M Phosphate Buffer pH 7.4	5.0 ml
Sterile Deionized water	3.35 ml
S9 Fraction	1.0 ml

The S9 mix was kept on ice.

4. Test organisms: S. typhimurium strains

___ TA97 _X_ TA98 _X_ TA100 ___ TA102 ___ TA104
_X_ TA1535 _X_ TA1537 ___ TA1538; list any others:
Properly maintained? YES
Checked for appropriate genetic markers (rfa mutation, R factor)? YES

5. Test compound concentrations used:

with activation: 0.15, 0.05, 0.030, 0.015, 0.010, 0.005, 0.003 mg/plate

without activation: 0.015, 0.010, 0.005, 0.003, 0.0015, 0.0010, 0.0005 mg/plate

B. TEST PERFORMANCE

1. Type of assay:
   _X_ standard plate test
   ___ pre-incubation (___ minutes)
   ___ "Prival" modification (i.e. azo reduction method)
   ___ spot test
   ___ other (describe in a:)

a. Protocol (brief description, or attach copy to appendix, if appropriate; e.g. include mediums used, incubation times, assay evaluation):

The following components were consecutively added to 2.5 ml aliquots of molten top agar containing 50 μM biotin and 50 μM histidine: 100 μl of bacterial culture with a density between 1 and 2 x 10^9 bacteria/ml, 100 μl of the appropriate concentration of test substance or positive or negative control, and 500 μl of S9 mix or buffer (for the nonactivated assay). The tubes were mixed and poured onto plates containing 25 ml of minimal glucose agar made in-house using BBL Agar Lot #LIDVIP and FODSPP. Test plates were allowed to harden, inverted and incubated at 37°C for approximately 72 hours. The plates were then stored at 4°C until they were counted, or they were counted immediately. AgZn Zeolite was excessively toxic to the cells in the absence of S9 mix, therefore, tested concentrations were lower in the non-activated assays.

Revertant colonies were counted either manually or with an Artek Model 880 electronic colony counter. The mean number of revertants per plate and the standard deviation was calculated for each concentration and strain. A test was considered positive if a significant concentration-dependent increase over the negative control was seen. A significant increase was a two-fold increase when the background was 50 revertants/plate or greater; a three-fold increase when the background was between 10 and 49 revertants/plate; and a four-fold increase when the background was less than 10 revertants/plate.

2. Preliminary cytotoxicity assay: Toxicity to the bacterial strains was observed at concentrations of 0.05 mg/plate and above in the absence of S9 and 0.5 mg/plate and above in the presence of S9.

3. Mutagenicity assay: There was no significant increase in the number of revertants per plate with or without activation at any tested concentration. Triplicate plates were used for each test concentration. A second repeat assay confirmed the results of the first assay. Summary tables 3 and 5 from the report are attached.

All controls performed as expected. Solvent controls were within historical ranges and positive control results were appropriate.

4. Reviewer's discussion/conclusions: The study protocol conformed to the pertinent Federal guidelines. A preliminary range-finding study was performed to determine concentrations of AgZn Zeolite to test and data were consistent between replicate experiments. The study summary states that "The test substance was not soluble in any solvent", therefore it was tested as a suspension. The solubility determination was presumably made by the sponsor and not by Arthur D. Little as "The Sponsor has assumed responsibility for performing analysis to determine the characterization, homogeneity and stability of the test substance and concentration, homogeneity and stability analysis of the test substance mixture, as appropriate."

   There was no significant increase in the mean number of revertants/plate over the water control values at any concentration tested. The expected results were obtained with both the positive and solvent controls with and without activation.

   Although no analytical determinations of the dosing solution were done in this study, the cytotoxicity seen in the preliminary range-finding assay (section B.2. above) and the effects seen on the test bacteria and/or bacterial lawn at the highest doses in the actual mutagenicity assay (footnotes to tables 4 and 6), provide evidence that the test material was assayed to sufficiently high dose levels. In conclusion, this study showed that AgZn Zeolite was not mutagenic in the tested Salmonella strains at the tested concentrations either with or without exogenous metabolic activation.

5. Was the test performed under GLPs (is a quality assurance statement present)?
   YES

6. CBI appendix attached?
   NO

APPENDIX

Silver Zinc Zeolite Ames/Salmonella Mutagenesis Assay

TABLE 1

AMES SALMONELLA/MICROSOME MUTAGENICITY TEST WITH SILVER ZINC ZEOLITE
MEAN SUMMARY DATA
RANGE FINDER

	S-9	MEAN REVERTANTS/PLATE							
		TA 98		TA 100		TA 1535		TA 1537	
		x	sd	x	sd	x	sd	x	sd
WATER CONTROL	(-)	18	2	85	4	7	1	4	2
	(+)	28	6	108	8	7	6	5	2
POSITIVE CONTROLS	(-)	135	16	337	23	234	4	280	9
	(+)	251	4	385	28	89	2	112	10
TEST COMPOUND: (mg/plate)									
1.5	(-)	*****		*****		*****		*****	
0.5	(-)	*****		*****		*****		*****	
0.15	(-)	*****		*****		*****		*****	
0.05	(-)	*****		*****		*****		*****	
0.015	(-)	2	2	30	4	*****		*****	
0.005	(-)	15	6	77	3	4	4	4	3
0.0015	(-)	19	3	87	10	4	1	2	1
5	(+)	*****		*****		*****		*****	
1.5	(+)	*****		*****		*****		*****	
0.5	(+)	*****		*****		*****		*****	
0.15	(+)	23	3	66	6	3	2	4	2
0.05	(+)	21	5	98	5	5	2	3	1
0.015	(+)	17	3	95	12	5	1	6	5
0.005	(+)	18	5	102	5	4	2	4	2

*****: Chemical was toxic to the bacteria, plates could not be evaluated.

POSITIVE CONTROLS(-S9)			POSITIVE CONTROLS(+S9)	
TA 98	2-Nitrofluorene	3 ug/plate	2-Aminoanthracene	0.5ug/plate
TA 100	Sodium Azide	10 ug/plate	2-Aminoanthracene	1ug/plate
TA 1535	Sodium Azide	0.5 ug/plate	2-Aminoanthracene	2ug/plate
TA 1537	9-Aminoacridine	80 ug/plate	2-Aminoanthracene	3ug/plate

x=mean

sd=standard deviation

TABLE 2

AMES SALMONELLA/MICROSOME MUTAGENICITY ASSAY WITH SILVER ZINC ZEOLITE
INDIVIDUAL PLATE COUNT
RANGE FINDER

		Number of revertants per plate											
	S-9	TA 98			TA 100			TA 1535			TA 1537		
WATER CONTROL	(-)	18	16	20	83	90	83	6	8	6	4	2	5
	(+)	28	34	22	100	108	115	5	14	3	6	3	5
POSITIVE CONTROLS	(-)	133	120	151	362	333	316	233	239	231	288	271	281
	(+)	247	250	255	380	360	416	91	89	88	123	109	103
TEST COMPOUND: (mg/plate)													
1.5	(-)	*****			*****			*****			*****		
0.5	(-)	*****			*****			*****			*****		
0.15	(-)	*****			*****			*****			*****		
0.05	(-)	*****			*****			*****			*****		
0.015	(-)	3	0	2 A	30	26	34 A	*****			*****		
0.005	(-)	20	17	9	78	74	80	1	8	4 A	3	1	7 A
0.0015	(-)	17	21	c	98	81	82	4	3	5 A	3	3	1 A
5	(+)	*****			*****			*****			*****		
1.5	(+)	*****			*****			*****			*****		
0.5	(+)	*****			*****			*****			*****		
0.15	(+)	21	22	27 A	65	61	72 A	3	2	5 A	6	3	2 A
0.05	(+)	24	24	15 A	93	98	103	4	7	5	2	4	3 A
0.015	(+)	21	15	15	88	109	87	6	5	4	2	4	12 A
0.005	(+)	23	19	13	98	102	107	c	2	5	4	2	5 A

*****: Chemical was toxic to the bacteria, plates could not be evaluated.
A: Chemical slightly toxic to bacteria, however plates were evaluated for mutagenicity.
c: Plate was contaminated.

POSITIVE CONTROLS(-S9)

TA 98	2-Nitrofluorene	3 ug/plate
TA 100	Sodium Azide	10 ug/plate
TA 1535	Sodium Azide	0.5 ug/plate
TA 1537	9-Aminoacridine	80 ug/plate

POSITIVE CONTROLS (+S9)

2-Aminoanthracene	0.5 ug/plate
2-Aminoanthracene	1 ug/plate
2-Aminoanthracene	2 ug/plate
2-Aminoanthracene	3 ug/plate

EXPERIMENT I
TABLE 3

AMES SALMONELLA/MICROSOME MUTAGENICITY TEST WITH SLVER ZINC ZEOLITE
MEAN SUMMARY DATA

	S-9	MEAN REVERTANTS/PLATE							
		TA 98		TA 100		TA 1535		TA 1537	
		x	sd	x	sd	x	sd	x	sd
WATER CONTROL	(-)	48	4	114	8	8	2	4	2
	(+)	53	4	121	8	13	1	10	3
POSITIVE CONTROLS	(-)	331	43	1023	82	511	27	732	64
	(+)	711	44	1616	37	224	37	364	27
TEST COMPOUND: (mg/plate)									
0.015	(-)	33	4	64	6	3	2	4	2
0.010	(-)	39	4	81	4	4	2	2	2
0.005	(-)	39	4	107	8	5	1	2	1
0.003	(-)	44	3	111	8	7	3	2	1
0.0015	(-)	38	6	103	13	6	2	2	2
0.0010	(-)	41	3	120	6	5	2	2	2
0.0005	(-)	42	5	97	10	5	2	1	1
0.15	(+)	27	3	112	15	3	2	4	2
0.05	(+)	33	11	111	19	7	2	3	1
0.030	(+)	53	3	112	10	8	1	4	1
0.015	(+)	53	3	102	2	9	1	6	1
0.010	(+)	54	8	115	9	7	3	4	2
0.005	(+)	50	2	122	14	6	3	6	2
0.003	(+)	55	5	106	8	8	4	6	1

POSITIVE CONTROLS(-S9)			POSITIVE CONTROLS(+S9)	
TA 98	2-Nitrofluorene	3 ug/plate	2-Aminoanthracene	0.5ug/plate
TA 100	Sodium Azide	10 ug/plate	2-Aminoanthracene	1ug/plate
TA 1535	Sodium Azide	0.5 ug/plate	2-Aminoanthracene	2ug/plate
TA 1537	9-Aminoacridine	80 ug/plate	2-Aminoanthracene	3ug/plate

x=mean

sd=standard deviation

EXPERIMENT I
TABLE 4

AMES SALMONELLA/MICROSOME MUTAGENICITY ASSAY WITH SILVER ZINC ZEOLITE
INDIVIDUAL PLATE COUNT

		Number of revertants per plate											
	S-9	TA 98			TA 100			TA 1535			TA 1537		
WATER CONTROL	(-)	44	48	51	106	116	121	8	10	6	6	4	3
	(+)	50	58	52	114	120	130	13	14	13	11	12	6
POSITIVE CONTROLS	(-)	340	284	369	988	964	1116	531	523	480	784	751	661
	(+)	727	744	661	1645	1575	1628	267	199	207	341	357	393
TEST COMPOUND: (mg/plate)													
0.015	(-)	28	36	35 A	70	65	58 A	2	2	6 A	3	6	2 A
0.010	(-)	36	38	43 A	81	77	85 A	2	5	4 A	3	2	0 A
0.005	(-)	42	34	41	103	116	101	4	5	5 A	3	1	3
0.003	(-)	47	41	45	102	116	116	7	4	10	2	3	1
0.0015	(-)	34	45	36	93	98	118	4	8	7	1	2	4
0.0010	(-)	40	44	39	114	125	120	5	7	3	1	4	2
0.0005	(-)	43	46	37	86	103	102	4	5	7	1	1	2
0.15	(+)	29	24	27 A	99	109	129	1	4	3 A	7	3	3 A
0.05	(+)	34	44	22 A	128	91	115	6	7	9	3	4	3
0.030	(+)	50	53	56	102	113	121	7	8	9	3	4	4
0.015	(+)	50	54	55	101	100	104	10	8	10	7	5	6
0.010	(+)	59	57	45	125	111	108	4	7	9	4	2	6
0.005	(+)	48	50	52	110	119	138	6	9	4	4	6	7
0.003	(+)	57	49	58	109	111	97	4	7	12	6	6	5

A:Bacterial backgound lawn effected by the test chemical, but plates were evaluated for mutagenicity.

POSITIVE CONTROLS(-S9)

TA 98	2-Nitrofluorene	3 ug/plate
TA 100	Sodium Azide	10 ug/plate
TA 1535	Sodium Azide	0.5 ug/plate
TA 1537	9-Aminoacridine	80 ug/plate

POSITIVE CONTROLS (+S9)

2-Aminoanthracene	0.5 ug/plate
2-Aminoanthracene	1 ug/plate
2-Aminoanthracene	2 ug/plate
2-Aminoanthracene	3 ug/plate

Arthur D Little

EXPERIMENT II
TABLE 5

AMES SALMONELLA/MICROSOME MUTAGENICITY TEST WITH SILVER ZINC ZEOLITE
MEAN SUMMARY DATA

	S-9	MEAN REVERTANTS/PLATE							
		TA 98		TA 100		TA 1535		TA 1537	
		x	sd	x	sd	x	sd	x	sd
WATER CONTROL	(-)	31	4	85	11	4	1	5	1
	(+)	52	3	131	3	8	1	9	3
POSITIVE CONTROLS	(-)	258	33	689	26	406	7	268	36
	(+)	643	77	837	56	115	10	172	18
TEST COMPOUND: (mg/plate)									
0.015	(-)	25	2	69	9	2	2	3	1
0.010	(-)	19	6	70	12	4	2	4	1
0.005	(-)	24	5	64	16	3	2	4	2
0.003	(-)	24	4	66	9	6	2	4	3
0.0015	(-)	25	5	67	7	4	2	4	1
0.0010	(-)	24	4	80	6	4	3	4	1
0.0005	(-)	28	4	69	6	7	1	6	1
0.15	(+)	35	16	112	7	4	0	7	1
0.05	(+)	38	4	142	12	6	1	9	4
0.03	(+)	41	8	148	14	6	1	7	3
0.015	(+)	47	6	158	6	6	1	8	2
0.010	(+)	43	2	148	9	6	2	7	2
0.005	(+)	54	1	88	14	5	1	9	3
0.003	(+)	52	5	92	12	6	1	9	1

NOTE: TA1537 was tested in a subsequent assay.

POSITIVE CONTROLS(-S9)

TA 98	2-Nitrofluorene	3 ug/plate
TA 100	Sodium Azide	10 ug/plate
TA 1535	Sodium Azide	0.5 ug/plate
TA 1537	9-Aminoacridine	80 ug/plate

POSITIVE CONTROLS(+S9)

2-Aminoanthracene	0.5ug/plate
2-Aminoanthracene	1ug/plate
2-Aminoanthracene	2ug/plate
2-Aminoanthracene	3ug/plate

x=mean

sd=standard deviation

EXPERIMENT II
TABLE 6

AMES SALMONELLA/MICROSOME MUTAGENICITY ASSAY WITH SILVER ZINC ZEOLITE
INDIVIDUAL PLATE COUNT

		Number of revertants per plate											
	S-9	TA 98			TA 100			TA 1535			TA 1537		
WATER CONTROL	(-)	29	29	36	73	93	89	3	5	4	4	4	6
	(+)	49	52	54	131	134	128	8	7	9	10	6	11
POSITIVE CONTROLS	(-)	290	259	224	660	697	709	402	414	403	297	279	228
	(+)	556	673	701	835	782	894	114	105	125	174	153	189
TEST COMPOUND: (mg/plate)													
0.015	(-)	24	24	28 A	67	78	61 A	2	1	4 A	3	2	3 A
0.010	(-)	25	20	13 A	67	84	60 A	2	5	4 A	4	5	3 A
0.005	(-)	29	24	20	52	75	c	5	1	3	2	6	5
0.003	(-)	29	21	23	57	68	74	6	7	4	2	2	8
0.0015	(-)	24	21	31	64	62	75	2	4	5	4	4	3
0.0010	(-)	20	28	24	76	78	87	7	4	2	3	5	3
0.0005	(-)	26	26	33	64	75	68	8	6	6	6	7	5
0.15	(+)	26	54	26 A	114	104	117	4	4	4 A	6	7	7
0.05	(+)	34	42	38	151	147	128	6	6	5	6	13	9
0.03	(+)	35	39	50	140	164	139	5	5	7	5	10	7
0.015	(+)	42	45	54	162	161	152	6	5	7	8	6	10
0.010	(+)	42	43	45	157	148	139	8	4	7	8	9	5
0.005	(+)	53	55	54	74	90	101	6	6	4	9	12	6
0.003	(+)	56	53	47	104	81	91	6	6	7	10	9	8

A: The bacteria were effected by the test chemical, but plates were still evaluated for mutagenicity.
c: Plate was contaminated.

NOTE: TA1537 was tested in a subsequent assay.

POSITIVE CONTROLS(-S9)

TA 98	2-Nitrofluorene	3 ug/plate
TA 100	Sodium Azide	10 ug/plate
TA 1535	Sodium Azide	0.5 ug/plate
TA 1537	9-Aminoacridine	80 ug/plate

POSITIVE CONTROLS (+S9)

2-Aminoanthracene	0.5 ug/plate
2-Aminoanthracene	1 ug/plate
2-Aminoanthracene	2 ug/plate
2-Aminoanthracene	3 ug/plate

Arthur D Little

Reviewed by: H. Tim Borges, Ph.D., MT(ASCP)
Biomedical and Environmental Information Analysis Section
Health and Safety Research Division
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Oak Ridge, TN 37831-6050

Secondary Reviewer: SanYvette Williams, D.V.M. 11/12/92
EPA/OPP/HED/TB-2/Sec. 4

DATA EVALUATION REPORT

STUDY TYPE: Primary Dermal Irritation Study in Rabbits (81-5)

EPA IDENTIFICATION NUMBERS:

Tox. Chem. Number: 735
MRID Number: 420328-02

TEST MATERIAL: Silver zinc zeolite

SYNONYMS: None known or reported

SPONSOR: Kanebo Zeolite USA, Inc., 20th Floor, Empire State Building, 350 5th Ave., New York, NY

STUDY NUMBER: Arthur D. Little Reference Number 63613-12

TESTING FACILITY: Arthur D. Little, Inc., Acorn Park, Cambridge, MA

TITLE OF REPORT: Silver Zinc Zeolite Primary Dermal Irritation Study in Rabbits

AUTHOR: C. Nicholas James, H.N.D.

STUDY COMPLETED: 10/03/89

CONCLUSIONS: The Primary Irritation Index (PII) of silver zinc zeolite was 0.13. The test compound was considered to be a slight irritant to the skin of rabbits when 0.5 g was applied under a semi-occlusive patch for four hours. Slight erythema of the skin was observed for one hour after cessation of dermal exposure. No other treatment-related effects were observed.

TOXICITY CATEGORY: IV

CLASSIFICATION: Core - Supplementary. This study may be upgraded upon the submission of the stability of silver zinc zeolite.

A. MATERIALS

1. Test Material

Test material: Silver zinc zeolite
Receipt: 06/13/89
Purity of material: Sponsor reported purity of 99%. The [redacted] stability of silver zinc zeolite used in this study were not reported.
Physical description: White powder
Active ingredient: Not reported
Inactive ingredient: Not reported
Lot number: Not reported
pH: Not reported

2. Controls

Materials: Not needed
Animals: Not needed

3. Test Animals

Species: Rabbits (SPF)
Strain: New Zealand White
Source: Hazleton Research Laboratories, PA
Receipt Date: Not reported
Sex: Male and female
Numbers: Three male and three female
Housing: Housed individually in suspended stainless steel cages with grid bottoms. Rabbits were housed for a seven-day acclimation/quarantine period prior to initiation of study.
Age: Young adult
Weight: 2.2-2.4 kg
Feeding: Approximately six ounces/day Agway High Fiber Standard Rabbit Chow. Cambridge tap water provided ad libitum.
Assignment: Not reported
Location of raw data: Raw data is recorded in laboratory notebook #24124 retained by Arthur D. Little, Inc.

4. Exposure

Route of administration: Dermal
Dose level: 500 mg/kg silver zinc zeolite moistened with 0.5% carboxymethyl cellulose

B. TEST PERFORMANCE

Depilation was done one day prior to the test by shaving an area on the dorsal trunk free of fur. Only rabbits with intact skin were used in the study. Silver zinc zeolite, 0.5 g, was moistened with 0.3 ml of 0.5% carboxymethyl cellulose and mixed into a slurry. The slurry was evenly applied to an approximate 2 × 3 cm section of gauze and placed on the shaved dorsal trunk of the rabbit. The gauze was backed with semi-occlusive, non-irritating tape which in turn was backed by an elastic bandage. The complete dressing was wrapped with elastic bandage. Four

hours after application of the silver zinc zeolite, the patches were removed and excess test compound washed away with a gauze pad and water.

The shaved area of each rabbit treated with silver zinc zeolite was examined for erythema and edema 30-60 minutes, 22 hours, 44 hours, and 68 hours after removal of the patch. According to the author of the study, the deviation in protocol from the specified assessment of erythema and edema at 24, 48, and 72 hours was not thought to have influenced the results. The presence of erythema and edema was scored according to the method described in the Federal Register, Vol. 50, No. 188, September 27, 1985, page 39430. At the end of the last observation, the rabbits were killed by an intravenous injection of T-61 solution. Necropsies were not done.

C. RESULTS AND STUDY AUTHOR'S CONCLUSIONS

No rabbits died during the study period. The only clinical observation noted during the study was a slight erythema in three animals at the 30-60 minute assessment. The reactions had subsided in these animals by the 22 hour assessment, and no further erythema or edema were noted at any time during the remainder of the observation period. The total scores for erythema and edema are shown in Table 1. When the scores are added together and divided by 24, a Primary Irritation Index (PII) of 0.13 is obtained. Tables were included in the report for body weight and the incidence of erythema and edema.

The author of the study concluded that silver zinc zeolite was regarded as a slight irritant to the skin of rabbits when 0.5 g is applied under semi-occlusive conditions for four hours.

