EPA REGISTRATION

NO. 74712-8

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
74712-8	10/13/15

Term of Issuance:
Conditional

Name of Pesticide Product:
AVANCID GL 50M

Name and Address of Registrant (include ZIP Code):

Special Materials Company
70 West 40th Street, 2nd Floor
New York, NY 10018

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

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

Registration is in no way to be construed as an endorsement or recommendation of this product by the 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 section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Julie Chao, Product Manager 33
Regulatory Management Branch I, Antimicrobials Division (7510P)

Date: 10/13/15

EPA Form 8570-6

2. You are required to comply with the data requirements described in the DCI identified below:

    - Glutaraldehyde GDCI-043901-30859

    You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI a listed above, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division

3. The data requirement for storage stability (Guideline 830.6317) is not satisfied. A one year study is required to satisfy this data requirement. You have 18 months from the date of registration to provide the data.

4. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 74712-8."

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 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. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated August 12, 2015

If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,

Julie Chao, Product Manager 33
Regulatory Management Branch 1

Enclosure: Accepted Label

AVANCID® GL 50M

FOR MANUFACTURING USE ONLY FOR FORMULATING INDUSTRIAL BACTERICIDES AND PRESERVATIVES. FORMULATORS USING THIS PRODUCT ARE RESPONSIBLE FOR PROVIDING DATA FOR THE EPA REGISTRATION OF THEIR FORMULATED PRODUCTS.

Active Ingredient:
Glutaraldehyde..... 50.0%
Other Ingredients:..... 50.0%
Total:..... 100.0%

ACCEPTED
Oct 13, 2015
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 74712-8

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID	
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. • Call a poison control center or immediately for treatment advice
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 a doctor for further treatment advice
If Swallowed	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person.
If Inhaled	· Move person to fresh air. · If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. If breathing is difficult, oxygen should be administered by a qualified professional. · Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER

IN CASE OF EMERGENCY endangering life or property involving this product, call 800-424-9300. Have product container or label with you when calling a poison control center or doctor or going to treatment.

NOTE TO PHYSICIAN

Aspiration may cause lung damage. Probable mucosal damage may contraindicate the use of gastric lavage.

EPA Reg. No.74712-I

EPA Est. No. XXXXX-XX-XXX

Special Materials Company
70 West 40th Street
New York, New York 10018

Net Contents: _____

Lot Number: _____

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER

Corrosive. Causes irreversible eye damage. Causes skin burns. May be fatal if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes asthmatic signs and symptoms in hyper -reactive individuals.
Do not get in eyes, on skin, on clothing. Avoid breathing vapor. Do not swallow. Wear goggles, protective clothing, and butyl or nitrile gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

User Safety Recommendations

BEFORE HANDLING OR USING THIS PRODUCT, SEE YOUR EMPLOYER AND READ THE CURRENT SAFETY DATA SHEET. Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must wash hands before eating, drinking, chewing gum, or using the toilet. Users must remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

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

FOR FORMULATION OF INDUSTIAL BACTERICIDES AND PRESERVATIVES FOR USE IN:

- AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS, RECIRCULATING COOLING AND PROCESS WATER SYSTEMS INCLUDING THOSE THAT CONTAIN REVERSE OSMOSIS MEMBRANES, SERVICE WATER AND AUXILIARY SYSTEMS, HEAT TRANSFER SYSTEMS, WASTEWATER SYSTEMS INCLUDING WASTEWATER SLUDGE AND HOLDING TANKS.
- BEET SUGAR MILLS AND BEET SUGAR MILL PROCESS WATER SYSTEMS.
- PAPER MILLS AND PAPER MILL PROCESS WATER SYSTEMS, PIGMENTS AND FILLER SLURRIES FOR PAPER AND PAPERBOARD, WATER BASED COATINGS FOR PAPER AND PAPERBOARD

- FUNCTIONAL *FLUIDS AND LUBRICANTS* AND AQUEOUS METALWORKING FLUIDS AND IN INDUSTRIAL, INSTITUTIONAL AND CONSUMER PROCESSES AND PRODUCTS IN AQUEOUS-BASED SOLUTIONS, SLURRIES AND EMULSIONS.

- OIL WELL DRILLING, OIL FIELD PROCESSING APPLICATIONS, OIL FIELD WATER SYSTEMS, GAS PRODUCTION AND TRANSMISSION PIPELINES AND SYSTEMS AND GAS STORAGE FIELDS AND EQUIPMENT SUCH AS STEAM INJECTION WATER HOLDING TANKS, FLOOD WATER, INJECTION WATER, HOLDING POND WATER, DISPOSAL-WELL WATER, WATER HOLDING TANKS, FUEL STORAGE TANKS AND RELATED REFINERY AND OIL FIELD CLOSED, INDUSTRIAL RECIRCULATING WATER HANDLING SYSTEMS.

- ANIMAL PRODUCTION FACILITIES AND FARM EQUIPMENT SUCH AS: POULTRY & TURKEY HOUSES, SWINE HOUSING AND FARROWING AREAS, BARNS AND LARGE ANIMAL BUILDINGS, HATCHERS, SETTERS AND CHICK PROCESSING FACILITIES, CAGES AND TRANSPORT VEHICLES, AND HATCHING EGGS AND FOR SANITIZING INDUSTRIAL OR NON-FOOD CONTACT SURFACES SUCH AS EQUIPMENT FOR MIXING, PACKING, OR PACKAGING PRODUCTS, PRODUCT TRANSFER LINES, STORAGE TANKS, FLOORS, AND WALLS.

- USES NOT REGISTERED IN THE STATE OF CALIFORNIA: OIL PRODUCTION AND TRANSMISSION PIPELINES AND SYSTEMS, FRACTURING FLUIDS.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: This product is incompatible with many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc. The product can be stored and handled in baked phenolic -lined steel, polyethylene, stainless steel, or reinforced epoxy -plastic equipment. This product freezes at about -6°F (-