D. REVIEWER'S COMMENTS

The study author has correctly interpreted the test results. The PII for silver zinc zeolite was 0.13 which corresponds to Toxicity Category IV. The material should be considered as a mild irritant to the skin of male and female rabbits after 4 hours exposure. Because no data showing the stability [illegible] of the test material was included, this study is classified supplementary. It may be upgraded upon the submission of these data. It should be noted that the study author made an error in Section 3.2 -Dose Group Selection on page 19 of ADL report 63613-12. In this section the author states that the study group consisted of six female rabbits when elsewhere in the report and data sections the study group was composed of three male and three female rabbits. This error has no effect on the interpretation of the data, but should be corrected to accurately reflect the study.

E. COMPLIANCE

A signed and dated Quality Assurance Unit Statement was presented.
A signed and dated Good Laboratory Practice Statement was provided.

F. CBI APPENDIX

None presented.

TABLE 1: Individual Irritation Scores in Rabbits after Exposure to Silver Zinc Zeolite Primary Dermal Irritation Study

Animal ID/Sex	30-60 minuets		22 Hours		44 Hours		*68* Hours	
	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema
B42832/M	1	0	0	0	0	0	0	0
B43532/M	0	0	0	0	0	0	0	0
B44544/M	1	0	0	0	0	0	0	0
C50095/F	0	0	0	0	0	0	0	0
B44447/F	0	0	0	0	0	0	0	0
B44607/F	1	0	0	0	0	0	0	0
Subtotal	3	0	0	0	0	0	0	0
Total	3		0		0		0	

PII = 3/24 = 0.13

Reviewed by: H. Tim Borges, Ph.D., MT(ASCP)
Biomedical and Environmental Information Analysis Section
Health and Safety Research Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831-6050

Secondary Reviewer: SanYvette Williams, D.V.M.
EPA/OPP/HED/TB-2/Sec. 4

DATA EVALUATION REPORT

STUDY TYPE: Guinea Pig Sensitization Study - Buehler Method (81-6)

EPA IDENTIFICATION NUMBERS:

Tox. Chem. Number: 735
MRID Number: 420328-02

TEST MATERIAL: Silver zinc zeolite

SYNONYMS: None known or reported

SPONSOR: Kanebo Zeolite USA, Inc., 20th Floor, Empire State Building, 350 5th Ave., New York, NY

STUDY NUMBER: Arthur D. Little Reference Number 63613-15

TESTING FACILITY: Arthur D. Little, Inc., Acorn Park, Cambridge, MA

TITLE OF REPORT: Silver Zinc Zeolite Guinea Pig Sensitization Study - Buehler Method

AUTHOR: C. Nicholas James, H.N.D.

STUDY COMPLETED: 10/03/89

CONCLUSIONS: Silver zinc zeolite, when tested at concentrations as high as 60% in 0.5% carboxymethyl cellulose, was a non-sensitizing agent in guinea pigs when the Buehler technique is employed.

CLASSIFICATION: Core - Supplementary. This study may be upgraded upon the submission of the [illegible] stability of silver zinc zeolite.

A. MATERIALS

1. Test Material

Test material: Silver zinc zeolite
Receipt: 06/13/89
Purity of material: Sponsor reported purity of 99%. The [illegible] stability of silver zinc zeolite used in this study were not reported.
Physical description: White powder
Active ingredient: Not reported
Inactive ingredient: Not reported
Lot number: Not reported
pH: Not reported

2. Controls

Material: 0.1% Dinitrochlorobenzene (DNCB) - Positive Control (Sigma Chemical Co., Lot Number 44F-0565)
Animals: 10 female guinea pigs - DNCB positive control; 10 female guinea pigs - silver zinc zeolite challenge negative control

3. Test Animals

Species: Guinea pigs (Viral Antibody Free)
Strain: Albino outbred
Source: Charles River Breeding Laboratories, Portage MI
Receipt Date: Not reported
Sex: Female
Numbers: 10
Housing: All control and test guinea pigs were housed individually in solid bottom cages with Litterclean® wood shavings (New England Kennel Supply, Cambridge, MA). The guinea pigs were housed for a seven-day acclimation/quarantine period prior to initiation of study.
Age: Young adult
Weight: Group/Mean Body Weight at Induction Phase of Study/Standard Deviation; DNCB Positive Control/383 g/19 g; silver zinc zeolite test/383 g/17 g; silver zinc zeolite negative control/496 g/47 g (The body weight of the negative control group was measured at Challenge Phase of study. This is a deviation from the experimental protocol. The animals should have been weighed at the beginning of the Induction Phase. According to the author, this deviation was not considered to have affected the outcome of the study.)
Feeding: Agway Standard Guinea Pig Chow (Agway, Syracuse, NY) and Cambridge tap water provided ad libitum to all animals during the quarantine and study period.
Assignment: Random on the basis of body weight.
Location of raw data: Raw data is recorded in laboratory notebook #24127 retained by Arthur D. Little, Inc.

4. Exposure

Route of administration: Dermal
Dose level: 60% suspension of silver zinc zeolite in 0.5% carboxymethyl cellulose

B. TEST PERFORMANCE

This study was conducted in accordance with the procedure described by E.V. Buehler (Buehler, E.V., 1965, Delayed contact hypersensitivity in the guinea pig, Arch. Demat. 91: 171-175.)

Range Finding Study: Prior to the beginning of the sensitization study, four naive animals were used to determine the maximum non-irritating concentration of silver zinc zeolite to the skin. The backs of the four guinea pigs were shaved. Twenty-four hours later, a saturated 2 × 2 cm Webril cotton patch containing a concentration of 60%, 50%, 25%, or 12.5% silver zinc zeolite in 0.5% carboxymethyl cellulose was applied to the non-abraded shaved area. The Webril cotton patch was backed by an occlusive, non-porous surgical tape and secured to the shaved area by a strip of elastic adhesive bandage. Six hours later the bandage was removed and the application area wiped clean of silver Zinc Zeolite with a gauze moistened in carboxymethyl cellulose. Dermal reactions to silver Zinc Zeolite were evaluated 24 and 48 hours after removal of the patch.

Sensitization Study:
Induction Phase: Two groups of 10 female guinea pigs each were used in this portion of the study. Group 1 was composed of the DNCB positive control animals, whereas, Group 2 was composed of the silver zinc zeolite test animals. The hair on the left flank of each animal in both treatment groups was shaved. Twenty-four hours later, 0.4 ml of 0.1% DNCB or 60% silver zinc zeolite was applied to a 2 × 2 cm Webril cotton patch backed by an occlusive, non-porous surgical tape. The patch was applied to the shaved skin of the appropriate treatment group animals and secured with an elastic adhesive bandage. Six hours later, the dressing was removed and excess applied material was removed with a gauze pad wetted with 0.5% carboxymethyl cellulose. This process was repeated at weekly intervals for a total of three exposure periods.

Challenge Phase: Two weeks after the final induction exposure, the guinea pigs in Groups 1 and 2 plus a third group, Group 3 composed of 10 female guinea pigs serving as silver zinc zeolite negative controls, were challenged. A site on the right flank of each animal in each group was shaved free of hair. Twenty-four hours later, a 2 × 2 cm Webril cotton patch backed by an occlusive, non-porous surgical tape containing 0.1% DNCB (Group 1) or 60% silver zinc zeolite (groups 2 and 3) was applied to the shaved skin of the guinea pigs and secured in place with elastic adhesive bandage. After 6 hours, the patch and excess material removed using carboxymethyl cellulose wetted gauze. The treated area was evaluated for dermal reactions 24, 48, and 72 hours from the time the patch was first applied.

C. RESULTS AND STUDY AUTHOR'S CONCLUSIONS

Range Finding Study: The highest concentration, 60%, did not induce any adverse skin reactions at 24 or 48 hour post 6 hour exposure to silver zinc zeolite. Based on these results, the 60% suspension of silver zinc zeolite in 0.5% carboxymethyl cellulose was used for the sensitization study. A table listing the skin reactions recorded for the range finding study was included with the report. All guinea pigs survived until the completion of the study and were killed by CO_2 asphyxiation. No necropsies were done.

Sensitization Study: The incidence and severity of the Challenge readings are shown in Table 1. Silver zinc zeolite did not induce dermal reactions in either the study group or in the negative control group. Ten of ten guinea pigs treated with DNCB had positive dermal reactions indicating it to be a skin sensitizer. Tables providing a summary of the challenge study results, body weights, and the individual animal scores recorded during the challenge study were included with

the with the study authors report. All guinea pigs survived until the completion of the study and were killed by CO_2 asphyxiation. No necropsies were done.

D. REVIEWER'S COMMENTS

The study author has correctly interpreted the test results. Based on the lack of positive results during the challenge portion of this study, silver zinc zeolite should be regarded as a non-sensitizing agent to the skin of guinea pigs when applied as a 60% solution. Because no data showing the stability [illegible] of the test material was included, this study is classified supplementary. It may be upgraded upon the submission of these data. It should be noted that an error exists on page 14 of the submitted report. Table 2: Summary Challenge Results indicates that 0 animals were used in treatment groups 2 and 3, when in fact these groups contained 10 animals each. This error has no impact on the adequacy of the study but should be rectified to accurately reflect the study.

E. COMPLIANCE

A signed and dated Quality Assurance Unit Statement was presented.
A signed and dated Good Laboratory Practice Statement was provided.

F. CBI APPENDIX

None presented.

TABLE 1: Summary Challenge Results

Group[a]		Challenge Readings 24 Hours	48 Hours	72 Hours
1	Incidence Index (%)	100	100	100
	Severity Index	2.1	1.7	1.4
	Number of Animals	10	10	10
2	Incidence Index (%)	0	0	0
	Severity Index	0	0	0
	Number of Animals	10	10	10
3	Incidence Index (%)	0	0	0
	Severity Index	0	0	0
	Number of Animals	10	10	10

[a]Group	Chemical
1	0.1% DNCB (Positive Control Group
2	60% silver zinc zeolite (Test Group)
3	60% silver zinc zeolite (Negative Control Group)

Reviewed by: H. Tim Borges, Ph.D., MT(ASCP)
BEIA, Health and Safety Research Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831-6050

Secondary Reviewer: SanYvette Williams, D.V.M. 4/12/92
EPA/OPP/HED/TB-2/Sec. 4

DATA EVALUATION REPORT

STUDY TYPE: Primary Eye Irritation Study in Rabbits (81-4)

EPA IDENTIFICATION NUMBERS:

Tox. Chem. Number: 735
MRID Number: 420328-02

TEST MATERIAL: Silver zinc zeolite

SYNONYMS: None known or reported

SPONSOR: Kanebo Zeolite USA, Inc., 20th Floor, Empire State Building, 350 5th Ave., New York, NY

STUDY NUMBER: Springborn Laboratories Study Number 3214.2

TESTING FACILITY: Springborn Laboratories, Inc., Mammalian Toxicology Division, 553 N. Broadway, Spencerville, OH

TITLE OF REPORT: Primary Eye Irritation Study in Rabbits with Silver Zinc Zeolite

AUTHOR: Rusty E. Rush

STUDY COMPLETED: 10/04/89

CONCLUSIONS: In the No Rinse group, silver zinc zeolite is a slight to moderate irritant to the ocular tissue of the rabbit. The maximum mean total score, calculated according to the Draize method for grading ocular effects, was 16.0. The score was calculated 48 hours postinstillation.

TOXICITY CATEGORY: III

CLASSIFICATION: Core - Supplementary. This study may be upgraded upon the submission of the purity and stability of silver zinc zeolite used.

A. MATERIALS

1. Test Material

Test material: Silver zinc zeolite
Receipt: 06/14/89
Purity of material: The purity and stability of silver zinc zeolite used in this study were not reported.
Physical description: White powder
Active ingredient: Not reported
Inactive ingredient: Not reported
Storage: Room temperature
Lot number: Not reported
pH: Not reported

2. Controls

Materials: Not needed
Animals: Eye not instilled with the test material.

3. Test Animals

Species: Rabbits
Strain: New Zealand White
Source: Mohican Valley Rabbitry, Loudonville, OH
Receipt Date: Not reported
Sex: Male and female
Numbers: Four male, five female
Housing: Housed individually in suspended stainless steel cages with grid bottoms. Rabbits were housed for a minimum five-day acclimation/quarantine period prior to initiation of study.
Age: Not reported/Adult
Weight: 2.0-2.4 kg
Feeding: Agway Prolab Rabbit Ration and fresh water provided ad libitum throughout the study.
Assignment: Not reported

4. Exposure

Route of administration: Ocular
Dose level: 0.058 g silver zinc zeolite (instilled into the right eye of nine rabbits)

B. TEST PERFORMANCE

Each of the nine rabbits received a pretest ocular exam within 24 hours prior to the start of the study. The exam consisted of a macroscopic evaluation of both eyes for ocular irritation. In addition, one drop of fluorescein dye was instilled into each eye, the eye rinsed with saline, and the corneal surface examined for dye retention under long-wave UV light. The nine rabbits selected for the study were negative for eye irritation, ocular defects, and pre-existing corneal lesions.

Each of the nine rabbits received a dose of 0.058 g of silver zinc zeolite (0.1 ml equivalent, vehicle not identified) instilled into the conjunctival sac of the right eye. Immediately after dosing, the upper and lower eyelids were held together for one second. The contralateral eye of each rabbit was untreated and served as the control. Thirty seconds postinstillation, both eyes of three rabbits (rinse group) were rinsed with 50 ml of normal saline. The eyes of the remaining six rabbits (no rinse group) were not rinsed.

Both eyes of all rabbits were examined for irritation 1, 24, 48, and 72 hours postinstillation. The grading system used is shown in Table 1A and 1B. After macroscopic examination 24 hours postinstillation, a fluorescein examination similar to that described above was repeated on all rabbit test and control eyes. If the fluorescein dye retention test was positive at 24 hours, a fluorescein exam was done on the affected eyes at each subsequent interval until it was negative. The ocular irritation scores were added for each animal and the group mean irritation score was calculated for each scoring interval.

At the completion of the study, all rabbits were killed by T-61 intravenous euthanasia and discarded. No necropsies were conducted.

C. RESULTS AND STUDY AUTHOR'S CONCLUSIONS

Rinsed Group

The results of this study are shown in Table 2. One hour after exposure, silver zinc zeolite produced a slight iritis in 3/3 treated eyes. This condition was resolved within 24 hours. Conjunctivitis was found in the treated eyes up to 24 hours after treatment, but had disappeared within 48 hours. The highest Group Mean Irritation Score was 14.3 at 1 hour postinstillation. The Group Mean Irritation Score decreased throughout the study, being 3.3 at 24 hours, 1.3 at 48 hours, and 0.0 at 72 hours.

No rinse Group

The results of this study are shown in Table 3. One hour after exposure, silver zinc zeolite induced iritis and conjunctivitis in 6/6 treated eyes. Within 24 hours, iridal irritation had resolved. The conjunctival irritation was decreased 48 hours after exposure and was no longer present in 4/6 rabbits after 72 hours. Conjunctival irritation was not present in any rabbits 7 days postinstillation. The highest Group Mean Irritation Score was 16.0 at 1 hour post instillation. The Group Mean Irritation Score decreased throughout the study, being 3.7 at 24 hours, 2.0 at 48 hours, 0.7 at 72 hours, and 0.0 at 7 days.

The author of the study concluded that the no rinse test data indicated silver zinc zeolite was a slight to moderate irritant to the ocular tissue of the rabbit.

D. REVIEWER'S COMMENTS

The author of the report did not state the vehicle used for the instillation of silver zinc zeolite. While this is not required by the regulations described in Federal Register, Vol. 50, No. 188, Sept. 27, 1985, page 39430-39431, and it is unlikely that the vehicle is responsible for the ocular effects found, the possibility can not be eliminated. This is particularly true since historical vehicle control results were not reported nor were vehicle controls used in the study.

Silver zinc zeolite induced iritis in 6/6 rabbits in the No Rinse treatment group 1 hour postinstillation. The condition, however, was resolved within 24 hours. One hour after treatment, the mean score for iridal effects was 5.0. The test chemical also induced conjunctival redness, chemosis, and discharge in 6/6 rabbits one hour postinstillation. The mean score for conjunctival effects 1 hour postinstillation was 11.0. The mean score for conjunctival effects decreased throughout the remainder of the observation period, being 3.7 at 24 hours, 2.0 at 48 hours, 1.3 at 72 hours, and 0.0 seven days postinstillation.

In the Rinsed Silver Zinc Zeolite Treatment Group, the test chemical induced iritis in 3/3 rabbits within 1 hour postinstillation resulting in a mean score for iridal effects of 5.0. The condition resolved within 24 hours, however. Silver zinc zeolite also induced conjunctival redness, chemosis and discharge in 3/3 rabbits 1 hour postinstillation, but the effects were not as severe nor as persistent in the No Rinse treatment group.

The author has correctly interpreted the silver zinc zeolite study based on the results obtained in the No Rinse treatment group. In this study, silver zinc zeolite did not induce corneal opacity, but did initially induce iridal and conjunctival effects. These effects were completely resolved in all rabbits within 7 days. Based on the maximum Group Mean Irritation Score recorded one hour postinstillation, silver zinc zeolite should be classified in Category III as a moderate irritant. Because no data showing the stability or purity of the test material was included, this study is classified supplementary. It may be upgraded upon the submission of these data.

E. COMPLIANCE

A signed and dated Quality Assurance Unit Statement was presented.
A signed and dated Good Laboratory Practice Statement was provided.

F. CBI APPENDIX

None presented.

TABLE 1A: OCULAR IRRITATION GRADING SYSTEM

CORNEA	SCORE
(A) Opacity - Degree of density (area most dense taken for reading)	
No ulceration or opacity	0
Scattered or diffuse areas of opacity (other than slight dulling of normal luster), details of iris clearly visible	1*
Easily discernible translucent area, details of iris slightly obscured	2*
Opalescent (nacreous) area, no details of iris visible, size of pupil barely discernible	3*
Opaque cornea, iris not discernible through opacity	4*
(B) Area of cornea involved	
One quarter (or less) but not zero	1
Greater than one quarter, but less than half	2
Greater than half, but less than three quarters	3
Greater than three quarters, up to a whole area	4

Score = A x B x 5 Total Maximum = 80

IRIS	
(A) Values	
Normal	0
Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combination of any thereof) iris is still reacting to light (sluggish reaction is positive)	1*
No reaction to light, hemorrhage, gross destruction (any or all of these)	2*

Score = A x 5 Total Maximum = 10

CONJUNCTIVAE	
(A) Redness (refers to palpebral and bulbar conjunctivae excluding cornea and iris)	
Blood vessels normal	0
Blood vessels definitely injected (hyperemic) above normal (slight erythema)	1*
More diffuse, deeper crimson red, individual vessels not easily discernible (moderate erythema)	2*
Diffuse beefy red (marked erythema)	3*

TABLE 1: OCULAR IRRITATION GRADING SYSTEM (continued)

CONJUNCTIVAE	SCORE
(B) Chemosis	
No swelling	0
Any swelling above normal (includes nictitating membrane, slightly swollen)	1
Obvious swelling with partial eversion of lids	2*
Swelling with lids about half closed	3*
Swelling with lids more than half closed	4*
(D) Discharge	
No discharge	0
Any amount different from normal (does not include small amounts observed in inner canthus of normal animals)	1
Discharge with moistening of the lids and hairs just adjacent to lids	2
Discharge with moistening of the lids and hairs and considerable area around the eye	3

Score = (A + B + C) x 2 Total Maximum = 20

TABLE 1B: OCULAR EVALUATION CRITERIA

Evaluation Criteria	Irritation Rating
Maximum mean irritation score ≤ 1.0	Nonirritant
Mean irritation score ≤ 6.0 at 24 hours and no corneal or iridal irritation. Irritation must be completely reversible by day 7	Slight Irritant
Mean irritation score > 6.0 at 24 hours, but maximum mean irritation score ≤ 30.0 and any corneal or iridal changes are completely reversible by day 14.	Moderate Irritant
Maximum mean irritation score > 30.0, or any corneal or iridal findings persist at 14 or 21 days.	Sever Irritant
Irreversible alteration - gross destruction	Corrosive

Table 2

Ocular Irritation Scores
(Rinse Group)

Animal Number/Sex	Interval	Cornea A	Cornea B	Cornea Score AX5	Iris A	Iris Score AXBX5	Conjunctivae A	Conjunctivae B	Conjunctivae C	Conjunctivae Score (A+B+C)2	Conjunctivae Total	Fluorescein Examination	Comments
3742/M	1 Hour	0	0	0	1	5	2	2	1	10	15		
	24 Hours	0	0	0	0	0	2	1	0	6	6	negative	
	48 Hours	0	0	0	0	0	1	0	0	2	2		
	72 Hours	0	0	0	0	0	0	0	0	0	0		
3749/M	1 Hour	0	0	0	1	5	2	2	1	10	15		
	24 Hours	0	0	0	0	0	1	0	0	2	2	negative	
	48 Hours	0	0	0	0	0	1	0	0	2	2		
	72 Hours	0	0	0	0	0	0	0	0	0	0		
3776/F	1 Hour	0	0	0	1	5	1	2	1	8	13		
	24 Hours	0	0	0	0	0	1	0	0	2	2	negative	
	48 Hours	0	0	0	0	0	0	0	0	2	2		
	72 Hours	0	0	0	0	0	0	0	0	0	0		

[a]Fluorescein examination results: (+) positive retention; (-) nrgative retention.
[b]See page 10 of 26 for comment code.

Group Mean Irritation Scores
1 Hour = 14.3
24 Hours = 3.3
48 Hours = 1.3
72 Hours = 0.0

Table 3

Ocular Irritation Scores
(No Rinse Group)

Animal Number/Sex	Interval	Cornea			Iris		Conjunctivae					Fluorescein Examination	Comments
		A	B	Score AX5	A	Score AXBX5	A	B	C	Score (A+B+C)2	Total		
3773/F	1 Hour	0	0	0	1	5	2	2	2	12	17		SCE[a]
	24 Hours	0	0	0	0	0	1	1	0	4	4	negative	
	48 Hours	0	0	0	0	0	1	1	0	4	4		
	72 Hours	0	0	0	0	0	0	0	0	0	0		
375/F	1 Hour	0	0	0	1	5	2	2	1	10	15		
	24 Hours	0	0	0	0	0	1	1	0	4	4	negative	
	48 Hours	0	0	0	0	0	1	0	0	2	2		
	72 Hours	0	0	0	0	0	0	0	0	0	0		
3776/F	1 Hour	0	0	0	1	5	2	2	2	12	17		
	24 Hours	0	0	0	0	0	2	1	0	6	6	negative	
	48 Hours	0	0	0	0	0	1	0	0	2	2		
	72 Hours	0	0	0	0	0	1	0	0	2	2		
	7 Days	0	0	0	0	0	0	0	0	0	0		
3737/M	1 Hour	0	0	0	1	5	1	2	2	10	15		
	24 Hours	0	0	0	0	0	1	0	0	2	2	negative	
	48 Hours	0	0	0	0	0	0	0	0	0	0		
	72 Hours	0	0	0	0	0	0	0	0	0	0		
3737/M	1 Hour	0	0	0	1	5	2	2	2	12	17		
	24 Hours	0	0	0	0	0	1	1	0	4	4	negative	
	48 Hours	0	0	0	0	0	1	0	0	2	2		
	72 Hours	0	0	0	0	0	0	0	0	0	0		

[a]Sloughing of corneal epithelium

Table 3 (Continued)

Animal Number/Sex	Interval	Cornea A	Cornea B	Cornea Score AX5	Iris A	Iris Score AXBX5	Conjunctivae A	Conjunctivae B	Conjunctivae C	Conjunctivae Score (A+B+C)2	Conjunctivae Total	Fluorescein Examination	Comments
3739/M	1 Hour	0	0	0	1	5	1	2	2	10	15		
	24 Hours	0	0	0	0	0	1	0	0	2	2	—	
	48 Hours	0	0	0	0	0	1	0	0	2	2		
	72 Hours	0	0	0	0	0	0	0	0	0	0		

[a]Fluorescein examination results: (+) positive retention; (-) nrgative retention.
[b]See page 10 of 26 for comment code.

Group Mean Irritation Scores

1 Hour = 14.3
24 Hours = 3.3
48 Hours = 1.3
72 Hours = 0.0

Reviewed by: H. Tim Borges, Ph.D., MT(ASCP)
Biomedical and Environmental Information Analysis Section
Health and Safety Research Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831-6050

Secondary Reviewer: SanYvette Williams, D.V.M. 11/12/92
EPA/OPP/HED/TB-2/Sec. 4

DATA EVALUATION REPORT

STUDY TYPE: Acute Inhalation Toxicity Study in Rats (81-3)

EPA IDENTIFICATION NUMBERS:

Tox. Chem. Number: 735
MRID Number: 420328-02

TEST MATERIAL: Silver zinc zeolite

SYNONYMS: None known or reported

SPONSOR: Kanebo Zeolite USA, Inc., 20th Floor, Empire State Building, 350 5th Ave., New York, NY

STUDY NUMBER: Arthur D. Little Reference Number 63613-19

TESTING FACILITY: Arthur D. Little, Inc., Acorn Park, Cambridge, MA

TITLE OF REPORT: Silver Zinc Zeolite Acute Inhalation Toxicity Study in Rats

AUTHOR: Bruce O. Stuart, Ph.D.

STUDY COMPLETED: 09/27/89

CONCLUSIONS: No mortalities were observed in any of the animals on test during the fourteen day observation period. Under the conditions of this study, the acute inhalation LC_{50} of silver zinc zeolite in Sprague-Dawley rats is expected to be greater than 1.43 mg/L.

TOXICITY CATEGORY: III

CLASSIFICATION: Core - Supplementary. This study may be upgraded upon the submission of the [illegible] stability of silver zinc zeolite used.

A. MATERIALS

1. Test Material

Test material: Silver zinc zeolite
Receipt: 06/13/89
Purity of material: Sponsor reported purity of 99%. The [illegible] stability of silver zinc zeolite used in this study were not reported.
Physical description: White powder
Active ingredient: Not reported
Inactive ingredient: Not reported
Lot number: Not reported
pH: Not reported

2. Controls

Materials: Not needed
Animals: Not needed

3. Test Animals

Species: Rats
Strain: Sprague-Dawley
Source: Taconic Farms, Germantown, NY
Receipt Date: Not reported
Sex: Male and female
Numbers: Five male, five female
Housing: Housed individually in suspended stainless steel cages with wire mesh bottoms. Animals were housed for a seven-day acclimation/quarantine period prior to initiation of study.
Age: Young adult
Weight: Day 1 mean $\pm$ SD, male, 323 $\pm$ 15.7 g; female, 202 $\pm$ 3.6 g
Day 1 range, male, 303-347 g; female 198-207 g
Weight variation did not exceed $\pm$20% of mean weight for each sex.
Feeding: Ad libitum Certified Purina® Rodent Chow® #5002 and Cambridge tap water for the duration of the study except during silver zinc zeolite exposure.
Assignment: Randomization
Location of raw data: Raw data is recorded in laboratory notebooks 24111 and 22628 retained by Arthur D. Little, Inc.

4. Exposure

Route of administration: Inhalation
Dose level: 1.43 mg/L

B. TEST PERFORMANCE

During the exposure period, the rats were in individual stainless steel cages within a 1.2 m^3 Hazleton-constructed New York University design, stainless steel chamber with a dynamic airflow of 12 changes per hour. Air entering the chamber during the exposure period was purified of particulate material and was supplied at a temperature of 24 °C and approximately 39% relative humidity. The airflow rate was regulated to a constant 240 L/min in the 1200 L chamber. Water was available at all times during the exposure period, but the food was removed and returned after exposure. After exposure, food and water were provided ad libitum during the 14 day observation period.

Particle size data are shown in Tables 1 and 2 and the summary of exposure conditions in Table 3. Silver zinc zeolite was generated into the chamber atmosphere using an NBS Dust Generator. The nominal test atmosphere concentration of 10.3 mg/L was calculated by dividing the total amount of test material used by the total amount of air supplied to the chamber. At a generator pressure of 30 psi, the average actual concentration of the test atmosphere was 1.43 mg/L; the highest that could be obtained under the conditions of the study. The average actual silver zinc zeolite atmospheric concentration was determined gravimetrically by measuring the change in weight of pre-weighed glass-fiber filters. The filters were collected at one hour intervals during the four hour exposure period from the breathing zones of the rats through samplers. Particle size analysis was determined during the second and fourth hour of exposure by drawing a measured volume of atmosphere through a seven-stage impactor collector and the change in weight of the stages determined.

The rats were observed for abnormal clinical signs after the 4 hour exposure period on Day 1 and daily thereafter for a total of 14 days. The observations were made at least 4 hours after the daily mortality checks and included changes in skin and fur, eyes and mucous membranes, respiratory, gastrointestinal and neuromuscular systems, and general behavior. The date of onset and the duration of all toxic signs were recorded. Body weights were recorded on Day 1 (day of exposure), Day 8 and Day 15 (date of necropsy). At necropsy, the animals were asphyxiated with CO_2, and the external surfaces, orifices and major organs of the cranial, thoracic and peritoneal cavities were examined. Because treatment with silver zinc zeolite did not cause death, statistics other than the determination of the mean and standard deviation of body weights on Days 1, 8, and 15 were not done.

C. RESULTS AND STUDY AUTHOR'S CONCLUSIONS

All rats appeared in good health and none died during the 14-day observation period. The most frequent clinical observations recorded within two days post-exposure included: discoloration around the ears, nose and mouth, wheezing, and nasal discharge. These treatment-related effects disappeared after two days and no others were recorded throughout the remainder of the observation period. No treatment-related effects were found at necropsy. Tables were included with the authors report that provide the clinical observations, body weights, and necropsy results of the study.

Because no mortalities were observed in any of the rats during the 14 day observation period, the author concluded that under the conditions of the study, the acute inhalation LC_{50} is greater than 1.43 mg/L, the highest attainable concentration of silver zinc zeolite.

D. REVIEWER'S COMMENTS

Based on the lack of mortality and the lack of grossly observable treatment-related signs of toxicity in tissues at necropsy, the study author correctly interpreted the test results. The acute inhalation LC_{50} of silver zinc zeolite in male and female rats is greater than 1.43 mg/L, which corresponds to a Toxicity Category of III. Silver zinc zeolite was tested at the highest obtainable concentrations under the conditions of this study. Because no data showing the stability of the test material was included, this study is classified supplementary. It may be upgraded upon the submission of these data.

E. COMPLIANCE

A signed and dated Quality Assurance Unit Statement was presented.
A signed and dated Good Laboratory Practice Statement was provided.

F. CBI APPENDIX

None presented.

TABLE 1: Silver Zinc Zeolite Particle Size Data - Hour 2

From Graphical Analysis
Particle Size Diameter (microns)
15.9% = 1.54
50% Mass Median Aerodynamic Diameter (MMAD) = 3.4
84.1% = 7.6
Geometric Standard Deviation[a] = 2.2
Particles Less than 1 micron = 7%
Impactor Flow Rate = 1.0 L/min

		Filter Weight (mg)				
Stage	ECD[b] (microns)	Pre-Test	Post-Test	Wt. Change	Cumulative Weight	Cumulative Percent
1	4.6	144.116	145.500	1.384	2.623	100
2	3.0	131.226	131.445	0.219	1.239	47.2
3	2.15	137.378	138.006	0.628	1.02	38.9
4	1.58	131.584	131.832	0.248	0.392	14.94
5	1.05	141.876	141.952	0.076	0.144	5.49
6	0.72	130.267	130.298	0.031	0.068	2.59
7	0.33	133.023	133.032	0.009	0.037	1.41
Filter		30.088	30.116	0.028	0.028	1.07

[a]Geometric Standard Deviation

$$\frac{84.1\% \text{ diameter}}{50.0\% \text{ diameter}}$$

$$\frac{50.0\% \text{ diameter}}{15.9\% \text{ diameter}}$$

[b]ECD - Effective Cut-off Diameter

TABLE 2: Silver Zinc Zeolite Particle Size Data - Hour 4

From Graphical Analysis
Particle Size Diameter (microns)
15.9% = 1.0
50% (MMAD) = 3.3
84.1% = 11.0
Geometric Standard Deviation[a] = 3.3
Particles Less than 1 micron = 16%
Impactor Flow Rate = 0.95 L/min

		Filter Weight (mg)				
Stage	ECD[b] (microns)	Pre-Test	Post-Test	Wt. Change	Cumulative Weight	Cumulative Percent
1	4.7	140.472	142.910	2.438	5.139	100
2	3.1	137.772	135.148	0.376	2.701	52.6
3	2.20	130.540	131.722	1.182	2.325	45.2
4	1.64	130.316	130.863	0.547	1.143	22.2
5	1.08	131.092	131.360	0.268	0.596	11.6
6	0.74	137.115	137.205	0.090	0.328	6.38
7	0.335	132.159	132.174	0.015	0.238	4.63
Filter		29.163	29.386	0.223	0.223	4.34

[a]Geometric Standard Deviation

$$\frac{84.1\% \text{ diameter}}{50.0\% \text{ diameter}}$$

$$\frac{50.0\% \text{ diameter}}{15.9\% \text{ diameter}}$$

[b]ECD - Effective Cut-off Diameter

TABLE 3: Summary of Exposure Conditions - Silver Zinc Zeolite

Nominal Concentration (mg/L)		10.3	
Actual Concentration (mg/L)			
Sample 1		1.20	
Sample 2		1.41	
Sample 3		1.44	
Sample 4		1.68	
Mean		1.43	
S.D.		0.20	
Generator Pressure (psi)		30	
Chamber Airflow Rate (L/min)		240	
Particle Size		Hour 2	Hour 4
MMAD (microns)		3.4	3.3
Geometric Standard Deviation		2.2	3.3
Less than 1 micron (%)		7	16
Chamber Conditions			
Initial Temperature	°C	24	
Final Temperature	°C	24	
Mean Temperature	°C	24 ± 0.0	
Temperature Range	°C	24 - 24	
Initial Relative Humidity	%	44	
Final Relative Humidity	%	38	
Mean Relative Humidity	%	39 ± 2.1	
Relative Humidity Range	%	37 - 44	
Initial Oxygen Content	%	20.9	
Final Oxygen Content	%	20.9	
Mean Oxygen Content	%	20.9 ± 0.0	
Oxygen Content Range	%	20.9 - 20.9	

Reviewed by: H. Tim Borges, Ph.D., MT(ASCP)
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Oak Ridge National Laboratory
Oak Ridge, TN 37831-6050

Secondary Reviewer: SanYvette Williams, D.V.M.
EPA/OPP/HED/TB-2/Sec. 4

DATA EVALUATION REPORT

STUDY TYPE: Acute Dermal Toxicity Study in Rabbits (81-2)

EPA IDENTIFICATION NUMBERS:

Tox. Chem. Number: 735
MRID Number: 420328-02

TEST MATERIAL: Silver zinc zeolite

SYNONYMS: None known or reported

SPONSOR: Kanebo Zeolite USA, Inc., 20th Floor, Empire State Building, 350 5th Ave., New York, NY

STUDY NUMBER: Arthur D. Little Reference Number 63613-06

TESTING FACILITY: Arthur D. Little, Inc., Acorn Park, Cambridge, MA

TITLE OF REPORT: Silver Zinc Zeolite Acute Dermal Toxicity Study in Rabbits

AUTHOR: C. Nicholas James, H.N.D.

STUDY COMPLETED: 10/03/89

CONCLUSIONS: No mortalities were observed in any of the animals on test during the fourteen day observation period. Under the conditions of this study, the acute dermal LD_{50} toxicity of silver zinc zeolite is expected to be greater than 5 g/kg.

TOXICITY CATEGORY: III

CLASSIFICATION: Core - Supplementary. This study may be upgraded upon the submission of the stability of silver zinc zeolite used.

A. MATERIALS

1. Test Material

Test material: Silver zinc zeolite
Receipt: 06/13/89
Purity of material: Sponsor reported purity of 99%. The stability of silver zinc zeolite used in this study were not reported.
Physical description: White powder
Active ingredient: Not reported
Inactive ingredient: Not reported
Lot number: Not reported
pH: Not reported

2. Controls

Materials: Not needed
Animals: Not needed

3. Test Animals

Species: Rabbits (SPF)
Strain: New Zealand White
Source: Hazleton Research Laboratories, PA
Receipt Date: Not reported
Sex: Male and female
Numbers: Five male, five female
Housing: Housed individually in suspended stainless steel cages with grid bottoms. Rabbits were housed for a seven-day acclimation/quarantine period prior to initiation of study.
Age: Young adult
Weight: Day -6 mean $\pm$ SD, male, 2.1$\pm$0.2 kg; female, 2.0$\pm$0.1 kg
Day -6 range, male, 1.9-2.3 kg; female, 1.9-2.1 kg
Day 1 mean $\pm$ SD, male, 2.3 $\pm$ 0.2 kg; female, 2.1 $\pm$ 0.1 kg
Day 1 range, male, 2.1-2.5 kg; female 2.0-2.1 kg
Feeding: Approximately six ounces/day Agway High Fiber Standard Rabbit Chow. Cambridge tap water provided ad libitum.
Assignment: Not reported
Location of raw data: Raw data is recorded in laboratory notebook #24121 retained by Arthur D. Little, Inc.

4. Exposure

Route of administration: Dermal
Dose level: 5000 mg/kg silver zinc zeolite moistened with 0.5% carboxymethyl cellulose

B. TEST PERFORMANCE

Depilation was done one day prior to the test by shaving an area on the dorsal trunk free of fur. Only rabbits with intact skin were used in the study. Silver zinc zeolite was moistened with 0.5% carboxymethyl cellulose to a concentration of 0.6 ml/g and mixed into a slurry. Each of the ten rabbits received a dose of 5000 mg/kg silver zinc zeolite applied evenly to a surgical gauze patch of approximately 10 × 13 cm. The patch was placed on the shaved portion of the rabbits back and wrapped with a strip of bandage, which in turn was held secure by an elastic tape. Twenty-four hours after application, the patches were removed and any excess silver zinc zeolite was removed using a dampened gauze pad containing 0.5% carboxymethyl cellulose.

The rabbits were observed each morning throughout the 14 day study for mortality and moribundity, except on Day 10. On Day 10, no recordings were made due to an oversight by the attending technician. According to the author, the oversight was not considered to have affected the integrity of the study. Clinical observations were made at least 4 hours after the daily mortality checks and included, but were not limited to, changes in skin and fur, eyes and mucous membranes, respiratory, gastrointestinal and neuromuscular systems, and general behavior. An untreated shaved area of skin served as the control for the observation of erythema and edema at the test chemical application site. The date of onset and the duration of all toxic signs were recorded. Body weights were recorded on Day -6, Day 1 (day of dosing), Day 8 and Day 15 (date of necropsy). A gross necropsy was done on all animals on Day 15 following intravenous injection of T-61 solution. The necropsy included examination of external surfaces, orifices and major organs of the thoracic and peritoneal cavities. The stomach and representative sections of the GI tract were opened for gross examination of treatment-related effects. Any grossly observable lesions at necropsy were recorded but not preserved. Because treatment with silver zinc zeolite did not cause death, statistics other than the determination of the mean and standard deviation of body weights on Days -6, 1, 8, and 15 were not done.

C. RESULTS AND STUDY AUTHOR'S CONCLUSIONS

No rabbits died during the study period. The only clinical observation recorded was a slight erythema of the treated skin of 2/5 male rabbits on Day 2 post-treatment. No other abnormal clinical signs were observed in any of the other male or female rabbits during the study period. All rabbits showed a slight increase in body weight by Day 14 of the observation period. Tables providing the incidence of clinical observation, body weights and necropsy results were provided with the report.

Because no mortalities were observed in any of the rabbits during the 14 day observation period, the author concluded that under the conditions of the study, the acute dermal LD_{50} of silver zinc zeolite is expected to be greater than 5 g/kg.

D. REVIEWER'S COMMENTS

Based on the lack of mortality, the lack of grossly observable treatment-related signs of toxicity in tissues at necropsy, and the lack of acute toxicity at the site of test application, the study author correctly interpreted the test results. The dermal LD_{50} of silver zinc zeolite in male and female rabbits is greater than 5000 mg/kg, which corresponds to a Toxicity Category of III. Silver zinc zeolite was tested for acute dermal toxicity at a concentration of 5000 mg/kg, a concentration above the EPA recommended dose level of at least 2000 mg/kg. Because no data showing the stability of the test material was included, this study is classified supplementary. It may be upgraded upon the submission of this data.

E. COMPLIANCE

A signed and dated Quality Assurance Unit Statement was presented.
A signed and dated Good Laboratory Practice Statement was provided.

F. CBI APPENDIX

None presented.

Reviewed by: H. Tim Borges, Ph.D., MT(ASCP)
Biomedical and Environmental Information Analysis Section
Health and Safety Research Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831-6050

Secondary Reviewer: SanYvette Williams, D.V.M. 10/19/93
EPA/OPP/HED/TB-2/Sec. 4

DATA EVALUATION REPORT

STUDY TYPE: Acute Oral Toxicity Study in Rats (81-1)

EPA IDENTIFICATION NUMBERS:

Tox. Chem. Number: 735
MRID Number: 420328-02

TEST MATERIAL: Silver zinc zeolite

SYNONYMS: None known or reported

SPONSOR: Kanebo Zeolite USA, Inc., 20th Floor, Empire State Building, 350 5th Ave., New York, NY

STUDY NUMBER: Arthur D. Little Reference Number 63613-03

TESTING FACILITY: Arthur D. Little, Inc., Acorn Park, Cambridge, MA

TITLE OF REPORT: Silver Zinc Zeolite Acute Oral Toxicity Study in Rats

AUTHOR: C. Nicholas James, H.N.D.

STUDY COMPLETED: 10/03/89

CONCLUSIONS: No mortalities were observed in any of the animals on test during the fourteen day observation period. Under the conditions of this study, the acute oral LD_{50} toxicity of silver zinc zeolite is expected to be greater than 5 g/kg.

TOXICITY CATEGORY: IV

CLASSIFICATION: Core - Supplementary. This study may be upgraded upon the submission of the stability of silver zinc zeolite used.

A. MATERIALS

1. Test Material

Test material: Silver zinc zeolite
Receipt: 06/13/89
Purity of material: Sponsor reported purity of 99%. The [illegible] stability of silver zinc zeolite used in this study were not reported.
Physical description: White powder
Active Ingredient: Not reported
Inactive Ingredient: Not reported
Lot number: Not reported
pH: Not reported

2. Controls

Materials: Not needed
Animals: Not needed

3. Test Animals

Species: Rats
Strain: Sprague-Dawley
Source: Taconic Farms, Germantown, PA
Receipt Date: Not reported
Sex: Male and female
Numbers: Five male, five female
Housing: Housed individually in suspended stainless steel cages with wire mesh bottoms. Animals were housed for a seven-day acclimation/quarantine period prior to initiation of study.
Age: Young adult
Weight: Day -7 mean ± SD, male, 229±4.5 g; female, 169±6.6 g
Day -7 range, male, 224-234 g; female, 163-179 g
Day 1 fasted body weight, mean ± SD, male, 242 ± 7.5 g; female, 172 ± 9.1 g
Day 1 fasted body weight range, male, 233-252 g; female 164-186 g
Weight variation did not exceed ±20% of mean weight for each sex.
Feeding: Ad libitum Certified Purina® Rodent Chow® #5002 and Cambridge tap water
Assignment: Animals randomly assigned to groups by computer generated randomization program.
Location of raw data: All raw data is recorded in laboratory notebook #24118 retained by Arthur D. Little, Inc.

4. Exposure

Route of administration: Gavage
Dose level: *5000 mg/kg silver zinc zeolite in 0.5% carboxymethyl cellulose*

B. TEST PERFORMANCE

Silver zinc zeolite was administered to five male and five female rats as a single 5000 mg/kg gavage dose in 0.5% carboxymethyl cellulose following an overnight fast. Prior to dosing on Day 1, the animals were weighed and the dose to be administered was calculated using a dose volume of 10 ml/kg body weight.

The rats were observed for abnormal clinical signs approximately 4 hours following dosing on Day 1 and daily thereafter for a total of 14 days. The observations were made at least 4 hours after the daily mortality checks and included changes in skin and fur, eyes and mucous membranes, respiratory, gastrointestinal and neuromuscular systems, and general behavior. The date of onset and the duration of all toxic signs were recorded. Body weights were recorded on Day -7, Day 1 (day of dosing), Day 8 and Day 15 (date of necropsy). A gross necropsy was done on all animals on Day 15 following asphyxiation with CO_2. The necropsy included examination of external surfaces, orifices and major organs of the thoracic and peritoneal cavities. The stomach and representative sections of the GI tract were opened for gross examination of treatment-related effects. Any grossly observable lesions at necropsy were recorded but not preserved. Because treatment with silver zinc zeolite did not cause death, statistics other than the determination of the mean and standard deviation of body weights on Days -7, 1, 8, and 15 were not done.

C. RESULTS AND STUDY AUTHOR'S CONCLUSIONS

No rats died during the limit test. Peri-nasal staining was observed in 4/5 male rats and 2/5 female rats. Diarrhea was observed in 1/5 male rats and 2/5 female rats. Urine stains were seen in 2/5 female rats. The author did not report whether these observations were related to treatment. No treatment-related findings were noted in any tissues on necropsy. Tables were provided for the incidence of clinical signs, necropsy results, and body weights for each rat included in the study. Body weight gains were reported on Days 8 and 15 following treatment. Tables were included in the report for the incidence of clinical signs, body weight and necropsy results.

Because no mortalities were observed in any of the rats during the 14 day observation period, the author concluded that under the conditions of the study, the acute oral LD_{50} of silver zinc zeolite is expected to be greater than 5 g/kg.

D. REVIEWER'S COMMENTS

Based on the lack of mortality and grossly observable treatment-related signs of toxicity in tissues at necropsy, the study author correctly interpreted the test results. The oral LD_{50} of silver zinc zeolite in male and female rats is greater than 5000 mg/kg, which corresponds to a Toxicity Category of IV. Based on EPA Guidelines, the test material was tested up to the required limit. Because no data showing the stability of the test material was included, this study is classified supplementary. It may be upgraded upon the submission of this data.

E. COMPLIANCE

A signed and dated Quality Assurance Unit Statement was presented.
A signed and dated Good Laboratory Practice Statement was provided.

F. CBI APPENDIX

None presented.

CONTAINS CBI APPENDIX

DP BARCODE : a. D157178 -R(1) b. D169928 -E

PC Code No.: a. 129057 b. 129103

Date Out of EFGWB: AUG 18 1993

TO: John Lee/Valdis Goncarovs
Product Manager #31
Registration Division (H7505C)

FROM: Akiva D. Abramovitch, Ph.D., Section Head
Environmental Chemistry Review Section #3
Environmental Fate and Ground Water Branch, EFED (H7507C)

THRU: Henry M. Jacoby, Chief
Environmental Fate and Ground Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of:

Reg./File #: a. 059824-R; b. 059824-E

Common Name: a. Silver-Copper Zeolite; CAS #130328-19-7
b. Silver-Zinc Zeolite; CAS #130328-20-0

Chemical Name: a. Aluminum Sodium Silicate, Silver-Copper Complex
b. Aluminum Sodium Silicate, Silver-Zinc Complex

Type product: Antimicrobial

Product Name: a. BACTEKILLER AC; b. BACTEKILLER AZ

Company Name: Kanebo Zeolite U.S.A., Inc.

Purpose: Review of data submitted for these products; Review label and other information submitted

Action Code: 116 EFGWB #: a. 91-0096 b. 92-0110 Total Reviewing Time: 8.0 days

EFGWB Guideline/MRID Summary Table: The review in this package contains:

		Acceptability of Study	Status of Data Requirement
161-1	41615816.....Ag-Cu Zeolite	Ancillary	Not Satisfied[1]
	42032805.....Ag-Zn Zeolite	Ancillary	Not Satisfied[1]
161-2	41615817.....Ag-Cu Zeolite	Unacceptable	Not Satisfied[2]
"163-1"	41615818.....Ag-Cu Zeolite	Ancillary	Not Satisfied[3]
"163-1"	42245401.....Ag-Cu Zeolite	Ancillary	Not Satisfied[3]

Revised label (2/12/93) for Ag-Zn Zeolite

[1] Required for INDOOR uses under NPDES permit (manufacturing use product)
[2] Required for OUTDOOR uses; [3] Required for treated commodities (such as polymeric matrices, paper, etc.).

1. CHEMICAL:

Common Name(s):

a. Silver-Copper Zeolite (PC #129057), "Ag-Cu Zeolite"
b. Silver-Zinc Zeolite (PC #129103), "Ag-Zn Zeolite"

Chemical Name(s):

The general chemical name(s) and CAS #s for these materials are

a. Aluminum sodium silicate, silver-copper complex; CAS #130328-10-7
b. Aluminum sodium silicate, silver-zinc complex; CAS #139328-20-0

Stoichiometry and Physical State:

a. "Ag-Cu Zeolite":

$(X_1Na_2O-X_2Ag_2O-X_3CuO)Al_2O_3-YSiO_2-ZH_2O$,

where X_2, X_2, X_3, Y and Z represent the number of each component in the zeolite structure.

Ag content by weight (anhydrous)..... 3.4%
Cu content by weight (anhydrous)..... 6.1%

Moisture content 20.7% (measured by Arthur D. Little, MA)

Physical state: Solid, powder
Color: Blue
Purity: 99%
Solubility: Not soluble
Melting Point: >2900 C
Density: 2.2 gcm^{-3} (Temperature not specified)
Solubility: "Almost insoluble" (< 5 ppb in water, alcohol, or polar and non-polar solvents)
pH of slurry in water: 9.0
Stability (storage): Maintains stability during storage up to a year.

b. "Ag-Zn Zeolite":

$(X_1Na_2O-X_2Ag_2O-X_3ZnO)-Al_2O_3-YSiO_2-ZH_2O$

where X_1, X_2, X_3, Y and Z represent the number of units of each component in the zeolite structure.

Ag content by weight (anhydrous)..... 3.6%
Zn content by weight (anhydrous)..... 6.1%

Moisture content 16.8% (measured by Arthur D. Little, MA)

Physical state: Solid, powder
Color: White
Purity: 99%
Melting Point: >2900 C
Density: 2.2 gcm^{-3} (Temperature not specified)
pH of slurry in water: 9.0
Stability (storage): Material maintains stability during storage up to a year.

2. STUDY/ACTION TYPE:

Review of data submitted towards registration of "Ag-Cu Zeolite" and "Ag-Zn Zeolite" for indoor uses. Determine status of data requirements for outdoor uses.

3. STUDY IDENTIFICATION:

a. "Ag-Cu Zeolite"

161-1 Hydrolysis (This is a release-from-the-matrix study)
- Harris, J.C. 1990. Release of Silver and Copper under Hydrolysis Conditions. Performed by Arthur D. Little, Cambridge, MA; ADL # 63614-02; Completed 8/3/90. Submitted by Kanebo Zeolite USA, Inc., New York, NY.
MRID #41615816

161-2 Photolysis in Water
- Harris, J.C. 1990. Release of Silver and Copper under Photolysis Conditions. Performed by Arthur D. Little, Cambridge, MA; ADL # 63614-03; Completed 8/3/90. Submitted by Kanebo Zeolite USA, Inc. New York, NY.
MRID #41615817

Special Study- Leaching from Impregnated Polymers (Not a 163-1 study)
- Harris, J.C. 1990. Leaching of Silver and Copper from Impregnated Polymers. Performed by Arthur D. Little, Inc., Cambridge, MA; Completed 7/30/90 (Draft) and 8/3/90 (Final):; ADL #63614-04; ADL MSS #63614-01. Submitted by Kanebo Zeolite USA, Inc., New York, NY.
MRID #41615818

"163-1": Leaching Study. This is not an actual 163-1 study, which requires the use of soils. This study should be classified as a 168-SS-1 study (that is, a special study) in which the release of Ag and Cu from different matrices were investigated.
- Loveday, K.S. 1992. Environmental Fate Data Leaching Study with Bactekiller AC. Performed by Arthur D. Little, Inc., Cambridge, MA; Completed 2/4/92. Submitted by Kanebo Zeolite USA, Inc., New York, NY.
MRID #42245401

b. "Ag-Zn Zeolite"

161-1 Hydrolysis
- Kryanos, J.N. 1991. Release of Silver and Zinc under Hydrolysis Conditions. Performed by Arthur D. Little, Cambridge, MA; ADL #66365-10; Completed 5/31/91. Submitted by Kanebo Zeolite USA, New York, NY.
  MRID #42032806

- Proposed Label "BACTEKILLER AZ"
  Received by EPA on 2/12/93

4. REVIEWED BY:

Silvia C. Termes, Ph.D.
Chemist, Review Section #3
OPP/EFED/EFGWB

Signature: [signature]
Date: August 18, 1993

5. APPROVED BY:

Akiva D. Abramovitch, Ph.D.
Section Head, Review Section #3
OPP/EFED/EFGWB

Signature: [signature]
Date: AUG 18 1993

6. CONCLUSIONS:

The reviewed studies in the submission were, in general, scientifically deficient. Specific defiencies for each of the studies are to be found in the Data Evaluation Records (DERs).

A. Manufacturing Use Product(s) versus "End-Use" Products

The "Hydrolysis" and "Photodegradation" studies apply to the "Ag-Cu Zeolite" and "Ag-Zn Zeolite" as manufacturing use products only. These materials are intended to be incorporated into other matrices (plastics, paints, papers, etc.). See BACKGROUND section, part a.

Further studies to support registration of the impregnated matrices may be required. Processes used to incorporate the "Ag-Cu Zeolite" or the "Ag-Zn Zeolite" into other matrices may significantly alter the rate of leaching of Ag, Cu and Zn. The only information on release from polymeric matrices available at this time is for the "Ag-Cu Zeolite" incorporated into polyester, polyester/cotton and polypropylene. Data are insufficient to evaluate the release of metal(s) and/or parent zeolite from impregnated materials .

B. Need for Better Characterization of the Manufacturing Use Product

A better characterization of the "Ag-Zeolite", "Ag-Cu Zeolite" and "Ag-Zn Zeolite" is needed. It is not clear from the data available at the Agency if the preparation of the Ag, Ag-Cu or Ag-Zn Zeolites (which involves ion exchange of sodium ions in the zeolite matrix with Ag^{+}, Cu^{2+} or Zn^{2+} ions) uses consistently the same zeolite matrix. That is, a natural zeolite or a synthetic zeolite and within these categories which specific zeolite.

The Branch believes that the registrant must clarify the consistency of the zeolite source and provide data on the variability of Ag, Ag-Cu, Ag-Zn distribution/concentration in the different zeolites if different zeolites are used as matrices. There are about 40 natural zeolites and about 150 synthetic zeolites. The rationale for EFGWB concern is presented under the BACKGROUND section, part b and was prepared by the EFGWB reviewer.

It should also be noted that fibrous erionite (a natural zeolite) has been classified by the USEPA as a Category B1 (possible human carcinogen) substance (FR 56 No. 214; Nov. 5, 1991; pp 56470-56472). Under section 5(a)[2] of TSCA, persons who intend to manufacture, import or process erionite fiber for any new use must notify the USEPA at least 90-days before beginning that activity.

In addition, the registrant must clarify the oxidation state of silver (i.e., Ag^{+} or Ag^{o}) in the manufacturing use "Silver Zeolites" as well as the oxidation state of copper (i.e., Cu^{+} or Cu^{2+}) in the "Ag-Cu Zeolite" manufacturing use products.

C. Clarification of Intended Uses

The registrant must clarify if the intended applications and Maximum Inhibitory Concentrations (MIC) of "Ag-Cu Zeolite" are the same as those indicated in the proposed label for "Ag-Zn Zeolite" received by the Agency on 2/12/93. A copy of this label is attached to the review.

D. Data Requirements (Manufacturing Use Products)

According to information from the Product Manager, the only use of these manufacturing use products at the present time is "Non-Food, INDOOR". The proposed label for the "Ag-Zn Zeolites" (manufacturing use product) carries a statement against discharge of unused material into natural bodies unless in accordance with an NPDES permit. It is not clear if a similar statement has been included for the "Ag-Cu Zeolite". Therefore, the Branch recommends that a similar statement be included in the label for the "Ag-Cu Zeolite", manufacturing use product.

The only data requirement for INDOOR uses under an NPDES permit is Hydrolysis (161-1). For both the "Ag-Cu Zeolite" and the "Ag-Zn Zeolite" "hydrolysis" studies have been submitted, which are actually release "rates" of Ag, Cu and Zn from the "Ag-Cu Zeolite" and the "Ag-Zn Zeolite" and not conventional 161-1 (Hydrolysis) studies (conventional hydrolysis

studies do not apply to these types of chemicals). The review of the studies (which were conducted in buffered systems) indicated that the data were, at the most, ANCILLARY. Multiple deficiencies were noted in these studies, which the registrant must address as indicated in Studies 1 and 4 reviews.

Data on the release of silver from the "Ag-Zeolite" may be required if this product is to be registered.

E. Data for Treated Products (Treated Polymeric Materials)- INDOORS

The submitted "leaching" of Ag and Cu from three polymeric materials treated with "Ag-Cu Zeolite" is not a conventional 163-1 (Mobility in Soil) study, but rather a release of metals from impregnated matrices.

The information provided by this study is limited. Data were only obtained with three treated polymeric matrices at a Maximum Inhibitory Concentration of 1.5% (dry basis). It is not clear at the present time if this is the maximum MIC intended for the "Ag-Cu Zeolite". In addition, the study does not address if "parent" Ag-Cu Zeolite also releases from the polymeric matrices.

No data for release of Ag and Zn and/or parent "Ag-Zn Zeolite" from impregnated materials are available.

For INDOOR registration of the "end-use products" (i.e., treated polymeric materials), the registrant must respond to EFGWB comments to Study 3. The registrant should provide data for other major impregnated materials.

Similar data to support registration of the "end-use products" (INDOOR uses) for the "Ag-Zn Zeolite" and "Ag-Zeolite" would be required.

F. Data Required for OUTDOOR Uses

It is not clear at this time if the registrant is seeking registration of Terrestrial or Aquatic OUTDOOR uses (or both). In any case, the Branch does not believe that typical Subdivision N guideline studies apply to these materials.

It is presumed that only the impregnated products will be used outdoors. However, as discussed in the CONCLUSIONS section in the review of "Study 1", the so-called "hydrolysis" studies ("Ag-Cu Zeolite" and "Ag-Zn Zeolite") do not realistically reflect environmental conditions because of the presence of buffer systems. The following approach is suggested by the Branch:

a. Conduct metal release studies ("Ag-Cu Zeolite"; "Ag-Zn Zeolite"; "Ag-Zeolite" in the absence of buffer systems, but incorporating metal ions that are ubiquitous in soils and natural waters (refer to Study 1 for details).

b. Conduct parallel studies with the polymeric materials impregnated with "Ag-Cu Zeolite", "Ag-Zn Zeolite" and "Ag-Zeolite" at the intended Maximum Inhibitory Concentration for each of the major impregnated materials.

c. Conduct photolysis studies at pH 5. The reviewed photolysis study (Ag-Cu Zeolite; pH 7) was considered unacceptable.

SUBMISSION OF PROTOCOLS FOR ALL OF THESE STUDIES IS STRONGLY RECOMMENDED.

G. Environmental Fate Assessment

As indicated earlier, the manufacturing use product(s) require an NPDES permit for discharge of unused material (at least for the "Ag-Zn Zeolite").

Although the short-term release of metals (Ag, Cu, Zn) from the zeolites appear to be below the concentration levels permitted by EPA in ambient waters (50 ug/L for Ag; 1000 ug/L for Cu), data are still insufficient to estimate long-term release. In addition, data on the release of metal and/or parent zeolite from polymeric materials or other materials to be impregnated by these zeolites are insufficient to assess the environmental impact of the treated commodities in outdoor environments.

7. RECOMMENDATIONS:

a. A better characterization of the parent material(s) should be requested from the registrant, as indicated in the CONCLUSIONS section.

b. All Data Evaluation Records should be made available to the registrant for response.

c. The registrant should clarify the present, intended uses for the "Ag-Cu Zeolite" and the "Ag-Zeolite".

d. The registrant should be informed of the status of data requirements for INDOOR uses (manufacturing use product(s); treated commodities) as explained in parts D and E of the CONCLUSIONS section.

e. The registrant should clarify the intended OUTDOOR uses of the treated commodities. The registrant should be informed of the approach suggested by EFGWB to generate data to satisfy data requirements for OUTDOOR uses. As indicated in part F of the CONCLUSIONS section, the registrant is strongly recommended to submit protocols for these special studies for approval by EFGWB prior to starting any of the studies.

8. BACKGROUND:

a. "Ag-Zeolite", "Ag-Cu Zeolite" and "Ag-Zn Zeolite" (type of zeolite not specified) are to be used as bacteria inhibitors in a variety of

treated commodities (mostly polymeric materials). The range of Maximum Inhibitory Concentration (MIC) on a dry basis of finished product is 0.75% to 2.0%. The zeolites will be incorporated (by different methods) into the desired commodity. Copies of the proposed labels for "Ag-Cu Zeolite" and "Ag-Zn Zeolite" appear in the appendix. The use pattern for the parent zeolite material is industrial/commercial indoors (non-food). The outdoor uses of the treated commodities are not well-defined at the present time.

b. GENERAL BACKGROUND ON ZEOLITES AND Ag-EXCHANGED ZEOLITES

Zeolite structures are based on tetrahedral networks of Si and Al coordinated to oxygen atoms and linked by corner-shared O^{2-} ions. This form an anionic lattice (framework) with charge-compensating cations (usually Na^+). The arrangement of atoms gives rise to channels and cavities (pores) in the framework structure. These channels and cavities vary in the different zeolites and influence the ion exchange capacity of the zeolite and the uptake/distribution of Ag, Cu or Zn ions the zeolite. The "leaching" of Ag, Cu or Zn ions from "Ag-Cu Zeolite" or "Ag-Zn Zeolite" could be affected by the distribution/crystallographic position of exchanged ions in the zeolite framework. In turn, the differences in sites of the exchanged ions can influence the strength of the sites towards adsorption (Boddenberg, B. and Waterman, J., "Site Blocking in Silver-exchanged Zeolite Y by Carbon Monoxide and Ethene Using Xenon Adsorption and ^{129}Xe NMR Spectroscopy", Chemical Physics Letters, Vol.203 (5-6), 1993, pp. 531-534; Baker, M.D. and Zhang, J. "Silver Ion Exchanged Zeolite Modified Electrodes: Observation of Electrochemically Distinct Silver Ions", Journal of Physical Chemistry, Vol.94, 1990, pp.87-3-8708).

There are evidences that Ag^+ ions can be reduced to Ag^0 (i.e, elemental silver) in silver-modified zeolites (for example, Blatter F. and Blazey, K.W., "Conduction Electron Spin Resonance of Silver Clusters in Zeolite AgY", Zeitschrift fur Physik D- Atoms, Molecules and Clusters, Vol.18, 1991, pp.427-429; Xu, B and Kevan, L., "Formation of Silver Ionic Clusters and Silver Metal Particles in Zeolite RHO Studied by Electron Spin Resonance and Far-Infrared Spectroscopies", Journal of Physical Chemistry, Vol.95. 1991, pp.1147-1151; Calzaferri, G., Suter, W. and Waldeck, B., "Reduction of Silver Cations in Silver Zeolites by Carbon Monoxide", Journal of the Chemical Society- Chemical Communications, 1990, pp. 485-487; Calzaferri, G., Hadener, K. and Li, J., "Quasi-reversible Silver Zeolite Electrode Prepared by Electrochemical Modification", Journal of the Chemical Society- Chemical Communications, 1991, pp. 653-654). These "zeolite-silver" clusters are believed to behave physically and chemically like the finely divided metal and thus, the properties of silver in these clusters would differ from those of bulk silver metal.

Molecular chlorine (Cl_2) evolution in Ag-zeolite ("Zeolite A") aqueous dispersions in the presence of chloride ions (Cl^-) has been observed upon irradiation at 370 nm. Chlorine evolution is pH-dependent and it is a maximum at about pH 4. As the pH was made alkaline, molecular oxygen (dioxygen; O_2) evolution prevailed. Chlorine and/or oxygen

evolution was observed to take place over the whole visible range (Calzaferri, G. and Spahni, W., "pH-Abhangigkeit der photochemischen Chlor- und Sauerstoffentwicklung in einer wassrigen chlorihaltigen Silberzeolith-Dispersion", Chimia, Vol.40 (12), 1986, pp 435-436).

The electronic structure and the chemical and physical properties of Cu and Ag-exchanged zeolites is expected to depend significantly on the metal concentration in the zeolite. Reversible color changes have been observed in these zeolites upon hydration-dehydration (Calzaferri, G. and Forss, L., "Copper and Silver Atoms in the Beta-Cage of a Zeolite: Model Calculations", Helvetica Chimica Acta, Vol.70, 1987, pp.465-479).

Physical and Chemical Properties and Characterization of Zeolites

i. Natural and Synthetic Zeolites- Chabazite, mordenite, and faujisite are common naturally occurring zeolites. Some naturally occurring zeolites form minable deposits of relatively high purity. Of the 41 to 43 natural zeolites, there are corresponding 25-26 framework structures.

Among the synthetic zeolites, "Zeolite A" ("Linde A") is one of the most widely used commercially although zeolites X, Y and ZSM-5 are also used extensively. These synthetic zeolites do not have a mineral counterpart.

ii. Uses of Zeolites

Three major areas of application can be identified based on the type of physical/chemical phenomenon involved:

(a) Adsorption- molecular sieves; selective separations; cryosorption;
(b) Ion Exchange- removal of NH_4^+; separation of metals; removal of metals from waste waters; detergent builders; radioisotope removal and storage
(c) Catalysis- hydrocarbon conversion; hydrogenation/dehydrogenation; methanation; dehydration; inorganic reactions.

The major factors determining the commercial use of zeolites are: (a) structural chemistry; (b) availability; (c) cost.

The structural characteristics of a zeolite determine or control the intended application. These include: (a) Framework, topology and composition; (b) Size of internal voids and channels; (c) Cation exchange properties; (d) Particle size and morphology; (e) Structural stability in hostile environments; (f) Structural defects.

iii. Characterization

Zeolite characterization (and methods frequently used) can be summarized as follows,

(a) Chemical Composition- Atomic absorption (AA); Inductively Coupled Plasma (ICP); Solid state nmr (^{29}Si) for low Si/Al zeolites;

Fast atom bombardment mass spectrometry (FARMS); X-ray photoelectron spectroscopy (XPS).

(b) Structural Determination- X-ray diffraction (XRD); Electron diffraction (ED); Neutron diffraction (ND); Tunneling electron microscopy; Infrared spectroscopy (IR).

(c) Acidity/Basicity Identification- Several methods are used to characterize the acidic or basic sites in zeolites, such as titration in aprotic solutions, thermochemical indicators, IR-spectroscopy, UV-VIS spectroscopy, high-resolution nmr, electron spin resonance (esr), microcalorimetry, desorption of suitable probe molecules, etc.

(d) Characterization of Modified Zeolites- Among the many modifications that can be made in zeolites, ion exchange is an important one. It is thus important to determine the framework of the ion-exchanged product. In the case of Ag-exchanged zeolites, reduction of silver ions to silver metal (elemental silver) can lead to metal particles occupying secondary pore structures and, therefore, the nature, size and location of the metal clusters must be known. ^{129}Xe nmr has been used for this purpose.

(e) Characterization of Defect Groups and Secondary Pore Structures- Defects and secondary pore structures tend to be prevalent in many synthetic zeolites.

References

Karge, H.G. and Nagy, J.B. "Characterization of Structural and Physico-Chemical Properties of Zeolitic Systems", chapter in Guidelines for Mastering the Properties of Molecular Sieves- Relationships between the Physicochemical Properties of Zeolitic Systems and Their Low Dimensionality; Edited by D. Barthomeuf, E.G. Derouane and W. Holderich NATO Advanced Research Workshop, France 1989. Plenum Press, New York.

Breck, D.W. "Potential Uses of Natural and Synthetic Zeolites in Industry", chapter in The Properties and Applications of Zeolites, Proceedings of a Conference organized jointly by the Inorganic Chemicals Group of The Chemical Society and The Society of Chemical Industry and held at The City University, London, April 18-20, 1979; R.P. Townsend, Editor. Published by The Chemical Society, London.

Proceedings of the Sixth International ZEOLITE Conference (Reno, NV; July 10-15, 1983). Edited by D. Olson and A. Bisio; Published by Butterworths, Surrey, UK (1984).

Zeolites and Clay Minerals as Sorbents and Molecular Sieves. Edited by R.M. Barber; Published by Academic Press, Inc., New York, NY (1978).

Intrazeolite Chemistry. Edited by G.D. Stucky and F.G. Dwyer; ACS Symposium Series 218; Published by the American Chemical Society, Washington, D.C. (1983).

9. DISCUSSION OF INDIVIDUAL STUDIES: Four studies were reviewed; refer to the Data Evaluation Records for each of these studies.

10. COMPLETION OF ONE-LINER: A "One-Liner" has been initiated for the "Ag-Cu Zeolite" and the "Ag-Zn Zeolite".

11. CBI APPENDIX: A CBI Appendix is attached to this review. The Appendix contains copies of the proposed labels. The reviews of the studies (DERs) are not considered CBI.

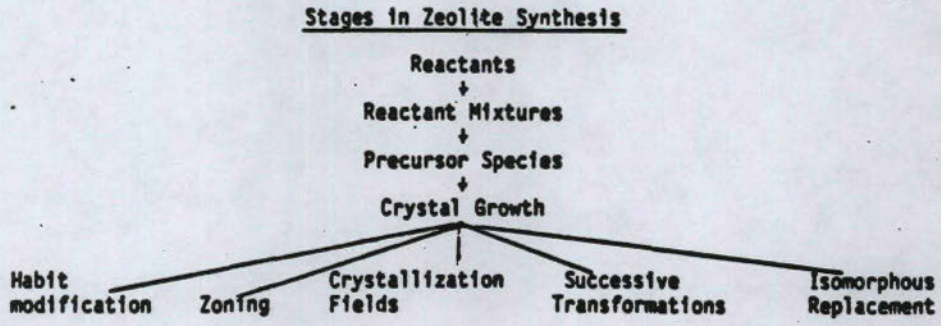
Proceeding of the Sixth ZEOLITE Conference

Table 1.

NATURAL ZEOLITES

Group (SBU)	Structure type*	Name	Typical unit cell content	Space-group	Approx. max. channel width (Å)	Sedimentary occurrence
S4R	PHI	Phillipsite	$K_2Ca_{1.5}Na\ Al_6Si_{10}O_{32} \cdot 12H_2O$	$P2_1/m$	3.9 x 4.4	x
	PHI	Harmotome	$Ba_2Ca_{0.5}\ Al_5Si_{11}O_{32} \cdot 12H_2O$	$P2_1/m$	3.9 x 4.4	x
	MER	Merlinoite	$K_5Ca_2\ Al_9Si_{23}O_{64} \cdot 24H_2O$	Immm	3.3 x 5.0	
	GIS	Gismondine	$Ca_4\ Al_8Si_8O_{32} \cdot 16H_2O$	$P2_1/a$	2.8 x 4.9	
	GIS	Amicite	$K_4Na_4\ Al_8Si_8O_{32} \cdot 10H_2O$	I2	3.1 x 3.8	
	GIS	Garronite	$NaCa_{2.5}\ Al_6Si_{10}O_{32} \cdot 14H_2O$	$I4_1/amd$	3.5	
	GIS	Gobbinsite	$Na_4(Ca,Mg,K_2)\ Al_6Si_{10}O_{32} \cdot 12H_2O$	$P4_22_12$ (?)	?	
	ANA	Analcime	$Na_{16}Al_{16}Si_{32}O_{96} \cdot 16H_2O$	Ia3d	2.2	x
	ANA	Wairakite	$Ca_8Al_{16}Si_{32}O_{96} \cdot 16H_2O$	I2/a	2.2	
	PAU	Paulingite	$(K_2,Na_2,Ca,Ba)_{76}\ Al_{152}Si_{520}O_{1344} \cdot 700H_2O$	Im3m	3.9	
	LAU	Laumontite	$Ca_4\ Al_8Si_{16}O_{48} \cdot 16H_2O$	C2/m	4.6 x 6.3	x
	YUG	Yugawaralite	$Ca_2\ Al_4Si_{12}O_{32} \cdot 8H_2O$	Pc	2.8 x 3.6	x
D6R	CHA	Chabazite	$Ca_2\ Al_4Si_8O_{24} \cdot 13H_2O$	$R\bar{3}m$	3.7 x 4.2	x
	CHA	Willhendersonite	$KCa\ Al_3Si_3O_{12} \cdot 4.5H_2O$	$P\bar{1}$	3.7 x 4.2 (?)	
	GME	Gmelinite	$Na_8\ Al_8Si_{16}O_{48} \cdot 24H_2O$	$P6_3/mmc$	7.0	
	FAU	Faujasite	$Na_{12}Ca_{12}Mg_{11}\ Al_{58}Si_{134}O_{384} \cdot 235H_2O$	Fd3m	7.4	
S6R	ERI	Erionite	$Na_2K_2Mg_{0.5}Ca_2\ Al_9Si_{27}O_{72} \cdot 27H_2O$	$P6_3/mmc$	3.6 x 5.2	x
	OFF	Offretite	$KCa_2\ Al_5Si_{13}O_{36} \cdot 15H_2O$	$P\bar{6}m2$	6.9	x
	LEV	Levyne	$NaCa_3\ Al_7Si_{11}O_{36} \cdot 18H_2O$	$R\bar{3}m$	3.2 x 5.1	
	MAZ	Mazzite	$Mg_2K_2Ca_{1.5}\ Al_9Si_{27}O_{72} \cdot 28H_2O$	$P6_3/mmc$	7.4	
4-1	NAT	Natrolite	$Na_{16}\ Al_{16}Si_{24}O_{80} \cdot 16H_2O$	Fdd2	2.6 x 3.9	x
	NAT	Tetranatrolite	$Na_{16}\ Al_{16}Si_{24}O_{80} \cdot 16H_2O$	$I\bar{4}2d$	2.6 x 3.9 (?)	
	NAT	Paranatrolite	$Na_{16}\ Al_{16}Si_{24}O_{80} \cdot 24H_2O$	F***	2.6 x 3.9 (?)	
	NAT	Mesolite	$Na_{16}Ca_{16}\ Al_{48}Si_{72}O_{240} \cdot 64H_2O$	Fdd2	2.6 x 3.9	x
	NAT	Scolecite	$Ca_8\ Al_{16}Si_{24}O_{80} \cdot 24H_2O$	Fidl	2.6 x 3.9	
	THO	Thomsonite	$Na_4Ca_8\ Al_{20}Si_{20}O_{80} \cdot 24H_2O$	Pncn	2.6 x 3.9	x
	THO	Gonnardite	$Na_4Ca_2\ Al_8Si_{12}O_{40} \cdot 14H_2O$	Pbmn (?)	2.6 x 3.9 (?)	
	EDI	Edingtonite	$Ba_2\ Al_4Si_6O_{20} \cdot 8H_2O$	$P2_12_12$	3.1 x 4.1	
5-1	MOR	Mordenite	$Na_8\ Al_8Si_{40}O_{96} \cdot 24H_2O$	Cmcm	6.7 x 7.0	x
	DAC	Dachiardite	$Na_5\ Al_5Si_{19}O_{48} \cdot 12H_2O$	C2/m	3.7 x 6.7	
	EPI	Epistilbite	$Ca_3\ Al_6Si_{18}O_{48} \cdot 16H_2O$	C2/m	3.2 x 5.3	
	FER	Ferrierite	$Na_{1.5}Mg_2\ Al_{5.5}Si_{30.5}O_{72} \cdot 18H_2O$	Immm	4.3 x 5.5	x
	BIK	Bikitaite	$Li_2\ Al_2Si_4O_{12} \cdot 2H_2O$	$P2_1$	3.2 x 4.9	
4-4-1	HEU	Heulandite	$Ca_4\ Al_8Si_{28}O_{72} \cdot 24H_2O$	C2/m	4.4 x 7.2	x
	HEU	Clinoptilolite	$Na_6\ Al_6Si_{30}O_{72} \cdot 24H_2O$	C2/m	4.4 x 7.2	x
	STI	Stilbite	$Na_2Ca_4\ Al_{10}Si_{26}O_{72} \cdot 34H_2O$	F12/m1	4.1 x 6.2	x
	STI	Stellerite	$Ca_8\ Al_{16}Si_{56}O_{144} \cdot 56H_2O$	Fmmm	4.1 x 6.2	
	STI	Barrerite	$Na_{16}\ Al_{16}Si_{56}O_{144} \cdot 52H_2O$	Amma	4.1 x 6.2	
	BRE	Brewsterite	$Sr_2\ Al_4Si_{12}O_{32} \cdot 10H_2O$	$P2_1/m$	2.3 x 5.0	
Unknown		Cowlesite	$Ca\ Al_2Si_3O_{10} \cdot 6H_2O$	?	?	
Structure		Goosecreekite	$Ca_2\ Al_4Si_{12}O_{32} \cdot 10H_2O$	$P2_1/m$	?	

* Structure type codes follow the recommendations by the International Union for Pure and Applied Chemistry (IUPAC), 1978



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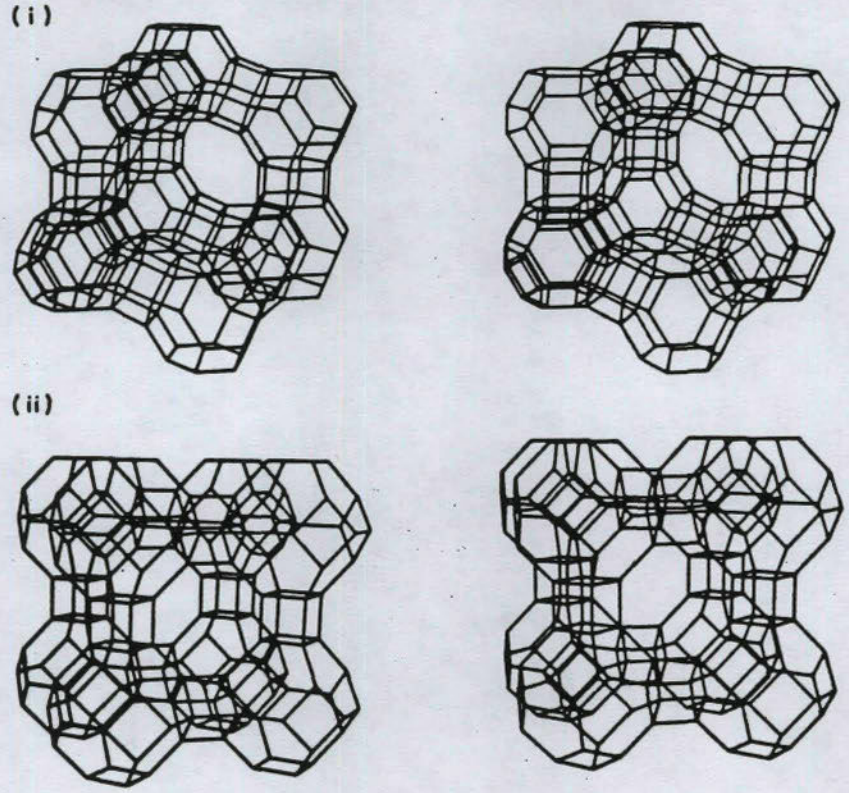

FIG. 7. The framework structures of (i) faujasite, viewed along [111] and (ii) zeolite *A* viewed along [100], shown as stereoscopic pairs.[4]

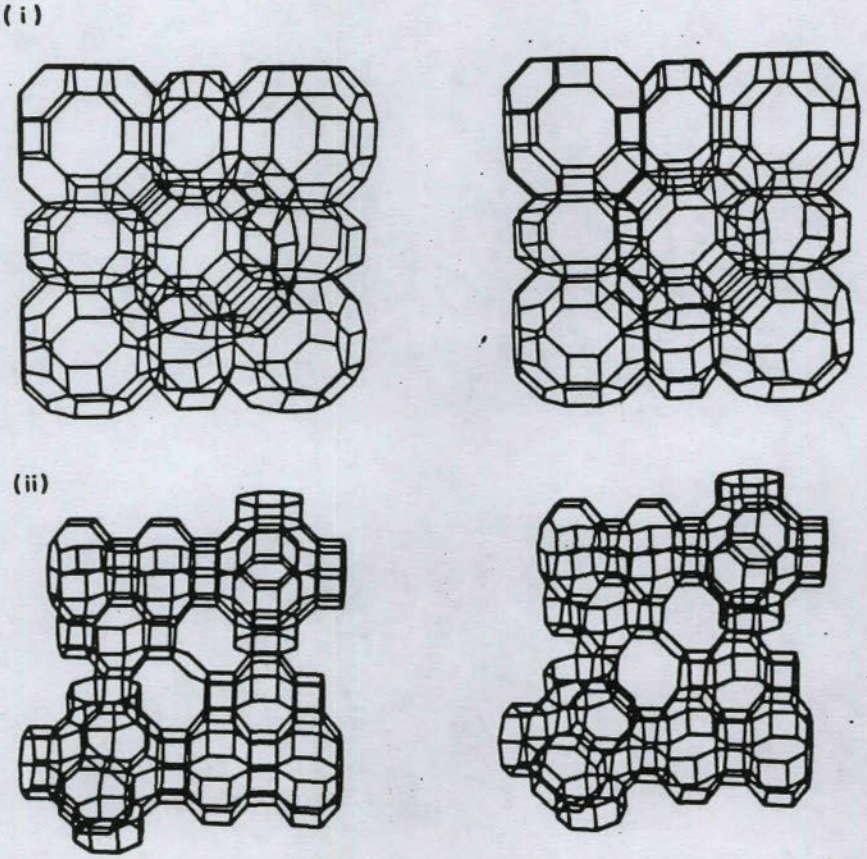

FIG. 6. The framework structures of (i) zeolite *ZK-5* viewed along [100] and (ii) paulingite viewed along [100], shown as stereoscopic pairs.[4]

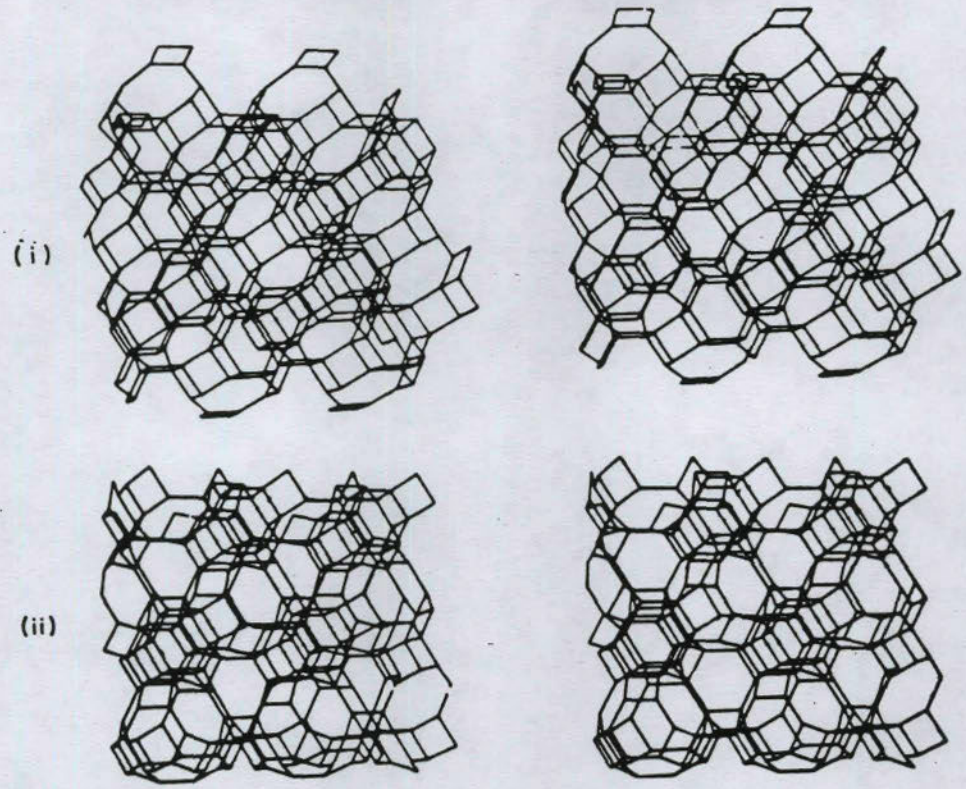

FIG. 8. Examples of frameworks chosen from the chabazite group all viewed along [001]: (i) chabazite; (ii) erionite; (iii) offretite; and (iv) zeolite *L*.[4]

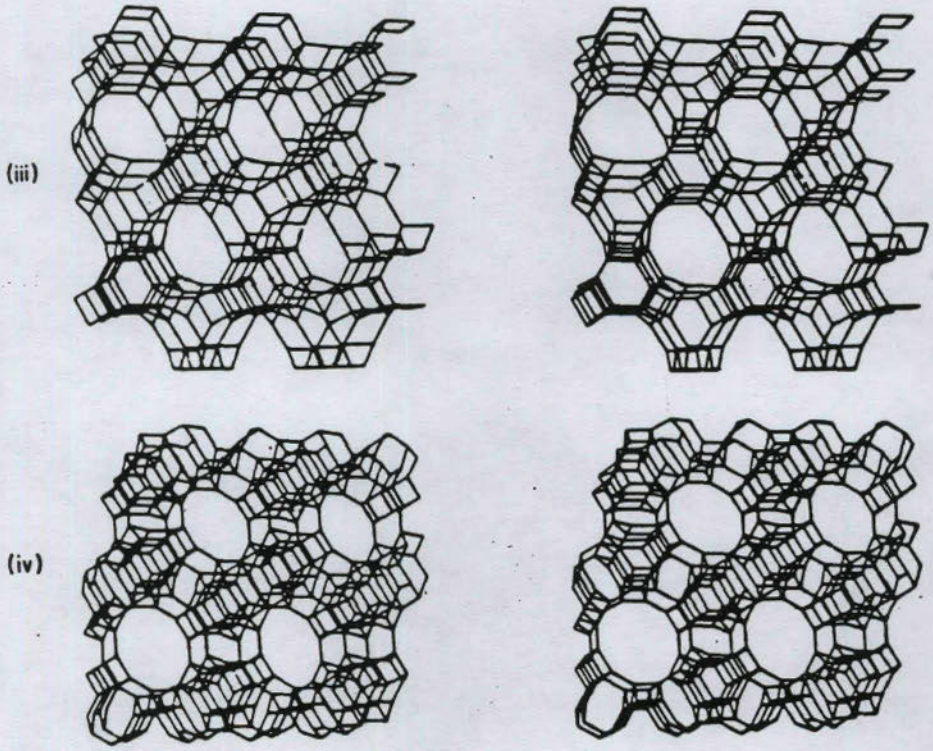

FIG. 8—*contd.*

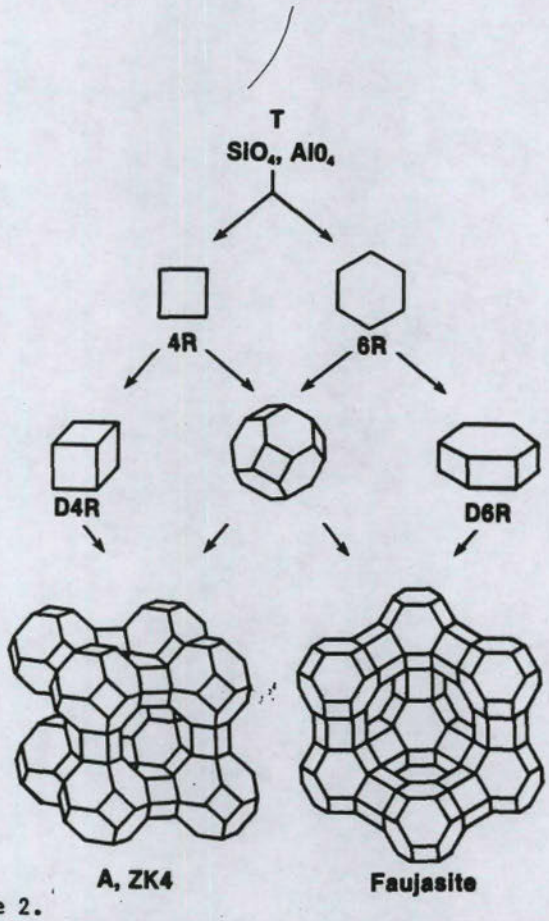

Figure 2.
Possible pathways for the formation of faujasite and A-type zeolites from SiO_4 and AlO_4 tetrahedra.

Intrazeolite Chemistry, ACS.

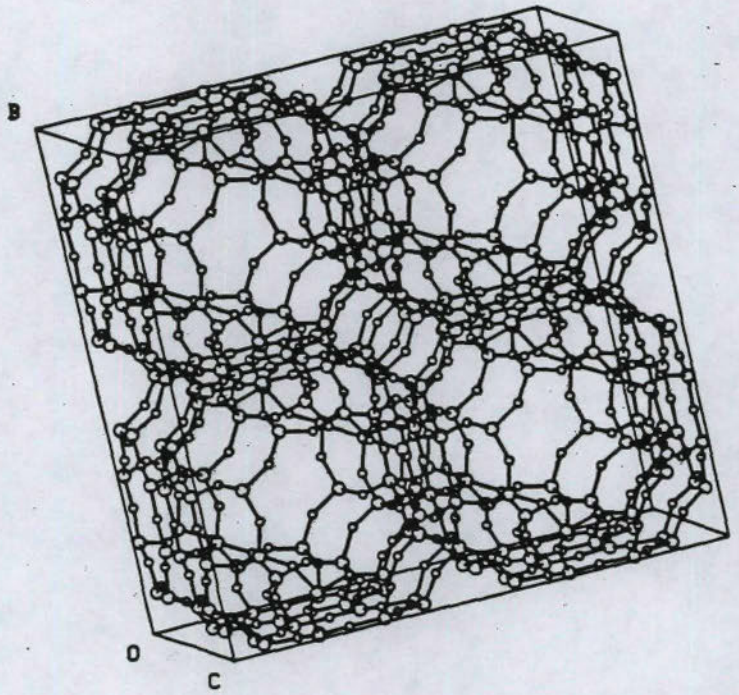

Figure 1.
The cubic (a ∿12.3 Å) sub-cell of zeolite-A; Si(Al) and oxygen atoms are shown as large and small spheres, respectively.

Intrazeolite chemistry, ACS

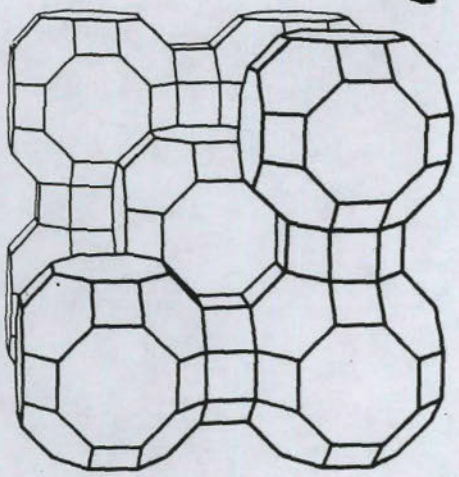

Figure 1. The framework structure of zeolite rho with full Im3m symmetry. Vertices correspond to (Si,Al) atoms.

Effect of temperature on the framework structure of zeolite rho

(Proceedings of the Sixth ZEOLITE Conference)

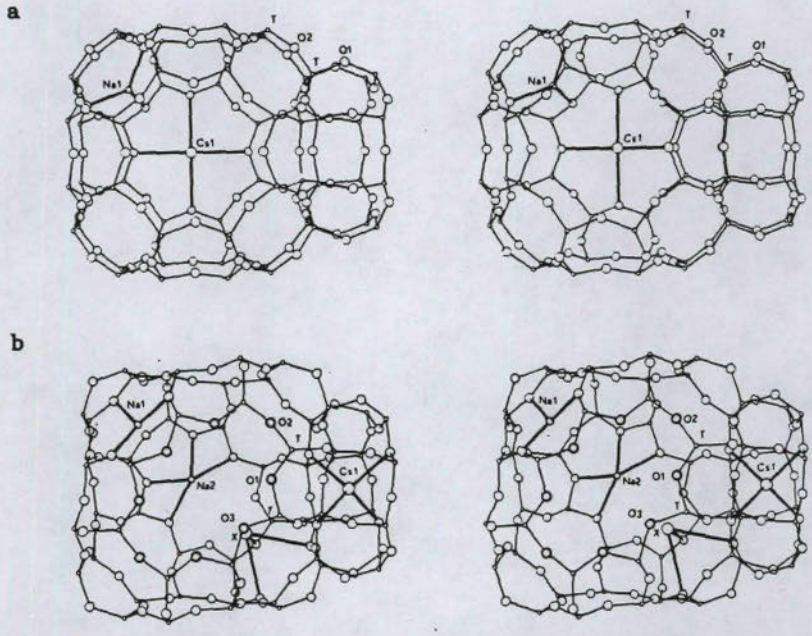

Figure 4. Stereo views[19] of the framework structures and cation sites of a)hydrated zeolite rho, and b) zeolite rho at 100°C. The oxygens of one 8-ring in the 100°C structure have been shaded to highlight the framework distortion. T = (Si,Al).

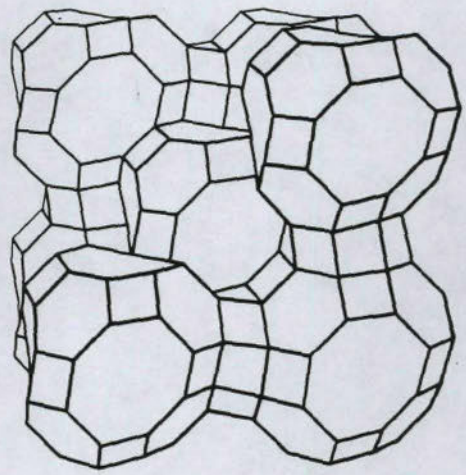

Figure 5. The framework structure of zeolite rho at 100°C with I43m symmetry. Vertices correspond to (Si,Al) atoms.

Table 1 - Discovery and/or Initial Commercial Investigations of Prominent Zeolite Deposits in the United States (1).

Deposit/ Occurrence	Zeolite	Discoverer or Initial Investigator and Affiliation	Date
ALABAMA			
Campbell	Clinoptilolite	W. R. Reynolds (2), Florida State University	1965
ARIZONA			
Bowie	Chabazite Erionite Clinoptilolite	K. G. Bell, Kennedy Minerals Company P. E. Galli, Union Carbide Corporation	1959
Dripping Springs Valley (Christmas)	Chabazite	T. H. Eyde, Union Carbide Corporation	1961
Horseshoe Dam	Clinoptilolite	T. H. Eyde, Union Carbide Corporation	1961
Union Pass	Mordenite	H. M. Wharton, Union Carbide Corporation	1960
Wellton	Clinoptilolite	T. H. Eyde, Union Carbide Corporation	1962
Wikieup	Analcime	C. S. Ross (3), U. S. Geological Survey	1928
	Clinoptilolite Phillipsite	P. E. Galli, Union Carbide Corporation H. M. Wharton, Union Carbide Corporation	1958 1959
CALIFORNIA			
Barstow (Rainbow Basin)	Analcime	C. J. Mankin, University of Southern California	1959
	Clinoptilolite Phillipsite	H. M. Wharton, Union Carbide Corporation	1959
Death Valley Junction	Clinoptilolite	H. D. Curry, Anaconda Minerals Company	1973
Hector	Clinoptilolite	L. L. Ames (4), Jr., University of Utah L. B. Sand, University of Utah R. H. Olson, Union Carbide Corporation H. M. Wharton, Union Carbide Corporation	1957 1958
Shoeshone (Lake Tecopa)	Clinoptilolite Erionite Phillipsite Analcime	K. G. Bell, Kennedy Minerals Company P. E. Galli, Union Carbide Corporation	1959
COLORADO			
Creede	Clinoptilolite	T. A. Steven (5), U. S. Geological Survey Delmar Brown, Colorado Lien Company	1970 1977

IDAHO			
Castle Creek	Clinoptilolite	T. H. Eyde, Union Caride Corporation	1961
NEVADA			
Ash Meadows	Clinoptilolite	H. M. Wharton, Union Carbide Corporation	1960
Eastgate	Erionite	P. E. Galli, Union Carbide Corporation	1958
	Mordenite	H. D. Curry, Shell Development Company	1962
Fish Creek Mountains	Clinoptilolite	K. S. Deffeyes (6), Princeton University R. H. Olson, Union Carbide Corporation F. A. Mumpton, Union Carbide Corporation	1957 1958
Hungry Valley	Chabazite Clinoptilolite	P. E. Galli, Union Carbide Corporation	1960
Jersey Valley	Erionite	K. S. Deffeyes (7), Princeton University R. H. Olson, Union Carbide Corporation F. A. Mumpton, Union Carbide Corporation	1957 1958
Lovelock	Mordenite Clinoptilolite	P. E. Galli, Union Carbide Corporation	1959
	Ferrierite	L. B. Sand (8) Norton Company A. J. Regis, Norton Company	1966
Pine Valley	Erionite	Jerome Regnier (9), Columbia University R. H. Olson, Union Carbide Corporation W. T. Kohler, Union Carbide Corporation	1957 1958
Pine Valley (Clay Mounds)	Phillipsite	Jerome Regnier (9), Columbia University R. H. Olson, Union Carbide Corporation F. A. Mumpton, Union Carbide Corporation	1957 1958
Reese River Valley	Erionite Clinoptilolite	K. S. Deffeyes (7) Princeton University R. H. Olson, Union Carbide Corporation	1957 1958
	Chabazite	F. A. Mumpton, Union Carbide Corporation H. M. Wharton, Union Carbide Corporation	1958 1959
NEW MEXICO			
Buckhorn	Clinoptilolite	T. H. Eyde, Union Carbide Corporation	1962
OREGON			
Durkee	Erionite Clinoptilolite Chabazite	F. A. Mumpton, Union Carbide Corporation R. H. Olson, Union Carbide Corporation R. A. Sheppard (10), U. S. Geological Survey A. J. Gude, 3rd, U. S. Geological Survey	1958 1970
Harney Lake (Narrows)	Clinoptilolite Erionite Mordenite	H. M. Wharton, Union Carbide Corporation	1959

Rome

Sheaville

SOUTH DAKOT

Pine Ridge Reservation

TEXAS

Marfa

Tilden

UTAH

Cove Fort

WYOMING

Beaver Divid

Fort LeClede (Washakie Basin)

REFERENCES

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Rome	Erionite	K. G. Bell, Kennedy Minerals Company	1957
		R. H. Olson, Union Carbide Corporation	1958
	Mordenite	H. D. Curry, Shell Development Company	1962
Sheaville	Clinoptilolite	R. H. Olson, Union Carbide Corporation	1958
SOUTH DAKOTA			
Pine Ridge Reservation	Clinoptilolite	K. S. Deffeyes (7), Princeton University	1958
		L. G. Schultz (11), U. S. Geological Survey	1961
TEXAS			
Marfa	Clinoptilolite	T. H. Eyde, Union Carbide Corporation	1962
Tilden	Clinoptilolite	D. H. Eargle (12), U. S. Geological Survey	1964
UTAH			
Cove Fort	Clinoptilolite	R. A. Sheppard, U. S. Geological Survey	1972
		A. J. Gude, 3rd, U. S. Geological Survey	
		T. A. Steven (13), U. S. Geological Survey	1979
		Gordon Ford, Fominco	1980
WYOMING			
Beaver Divide	Clinoptilolite	F. B. Van Houten (14), Princeton University	1957
	Erionite	R. H. Olson, Union Carbide Corporation	1958
	Chabazite	J. R. Boles (15), University of Wyoming	1966
Fort LeClede (Washakie Basin)	Clinoptilolite	H. W. Roehler (16), U. S. Geological Survey	1973
		T. I. Sharps, Rocky Mountain Energy Company	1977

REFERENCES

1. "Discovery" is herein defined as the act of identifying zeolite minerals in volcanoclastic sedimentary formations in the area in question and, for geologists employed in the public sector, announcing these data in such a manner so as to lead to eventual commercial examination and/or exploitation. "Initial Commercial Investigation" is herein defined as the first examination of known zeolitic formations in the area in question by a commercial organization, whether or not the area was exploited further by aquisition of mining rights or by mining. Thus, the original identification of chabazite in the Bowie area by Loew (1876) is not included because it played no role in the later discovery or examination of this area for zeolites. Moreover, despite the fact that the extensive nature of the clinoptilolite in the Barstow Formation was first reported by Sheppard and Gude (1969) and led Occidental Minerals Company to claim the area in 1974,

DATA EVALUATION RECORD

Chemical Code 129103 STUDY 4

CHEM "Ag-Zn Zeolite"

Kyranos, J.N. 1991. Release of Silver and Zinc under Hydrolysis Conditions. Performed by Arthur D. Little, Cambridge, MA; ADL #66365-10; Completed 5/31/91. Submitted by Kanebo Zeolite USA, Inc., New York, NY.
MRID #42032806

REVIEWED BY: S.C. Termes, Chemist
Review Section #3
OPP/EFED/EFGWB
(703) 305-5243

August 18, 1993

CONCLUSIONS

This study provides only ANCILLARY information at this time. There was apparent contamination of samples by zinc.

As indicated in the review of the "Ag-Cu Zeolite" (Study 1; MRID #41613816), the registrant must clarify which type of zeolite is used for exhange by silver and zinc. In addition, the oxidation state of silver in the parent "Ag-Zn Zeolite" must be clarified.

The registrant did not present the predominance of Ag and Zn species in the buffer systems used in the study. The data must be presented for both the the spiked solutions and the test solutions (refer to comments in Study 1).

For registration of potential OUTDOOR uses, refer to the "CONCLUSIONS" section in Study 1.

Scientific Conclusions

The data presented in this study are of uncertain value (apparent contamination of samples by zinc). As with the "Ag-Cu Zeolite", the release of Ag and Zn appears to decrease with increasing pH. However, it appears that less Ag is released from "Ag-Zn Zeolite" than from the "Ag-Cu Zeolite".

MATERIALS AND METHODS

Test Material: A "Ag-Zn Zeolite" provided by registrant (zeolite type not specified) containing 3.6% Ag and 6.1% Zn by weight (anhydrous). The moisture content measured was measured by the performing laboratory as 16.8%.

Test System: The test sytem(s) consisted of 40-mL amber glass vials fitted with screww caps and Teflon-faced septa.

Each vial contained 30-50 mg sample of the "Ag-Zn Zeolite" and 30 mL of the desired buffer system (pH 5= acetate buffer; pH 7=

phosphate buffer; pH 9= borate buffer). The ratio of zeolite to buffer was about 1 mL/mg.

Vials were placed in a temperature controlled chamber (25±1 C) and protected from light. Samples were agitated with a magnetic stirrer.

The initial pH of the hydrolysis medium was measured with pH paper.

Control Samples: Negative (neat buffer solutions) and positive (buffer with Ag^{+} or Zn^{2+} nominal concentrations of 100 ppb and 50 ppb, respectively) were used. Initial spiked solutions contained both Ag and Zn, but the standard zinc solution (which was in 2% HCl) seemed to have affected the "recovery" of silver.

Sampling Times: 0, 2, 4, 8, 16, 24, and 30 days.

Analytical Methodology: After removal from vial, hydrolysates were passed through 0.45 ug Teflon filters to ensure that only dissolved silver and copper were measured; filtrates were stabilized with nitric acid and stored at 4 C prior to analysis.

Hydrolysates and negative and positive standards were analyzed by Inductively Coupled Argon Plasma (ICAP). Calibration curves and calculated sample concentrations were based on the average area of the ICP peak signal for three sequential aspirations.

All release data ws corrected to unit weight of zeolite powder,

$$ug/mL = \frac{ppb(ug/L) \times 0.030L \text{ (hydrolysate volume)}}{\text{Weight of zeolite present}}$$

REPORTED RESULTS:

The release rates of Ag and Zn and % release at 30 days can be summarized as follows,

	pH 5		pH 7		pH 9	
	Ag	Zn	Ag	Zn	Ag	Zn
Release Rate (ug/mg zeolite/day)	0.029	0.082	0.19	0.29	0.0047	0.030
% of Total Metal after 30-Days	2.4%	4.0%	0.53%	0.48%	0.39%	1.5%

The study was conducted at 25± 1 C for a 30-day period.

REVIEWER'S COMMENTS:

1. There was no attempt to present the predominance of Ag and Zn species in hydrosylates and "spiked" controls. This would have been useful in for knowing a priori which Ag or Zn species would be expected at the different pHs. This information is needed.

2. There was apparent contamination of samples by zinc.

3. The data from this study applies only to the type of zeolite used for exchange with Ag and Zn. The data may not apply for "Ag-Zn Zeolites" in which the zeolite is different.

4. The use of pH papers to measure pH is not a desirable method.

Table 1 - Sample Weights and pH Values for pH 5 Hydrolysis Samples

SAMPLE	POWDER WT (mg)*	INITIAL pH	TEST DAY	TEST DATE	FINAL pH
HL-0A-5	35.49	5.0	0	3/25/91	5.0
HL-0B-5	32.05	5.0	0	3/25/91	5.0
HL-2A-5	38.05	5.0	2	3/27/91	5.0
HL-2B-5	29.86	5.0	2	3/27/91	5.0
HL-4A-5	29.10	5.0	4	3/29/91	5.0
HL-4B-5	30.06	5.0	4	3/29/91	5.0
HL-8A-5	35.70	5.0	8	4/2/91	5.6
HL-8B-5	30.73	5.0	8	4/2/91	5.6
HL-16A-5	42.29	5.0	16	4/10/91	5.0
HL-16B-5	29.97	5.0	16	4/10/91	5.0
HL-24A-5	27.82	5.0	24	4/18/91	5.0
HL-24B-5	24.36	5.0	24	4/18/91	5.0
HL-30A-5	32.97	5.0	30	4/24/91	5.0
HL-30B-5	28.21	5.0	30	4/24/91	5.0

* - Anhydrous basis (corrected for 16.82% moisture)

Table 2 - Hydrolysate Silver and Zinc Concentrations for pH 5 Hydrolysis

				SILVER				ZINC			
SAMPLE	TEST DAY	ANALYSIS DATE	DILUTION	SOL'N CONC (ppb)	AMNT RELSED (ug/mg)	AVERAGE (ug/mg)	RPD/RSD	SOL'N CONC (ppb)	AMNT RELSED (ug/mg)	AVERAGE (ug/mg)	RPD/RSD
HL-0A-5	0	3/29/91		594	0.50			592	0.50		
						0.55	16			0.55	16
HL-0B-5	0	3/29/91		633	0.59			632	0.59		
HL-2A-5	2	3/29/91		703	0.55			821	0.82		
						0.72	46			1.14	55
HL-2B-5	2	3/29/91		871	0.88			1444	1.45		
HL-4A-5	4	3/29/91		1321	1.36			1735	1.79		
HL-4A-5	4	3/29/91	1:5	1280	1.32			1740	1.79		
						1.33	4			1.77	2
HL-4B-5	4	3/29/91		1353	1.35			1775	1.77		
HL-4B-5	4	3/29/91	1:5	1275	1.27			1740	1.74		
HL-8A-5	8	4/9/91		931	0.78			1334	1.12		
HL-8A-5	8	4/9/91	1:10	1150	0.97			1310	1.10		
						0.97	13			1.39	24
HL-8B-5	8	4/9/91		1069	1.04			1747	1.71		
HL-8B-5	8	4/9/91	1:10	1100	1.07			1683	1.64		

* - Outlier not used in calculating average

4.5

Table 2 - Hydrolysate Silver and Zinc Concentrations for pH 5 Hydrolysis (Continued)

				SILVER				ZINC			
SAMPLE	TEST DAY	ANALYSIS DATE	DILUTION	SOL'N CONC (ppb)	AMNT RELSED (ug/mg)	AVERAGE (ug/mg)	RPD/RSD	SOL'N CONC (ppb)	AMNT RELSED (ug/mg)	AVERAGE (ug/mg)	RPD/RSD
HL-16A-5	16	4/15/91		496	0.35*			1144	0.81*		
HL-16A-5	16	4/15/91	1:10	626	0.44*			1031	0.73*		
HL-16B-5	16	4/15/91		1044	1.05	1.09	8	2428	2.43	2.34	8
HL-16B-5	16	4/15/91	1:10	1126	1.13			2235	2.24		
HL-24A-5	24	4/29/91		1687	1.82			4131	4.45		
HL-24A-5	24	4/29/91	1:10	1807	1.95			4055	4.37		
						2.00	10			4.38	3
HL-24B-5	24	4/29/91		1570	1.93			3410	4.20		
HL-24B-5	24	4/29/91	1:10	1854	2.28			3638	4.48		
HL-30A-5	30	4/29/91		1093	0.99			2499	2.27		
HL-30A-5	30	4/29/91	1:10	1283	1.17			2490	2.27		
						1.48	32			3.12	57
HL-30B-5	30	4/29/91		1711	1.82			3775	4.01		
HL-30B-5	30	4/29/91	1:10	1831	1.95			3679	3.91		

* - Outlier not used in calculating average

Arthur D Little

4.6

Table 3 - Sample Weights and pH Values for pH 7 Hydrolysis Samples

SAMPLE	POWDER WT (mg)*	INITIAL pH	TEST DAY	TEST DATE	FINAL pH
HL-0A-7	27.56	6.9	0	3/25/91	6.9
HL-0B-7	31.72	6.9	0	3/25/91	6.9
HL-2A-7	31.03	6.9	2	3/27/91	6.9
HL-2B-7	29.09	6.9	2	3/27/91	6.9
HL-4A-7	27.12	6.9	4	3/29/91	6.9
HL-4B-7	43.70	6.9	4	3/29/91	6.9
HL-8A-7	32.12	6.9	8	4/2/91	6.9
HL-8B-7	34.20	6.9	8	4/2/91	6.9
HL-16A-7	35.93	6.9	16	4/10/91	6.9
HL-16B-7	38.40	6.9	16	4/10/91	6.9
HL-24A-7	26.30	6.9	24	4/18/91	6.9
HL-24B-7	30.87	6.9	24	4/18/91	6.9
HL-30A-7	25.17	6.9	30	4/24/91	6.9
HL-30B-7	31.41	6.9	30	4/24/91	6.9

* - Anhydrous basis (corrected for 16.82% moisture)

Table 4 - Hydrolysate Silver and Zinc Concentrations for pH 7 Hydrolysis

				SILVER				ZINC			
SAMPLE	TEST DAY	ANALYSIS DATE	DILUTION	SOL'N CONC (ppb)	AMNT RELSED (ug/mg)	AVERAGE (ug/mg)	RPD/RSD	SOL'N CONC (ppb)	AMNT RELSED (ug/mg)	AVERAGE (ug/mg)	RPD/RSD
HL-0A-7	0	3/29/91		189	0.21	0.20	10	387	0.42	0.39	15
HL-0B-7	0	3/29/91		197	0.19			379	0.36		
HL-2A-7	2	3/29/91		207	0.20	0.21	5	342	0.33	0.35	11
HL-2B-7	2	3/29/91		205	0.21			355	0.37		
HL-4A-7	4	3/29/91		199	0.22	0.19	32	305	0.34	0.29	40
HL-4B-7	4	3/29/91		229	0.16			335	0.23		
HL-8A-7	8	4/9/91		187	0.17	0.17	0	248	0.23	0.23	0
HL-8B-7	8	4/9/91		190	0.17			257	0.23		
HL-16A-7	16	4/15/91		172	0.14	0.14	0	163	0.14	0.14	7
HL-16B-7	16	4/15/91		185	0.14			170	0.13		
HL-24A-7	24	4/29/91		187	0.21	0.20	10	196	0.22	0.21	10
HL-24B-7	24	4/29/91		196	0.19			196	0.19		
HL-30A-7	30	4/29/91		192	0.23	0.21	19	315	0.38	0.41	12
HL-30B-7	30	4/29/91		194	0.19			453	0.43		

* - Outlier not used in calculating average

Table 5 - Sample Weights and pH Values for pH 9 Hydrolysis Samples

SAMPLE	POWDER WT (mg)*	INITIAL pH	TEST DAY	TEST DATE	FINAL pH
HL-0A-9	41.64	9.0	0	3/25/91	9.0
HL-0B-9	38.40	9.0	0	3/25/91	9.0
HL-2A-9	40.17	9.0	2	3/27/91	9.0
HL-2B-9	35.21	9.0	2	3/27/91	9.0
HL-4A-9	42.90	9.0	4	3/29/91	9.0
HL-4B-9	27.31	9.0	4	3/29/91	9.0
HL-8A-9	35.19	9.0	8	4/2/91	9.0
HL-8B-9	42.04	9.0	8	4/2/91	9.0
HL-16A-9	41.74	9.0	16	4/10/91	9.0
HL-16B-9	37.92	9.0	16	4/10/91	9.0
HL-24A-9	30.41	9.0	24	4/18/91	9.0
HL-24B-9	37.25	9.0	24	4/18/91	9.0
HL-30A-9	39.25	9.0	30	4/24/91	9.0
HL-30B-9	27.42	9.0	30	4/24/91	9.0

* - Anhydrous basis (corrected for 16.82% moisture)

Table 6 - Hydrolysate Silver and Zinc Concentrations for pH 9 Hydrolysis

				SILVER				ZINC			
SAMPLE	TEST DAY	ANALYSIS DATE	DILUTION	SOL'N CONC (ppb)	AMNT RELSED (ug/mg)	AVERAGE (ug/mg)	RPD/RSD	SOL'N CONC (ppb)	AMNT RELSED (ug/mg)	AVERAGE (ug/mg)	RPD/RSD
HL-0A-9	0	3/29/91		30	0.022			8	0.0058		
						0.024	17			0.0079	53
HL-0B-9	0	3/29/91		33	0.026			13	0.010		
HL-2A-9	2	3/29/91		46	0.034			71	0.053		
						0.034	3			0.057	14
HL-2B-9	2	3/29/91		39	0.033			72	0.061		
HL-4A-9	4	3/29/91		49	0.034			117	0.082		
						0.044	45			0.12	65
HL-4B-9	4	3/29/91		49	0.054			142	0.16		
HL-8A-9	8	4/9/91		115	0.098			457	0.39		
						0.083	36			0.32	47
HL-8B-9	8	4/9/91		95	0.068			343	0.24		
HL-16A-9	16	4/15/91		184	0.13			888	0.64		
HL-16A-9	16	4/15/91		171	0.12	0.13	8	852	0.61	0.63	5
HL-16B-9	16	4/15/91		42	0.033*			84	0.066*		
HL-16B-9	16	4/15/91		34	0.027*			82	0.065*		
HL-24A-9	24	4/29/91		117	0.12			640	0.63		
						0.11	23			0.53	40
HL-24B-9	24	4/29/91		118	0.095			516	0.42		
HL-30A-9	30	4/29/91		164	0.13			956	0.73		
						0.18	26			1.03	26
HL-30B-9	30	4/29/91		202	0.22			1076	1.18		
HL-30B-9	30	4/29/91	1:10	184	0.20			1090	1.19		

* - Outlier not used in calculating average

Table 7 - Results for Hydrolysis Study Negative Controls (Blanks)

SAMPLE	INITIAL pH	TEST DAY	TEST DATE	FINAL pH	ANALYSIS DATE	SILVER (ppb)	ZINC (ppb)
BL-0-5	5.0	0	3/25/91	5.0	3/29/91	ND	4
BL-2-5	5.0	2	3/27/91	5.0	3/29/91	29	10
BL-16-5	5.0	16	4/10/91	5.0	4/15/91	ND	101
BL-30-5	5.0	30	4/24/91	5.0	4/29/91	ND	25
BL-0-7	6.9	0	3/25/91	6.9	3/29/91	ND	19
BL-4-7	6.9	4	3/29/91	6.9	3/29/91	ND	13
BL-24-7	6.9	24	4/18/91	6.9	4/29/91	ND	15
BL-30-7	6.9	30	4/24/91	6.9	4/29/91	ND	16
BL-0-9	9.0	0	3/25/91	9.0	3/29/91	ND	2
BL-8-9	9.0	8	4/2/91	9.0	4/9/91	8	11
BL-30-9	9.0	30	4/24/91	9.0	4/29/91	ND	8

Table 8 - Results for Hydrolysis Study Positive Controls (Spikes)

SAMPLE	INITIAL pH	TEST DAY	TEST DATE	FINAL pH	ANALYSIS DATE	DILUT FACTOR	SILVER (ppb)	ZINC (ppb)**	PERCENT RECOVERY SILVER %	PERCENT RECOVERY ZINC %
SP-0-5	5.0	0	3/25/91	5.0	3/29/91		14	131	28	131
SP-0-5-Ag	5.0	0	4/1/91	5.0	4/9/91		58	33*	116	
SP-8-5	5.0	8	4/2/91	5.0	4/9/91		18	114	36	114
SP-8-5-Ag	5.0	8	4/9/91	5.0	4/9/91		50	133*	100	
SP-30-5	5.0	30	4/24/91	4.5	4/29/91		7	100	14	100
SP-30-5-Ag	5.0	30	5/1/91	5.0	5/15/91		35	27*	70	
SP-0-7	6.9	0	3/25/91	6.9	3/29/91		17	126	34	126
SP-0-7-Ag	6.9	0	4/1/91	6.9	4/9/91		57	34*	114	
SP-2-7	6.9	2	3/27/91	6.9	3/29/91		15	106	30	106
SP-2-7-Ag	6.9	2	4/3/91	6.9	4/9/91		45	112*	90	
SP-4-7***	6.9	4	3/29/91	6.9	3/29/91		33	133	66	133
SP-16-7	6.9	16	4/10/91	6.9	4/15/91		ND	184	0	184
SP-16-7-Ag	6.9	16	4/17/91	6.9	4/29/91		16	29*	32	
SP-30-7	6.9	30	4/24/91	6.9	4/29/91		10	121	20	120
SP-30-7-Ag	6.9	30	5/1/91	6.9	5/15/91		12	28*	24	
SP-0-9	9.0	0	3/25/91	9.0	3/29/91		9	120	18	120
SP-0-9-Ag	9.0	0	4/1/91	9.0	4/9/91		61	27*	122	
SP-4-9	9.0	4	3/29/91	9.0	3/29/91		27	136	54	136
SP-4-9-Ag	9.0	4	4/5/91	9.0	4/9/91		39	107*	78	
SP-24-9	9.0	24	4/18/91	9.0	4/29/91		2	150	4	150
SP-24-9-Ag	9.0	24	4/25/91	9.0	4/29/91		15	29*	30	
SP-30-9	9.0	30	4/24/91	9.0	4/29/91		6	133	12	133
SP-30-9-Ag	9.0	30	5/1/91	9.0	5/15/91		9	24*	18	

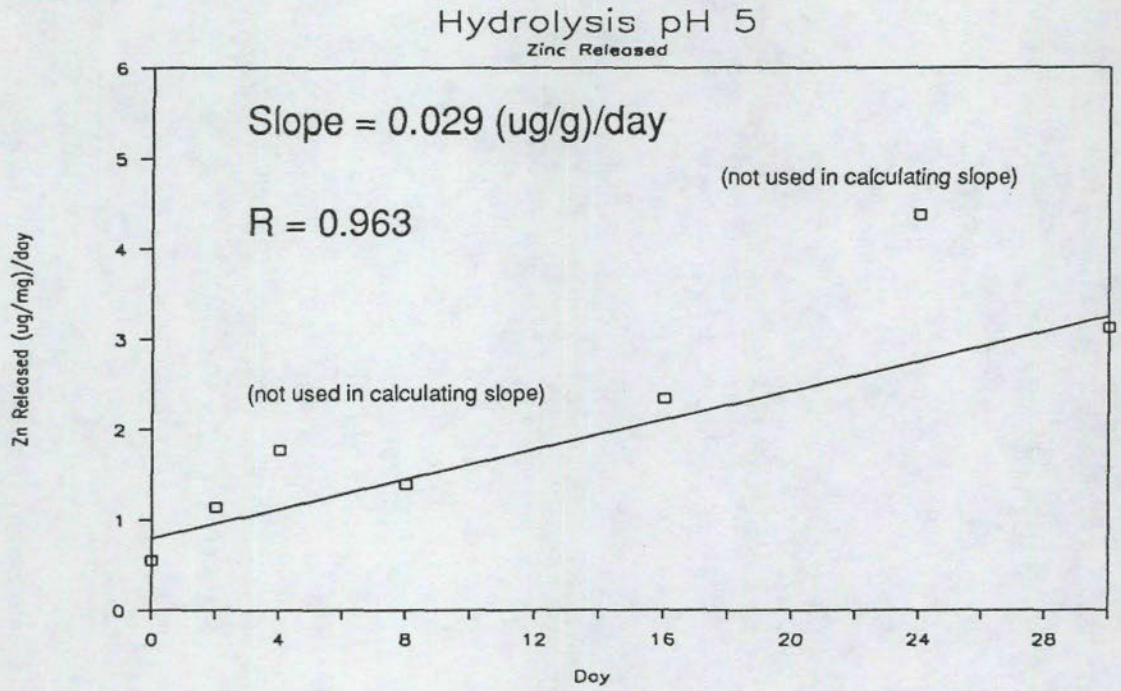
* - Zinc background interference. Not corrected for blank concentration

** - Corrected for blank concentration on corresponding day

*** - Contigency sample SP-C-7 used for analysis

4.12

Figure 1 - Graphical Representation of pH 5 Hydrolysis Results



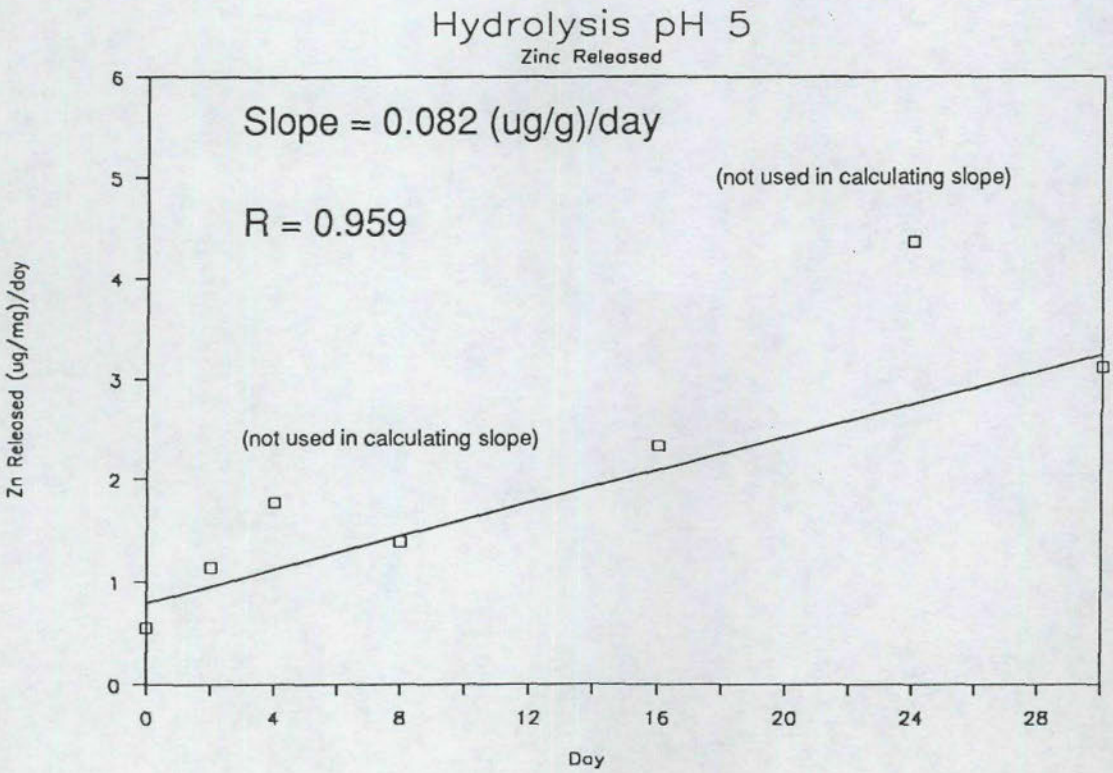
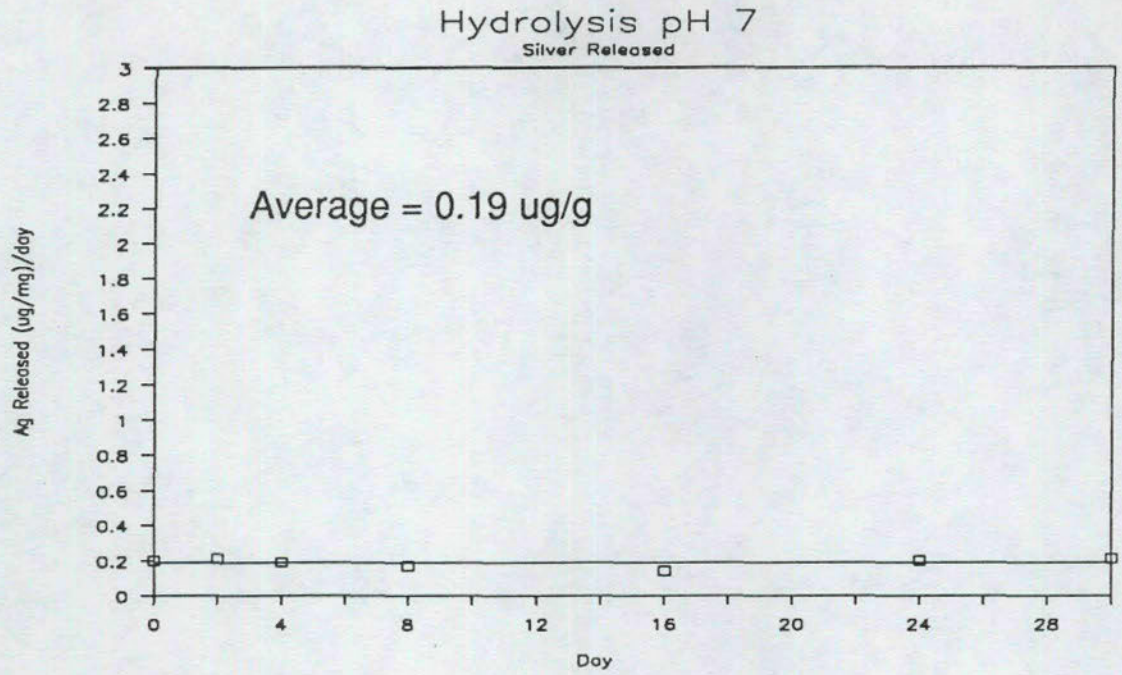
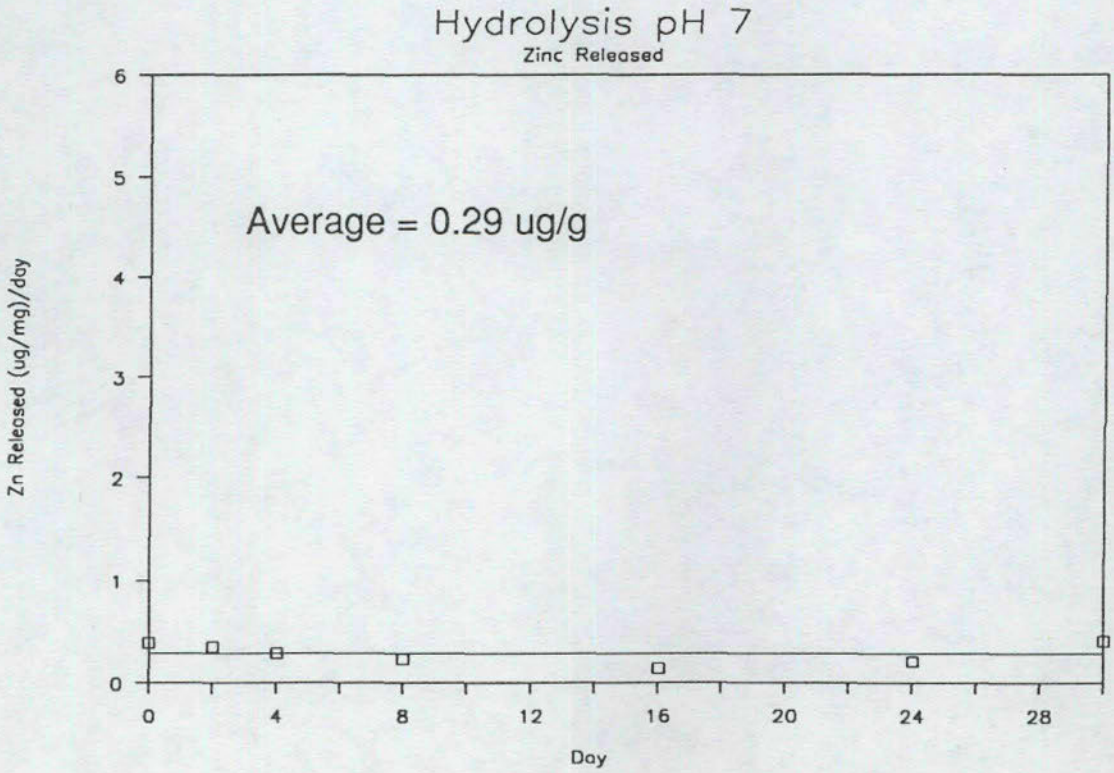


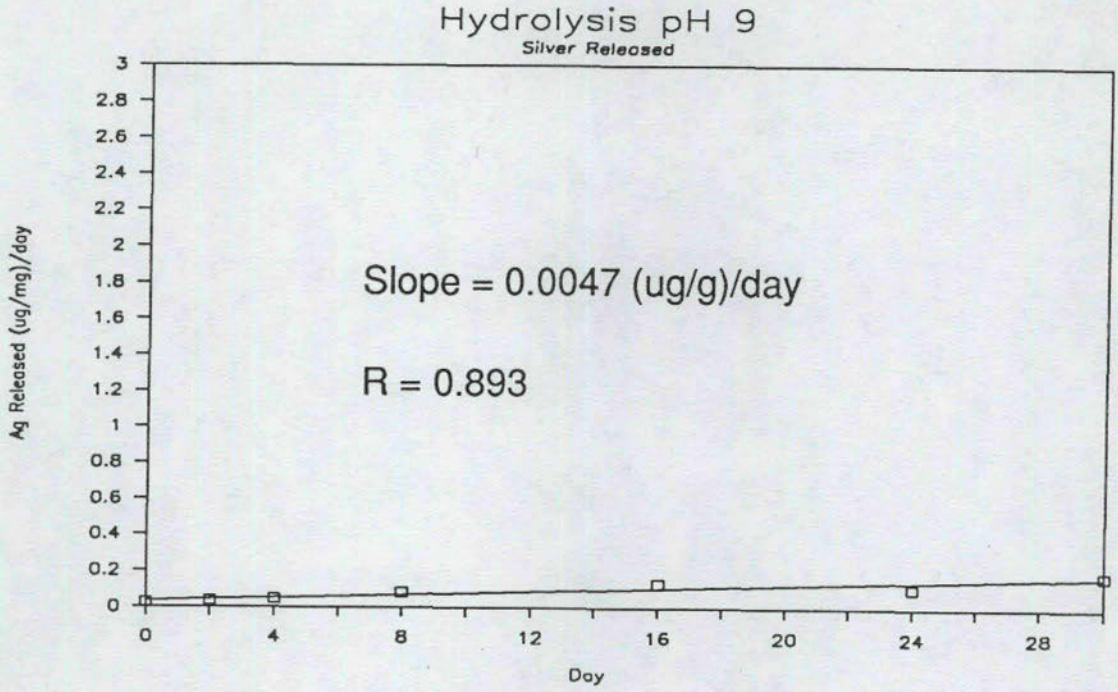
Figure 2 - Graphical Representation of pH 7 Hydrolysis Results

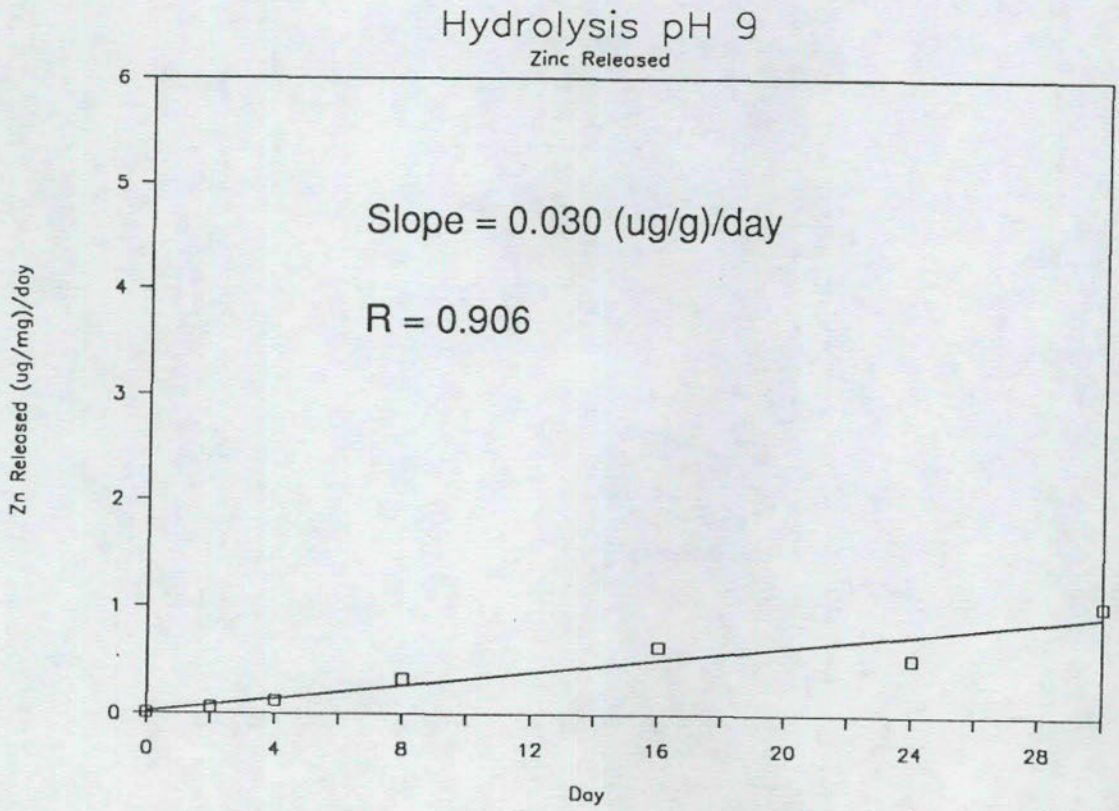




4.14

Figure 3 - Graphical Representation of pH 9 Hydrolysis Results





Reference Number _____

Input Date 226433

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 59824-E PM 31 |8| Action Code 160

|10| Descriptor (Amend/Resubmisions only) Aq2n 2edite 99%

|5| Intrastate Call-in ☐ (Y) Yes ☐ (N) No

|15| Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Perso ☐ (R) Non-residenti Use Only ☐ (N) Not-Applicabl

|20| Registration Type:

☐ (1) Conditional ☐ (2) Unconditional

|25| Proposed Classification:

☐ (R) Restricted ☐ (G) General

|30| Final Classification:

☐ (R) Restricted ☐ (N) Not Classified

|35| Date on Application: 0 6 2 2 8 8 (MO DAY YR)

|04| EPA Received Date: 0 6 2 4 8 8 (MO DAY YR)

|40| Date Received by PM ~~06 24 88~~ (MO DAY YR) 7-8-88

|80| Method of Support:

☐ (1) Cite-All ☐ (6) Owner Submission

☐ (4) Not Applicable ☐ (7) Total Submission

☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
RD					
PM					
PL				(10)	5/26/89
CH					
EF					

|108| Status: _____

|115| FINAL ACTION Response Code 10

|120| Response 0 5 3 1 8 9 (MO DAY YR)

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

MAY 31 1989

Kanebo, Ltd.
P.O. Box 125
Osaka 530, Japan

Attention: Robert Huntoon - U.S. Agent

Gentlemen:

Subject: Bactekiller AZ
EPA File Symbol 59824-E
Your Application Dated June 22, 1988

Your application package cannot be considered for review because it is incomplete. In order for us to process your application, you must submit a complete application for your proposed product.

A cursory review of our files indicates that this chemical will be treated as a new chemical since the Agency has never registered the chemical before. A full data base as outlined below will be required.

1. Product Chemistry;

2. Environmental Fate;

3. Toxicology; and

4. Fish and Wildlife.

Note: Your label claims should be more specific. What kind of manufactured materials? Data requirements differ among different products/uses.

Enclosed is a copy of 158 Guidelines and please pay close attention to the Data Charts.

The Agency may require additional data based upon the review of your proposed product.

50456:I:Lee:L-5:KENCO:05/30/89:07/08/89:CL:vo:ek:rw

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70)

OFFICIAL FILE COPY

This letter does not constitute registration and the product may not be lawfully marketed until it is registered.

If you have any questions concerning this letter, contact Valdis Goncarovs at (703) 557-3663.

Sincerely yours,

John H. Lee
Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

Form Approved OMB No. 2000-0012

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAM (TS-767)
WASHINGTON, D.C. 20460

APPLICATION FOR PESTICIDE: ☒ REGISTRATION ☐ AMENDMENT A

Please read instructions on reverse before completing.

SECTION I

1. COMPANY/PRODUCT NO.	2. DATE	3. PRODUCT MANAGER	4. PROPOSED CLASSIFICATION
59824-E	6-22-88	John Lee PM	31 ☒ GENERAL ☐ RESTRICTED

5. NAME AND ADDRESS OF APPLICANT (Include ZIP Code)

KANEBO, LTD
P.O. BOX 125
OSAKA 530, JAPAN

U. S. AGENT: ROBERT H. HUNTOON
HUNTEX MANAGEMENT CORP.
1500 LAUREL HOLLOW RD
SYOSSET, NY 11791

☐ CHECK IF THIS IS A NEW ADDRESS

6. PRODUCT NAME: BACTEKILLER AZ

SECTION II

1. SUBJECT OF AMENDMENT

☐ RESUBMISSION IN RESPONSE TO AGENCY LETTER DATED _____

☐ FINAL PRINTED LABEL IN RESPONSE TO AGENCY LETTER DATED _____

☐ OTHER (explain below)

SECTION III

1. WILL THIS PRODUCT BE PACKAGED IN:

CHILD-RESISTANT PACKAGING ☐ YES ☒ NO

UNIT PACKAGING ☐ YES ☐ NO

If YES, unit pkg. wt. _____ No. per container _____

WATER-SOLUBLE PACKAGING ☐ YES ☒ NO

If YES, pkg. wt. _____ No. per container _____

2. TYPE OF CONTAINER

☒ METAL
☐ PLASTIC
☐ GLASS
☐ PAPER
☐ OTHER (Specify)

Paper lined

3. LOCATION OF NET CONTENTS: ☒ LABEL ☐ CONTAINER

4. SIZE(S) OF RETAIL CONTAINER: 10, 20 & 100 lb. packages

5. LOCATION OF LABEL DIRECTIONS

☒ ON LABEL
☐ ON MATERIAL ACCOMPANYING PRODUCT

6. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT

☐ LITHOGRAPH ☐ OTHER (Specify)
☒ PAPER GLUED
☐ STENCILED

SECTION IV

1. CONTACT POINT (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

NAME: Robert H. Huntoon
Huntex Management, 1500 Laurel Hollow Rd.; Syosset, NY 11791

TITLE: U. S. AGENT

TELEPHONE NO. (Include Area Code): 516 692 9556

2. SIGNATURE: Robert H Huntoon

3. TITLE: U. S. Agent

4. TYPED NAME: Robert H. Huntoon

5. DATE SIGNED: 6-22-88

6. DATE APPLICATION RECEIVED (Stamped)

EPA Form 8570-1 (Rev. 5-81) PREVIOUS EDITION IS OBSOLETE.

INSTRUCTIONS

GENERAL

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). *(If not exempted by 40 CFR 162.9-1(b).*
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mock-up of the proposed label. If prepared as a mock-up it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mock-up labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in three copies. In order to facilitate review, each type of data submitted must be bound separately, and clearly identified on the front cover including the date submitted.

A copy of the application form and a copy of the label should be bound in each separate volume of the data.

ALL DATA FOR WHICH CLAIMS OF CONFIDENTIALITY ARE ASSERTED MUST BE SUBMITTED, BOUND SEPARATELY AND CLEARLY MARKED AS SUCH.

SPECIFIC

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in BLOCK A, for which you are submitting this application. For applications submitted in connection with NEW REGISTRATION actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

BLOCK A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both REGISTRATION and AMENDED REGISTRATION actions.

1. Company/Product Number - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. Date - Fill in the appropriate date.
3. Product Manager - If known, fill in the name and number of the Product Manager.
4. Proposed Classification - Specify the proposed classification for this product.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

   An applicant NOT residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

AMENDMENT INFORMATION

Section II - This Section must be completed for all applications submitted in connection with AMENDED REGISTRATION.

1. Subject of Amendment - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements", etc.

PACKAGING AND CONTAINER INFORMATION

Section III - This Section must be completed for all applications submitted in connection with NEW REGISTRATION.

1. Type of Packaging - Check the appropriate block if you product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the statement of net contents.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Direction - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicate the method product labeling is attached to retail container.

CONTACT POINT

Section IV - This Section must be completed for all REGISTRATION and AMENDED REGISTRATION applications.

1-5. Self-explanatory.

6. EPA Use Only.

EPA Reg. No._____

EPA File Symbol_____

A-1 ADMINISTRATIVE CHECK LIST

We have received your application for registration but cannot process it until the items checked are corrected.

_____1. Please include an Application for Pesticide Registration/Amendment, EPA Form 8570-1. This form is required for all initital submissions, resubmissions (subsequent submissions prior to registration), and amendments.

_____2. Your application for amendment did not identify the EPA File Symbol or EPA Registration Number of the product. Please refer to the applicable EPA File Symbol or EPA Registration Number in all correspondence concerning the product.

_____3. The Data Reference Sheet, EPA Form 8570-20, was not included. This form must be submitted with all applications for new registration, reregistration, and with any other application which requires a change in information previously submitted on the form.

_____4. You must apply separately for registration for each pesticide product.

_____5. You must indicate the proposed classification of the pesticide product in Block 4 of the application.

_____6. You must specify the type of container in Section III of the application.

_____7. You must state in Section III, Block 1 of the application if child-resistant packaging will be used.

_____8. You must state the name of the pesticide product, not the active chemical, in Block 6 of the application.

_____9. You must indicate, in Section III, Block 5 of the application, the location of label directions.

____10. The manner in which the label is affixed to the product must be indicated in Section III, Block 6 of the application.

____11. The application form was not signed (Section IV, Block 2). We are, therefore, returning your application.

____12. The applicant's title must be indicated in Section IV, Block 1.

-OVER-

A-1 ADMINISTRATIVE CHECK LIST (continued)

____13. Your application did not include a statement regarding data compensation in accordance with PR Notice 83-1.

____14. The applicant's name was not printed in Section IV.

____15. The application date must be indicated in Section IV, Block 4.

____16. Each product must have a different product name. The name listed on the application form is the same as for the product under (EPA File Symbol) (EPA Reg. No.)_____. We are, therefore, returning your application.

____17. An application for amending the registration which involves a significant ingredient change is considered as an application for the registration of a new product. Therefore, we are returning your application. If you wish to resubmit it, please complete a new EPA Form 8570-1. The product name should be modified so as to be distinguishable from the old product name. You sould inform this office of your intentions with respect to the product registered under EPA Reg. No. _____.

____18. Please clearly indicate the nature of the amendment in Section III, Block 1 of the application.

____19. Two (2) legible and identical copies of the proposed labeling must be submitted. Labeling submitted with the application should be in typewritten draft form. You will be notified if copies of final printed labeling are required.

____20. The product name on the labeling differs from that stated on the application/letter.

✓____21. The Confidential Statement of Formula, EPA Form 8570-4, declaring the name and percentage by weight of each active and each inert ingredient, must be included.

____22. Declaration of the term "inert ingredients" on the Confidential Statement of Formula is not acceptable. If the complete chemical composition of the product is not known to you, send a separate copy of this form to your supplier, and request him to submit it to us. This form should clearly identify the applicable EPA Registration Number(s)/File Symbol(s).

____23. The Confidential Statement of Formula was not signed and/or is incomplete. It is, therefore, being returned.

____24. We have not received the formal authorization from your supplier to use the confidential formulaltion of your label. We cannot review your label until you furnish this information.

COMPANY: KANEBO, LTD.
C/O NICHIMEN (AMERICA), INC.
1185 Ave. Of The Americas
New York, NY 10036

Product Name: BACTEKILLER AZ
(silver-zinc zeolite)

Company No.:

Regulatory
Action: Application for new product registration

PLEASE SEND ALL CORRESPONDENCE TO AGENT:

MR. ROBERT H. HUNTOON
HUNTEX MANAGEMENT CORPORATION
1500 LAUREL HOLLOW ROAD
SYOSSET, N.Y. 11791

Telephone: (516) 692-9556

VOLUME 1

ADMINISTRATIVE MATERIALS

CERTIFICATION WITH RESPECT TO CITATION OF DATA

EPA File Symbol/Reg. No. _____ Date of application 6-22-88

Name of Product BACTEKILLER AZ

Applicant's Name and Address KANEBO, LTD. C/O NICHIMEN (AMERICA) INC.
1185 Avenue of the Americas
New York, NY 10036

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study, I have obtained the written permission of the original data submitter to cite that study.

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

I have obtained the written permission of the original data submitter to cite that study; or

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

[x] All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (Cite-all method or cite-all option under Selective Method). (Also sign the General Offer to Pay Statement below.)

[ ] Those companies who have submitted the studies which I have cited (Selective method)

Date 6-22-88 Signature Robert H Hunton

Title U. S. Agent

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D).

Date 6-22-88 Signature Robert H Hunton

Title U. S. Agent

EPA Form (April 1985)

(Front Panel)

BACTEKILLER AZ

A bacteriostatic powder for COMMERCIAL AND INDUSTRIAL USE designed to be incorporated into various materials in various steps of the manufacturing process to impart bacteriostatic activity to the manufactured materials.

ACTIVE INGREDIENT

SILVER.ZINC ZEOLITE 99.0%

INERT INGREDIENTS 1.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS: CAUTION

May be harmful if swallowed. Avoid contact with skin, eyes, or clothing. Avoid contamination of cooking utensils and food preparation surfaces.

STATEMENT OF PRACTICAL TREATMENT

If swallowed: Drink one or two glases of water and induce vomiting by touching the back of the throat with finger. Repeat until vomit fluid is clear. Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person.

If on skin: Remove contaminating clothing and wash affected area with soap and water. If irritation persists, contact a physician.

If in eyes: Flush eyes for at least 15 minutes with water. If irritation persists contact a physician.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Keep out of any natural body of water. Do not contaminate water by cleaning of equipment or disposal of wastes.

STORAGE & DISPOSAL

Do not store in areas accessible to children. Do not store in places where food or feed may come in contact with the product. CONTAINER DISPOSAL: Wrap empty container in several layers of newspaper before disposal in regular trash collection.

(Back Panel)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

BLENDING AND FORMULATION INSTRUCTIONS FOR THE LISTED MATERIALS

BACTEKILLER AZ is a silver zeolite powder designed to be incorporated into various materials at varying stages of their manufacturing process to impart bacteriostatic properties to the manufactured materials. The powder can be incorporated into these materials as an integral part of the finished product throughout their entire thickness, or as a film over the surfaces of the manufactured materials, depending on the particular method of manufacture of the finished materials and needs of the manufacturer.

Bactekiller AZ may be incorporated into the following materials at the specified Minimum Inhibitory Concentrations (MIC) on a dry weight basis of finished products.

APPLICATION	MIC
Plastic Film	
Polyethylene, polypropylene, polyvinyl chloride, polyacetate, polyesther	1.50 %
Paint (Water base & solvent base)	1.50 %
Paper	1.50 %
Synthetic Fiber	
Polyesther, Nylon, Polypropylene, Acrylic, and Rayon	1.50 %
Pigments: dyestuffs and inks	1.00 %
Textile Finishing and Manufacturing	0.75 %

(Supplemental Labeling)

BLENDING AND MANUFACTURING INSTRUTIONS
FOR BACTEKILLER AZ (SILVER-ZINC ZEOLITE)
FOR VARIOUS MATERIALS

In general BACTEKILLER AZ should be incorporated into the manufactured materials at the stage of the manufacturing process where maximum and intimate blending will occur. In the manufacture of materials which when finished are sold or used in a dry solid state, BACTEKILLER AZ should be incoroporated in amounts which will result in the Minimum Inhibitory Concentration (MIC) specified below, for each type of material, on a finished dry weight basis. In the case of finished materials which will be sold or used in a liquified suspension, the amount of BACTEKILLER AZ should be calculated and adjusted so that the specified MIC will result on a weight by weight basis of the finished liquid suspension, such as paints and inks.

PLASTIC FILM: MIC = 1.5% (Dry Weight Basis)

It is recommended that BACTEKILLER AZ powder be introduced into the film making process at the powder, or pellet (dry blending) stage, prior to mechanical blending or grinding.

PAINT: MIC = 1.0% on a weight by weight basis of finished product.

For both water and oil based paints it is recomended that BACTEKILLER AZ be introduced in the dry blending of the solids (including pigments) prior to addition of the liquid carriers. If inhibition of growth of microorganisms in the paint as it occurs in the can is desired, the amount of BACTEKILLER AZ should be calculated and adjusted so that the final MIC in the emulsified finished product will be 1.0% $\pm$ 0.1% on a weight by weight basis of finished product.

PAPER: MIC = 1.5% (Dry Weight Basis)

BACTEKILLER AZ may be added to the wet furnish stage or in the finishing or glazing stage, at an MIC of 1.5% of dry finished paper.

FIBER: MIC = 1.5% (Dry Weight Basis)

BACTEKILLER AZ and polymer are kneaded together to make a master chip which is then melt spun and extruded for polyesther fibers. For acrylic or cellulosic fibers BACTEKILLER AZ is mixed in the spun solvent step of fiber making.

BLENDING AND MANUFACTURING INSTRUCTIONS
FOR THE LISTED MATERIALS (Cont'd)
FOR BACTEKILLER AZ (SILVER-ZINC ZEOLITE)

PLYWOOD ADHESIVE COMPONENT: MIC = 2.0% (Dry Weight Basis)

BACTEKILLER AZ is mixed or blended in the normal adhesive mixing step, prior to the pressure and curing stage. The amount of BACTEKILLER AZ to be mixed with the wet adhesive must be calculated in advance, so that after curing and all water or solvent is driven off, the concentration of BACTEKILLER AZ in the finished glue layers will be 2.0% ± 0.1%.

PIGMENTS: DYESTUFFS AND INKS: MIC = 1.0% (Dry Weight Basis)

BACTEKILLER AZ may be added with the help of various anionic and cationic dispersion agents to the wet pigments. If the finished product is a liquified or emulsified suspension of pigments, the amount of BACTEKILLER AZ should be calculated in advance and adjusted so the the MIC will be 1.0% ± 0.1% on a weight by weight basis of the finished liquid suspension.

TEXTILE FINISHING AND MANUFACTURING: MIC = 0.75% ± 0.1% Dry Weight Basis

BACTEKILLER AZ may be incorporated in the wet topical treatment of all fabrics, or in the resin or thermal bonding step for non-woven fabrics.

Huntex Management Corporation
1500 Laurel Hollow Road • Syosset, N.Y. 11791

Robert H. Huntoon
President

(516) 692-9556

4/4

June 22, 1988

Mr. John Lee, PM 31
Insecticides-Rodenticides Branch
Registration Division (TS-767C)
401 M. St. S. W.
Washington, DC 20460

Subject: Kanebo Ltd.
Bactekiller AZ
Application for New Product Registration

Dear Mr. Lee:

I am a duly authorized agent for the subject Japanese company. A copy of the appointment letter is enclosed.

Herewith please find all of the necessary documents in this administrative package (Volume 1) for the registration of the product listed above. The pertinent product chemistry data have been submitted on this same date in a separate volume 2, in compliance with PR Notice 86-5 (July 29, 1986).

Since this is the first application to the EPA in connection with the registration of a product, no company number has been issued to Kanebo Ltd.

I hope that you will find all the required documents in order so that you can give this application your timely consideration. Thank you for your assistance and kind consideration.

Very truly yours,

Robert H. Huntoon

Robert H. Huntoon
Agent, Kanebo Ltd.

06/22/1988 13:19 NICHIMEN NEW YORK 212 245 8974 P.04
RCV BY:XEROX TELECOPIER 7010 ; 6-22-88 1:29PM ; 212 245 8974; 7035284251;# 4

FAX 703528 4251

No. 88 . 6 . 21 .

To: M/S FRC INC

From: KANEBO
MATSUO

Re:

MR. A.E. Castillo
FRC Inc.
(ATT M.R. OHGAWARA)

JUN 21, 1988

Please pass this message to Mr. OHGAWARA of KANEBO LTD, Osaka. Thanks in Advance.

Quote: ティンスワースムに対するハンツーンムに関する手紙のFAXは現在タイプ中にて明日FAX致します。

以上

エステル綿技術部 松尾.

UNQUOTE:

Translation attached

Kanebo, LTD.
OSAKA EKIMAE DAINI BUILDING
2-2 UMEDA 1-CHOME, KITA-KU, OSAKA 530 JAPAN
TELEX J63327 TELEFAX 06 348 5154

June 22, 1988

Mr. Edwin Tinsworth
Director Registration Division
(TS-767C)
Office of Pesticides Program
401 M-Street
S. W. Washington DC 20460
U. S. A.

Dear Mr. Tinsworth:

With this letter, I hereby authorize Mr. Robelt Huntoon located at, Huntex Management Corp. 1500 Laurel Hollow-RD Syosset, New York 11791 (516-692-955C) to deal with the Environment Protection Agency in all matters pursuant to the Registration of pesticide products on behalf of our firm.

Sincerely yours,

K. Sawada

Kazuo Sawada
General Manager
Polyester Staples

KS:sn

Kanebo

A4 -> A4

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1. Transmittal Document

2. Letter of Appointment of an Agent

3. Cover letter to Product Manager

4. Application for Registration of a Me-Too Product

5. Certification With Respect To Citation Of Data

6. Product Label (3 copies)

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

KANEBO, LTD
P.O. BOX 125
OSAKA 530, JAPAN,

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/24/88. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

Your submittal was found to be substantially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exception(s) noted below. A copy of your bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents, and correct the noted exception(s) in future data submittals. If deficiencies were found which apply to your overall submission, they are described following this paragraph. If the deficiencies apply to specific studies, they are listed below following the applicable identification number or MRID. Thank you for your cooperation.

Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions.

If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

* The transmittal document was received without an official signature.

MRID 40842801

In the future, please put the cross reference number(s) on the page of the study from which the confidential material has been removed.

TRANSMITTAL DOCUMENT

408428-00
not OCM

1. NAME AND ADDRESS OF SUBMITTER (APPLICANT)

KANEBO, LTD.
C/O NICHIMEN (AMERICA), INC.
1185 Ave Of The Americas
New York, NY 10036

Sole Agent for Submitter

Mr. Robert H. Huntoon
Huntex Manufacturing Corporation
1500 Laurel Hollow Road
Syosset, N.Y. 11791

2. REGULATORY ACTION TO BE TAKEN

Application for New Product Registration
Product Name: BACTEKILLER AZ
(Silver-Zinc Zeolite)
Company No.

3. TRASMITTAL DATE

June 22, 1988

4. LIST OF SUBMITTED STUDIES

Volume 1: Administrative Materials

40842801 Volume 2: Chemistry Data

Company Official: Robert H. Huntoon _____
(signature)

Company Name: KANEBO, LTD.

Company Contact: Robert H. Huntoon (516)-692-9556
(phone)

S9824-E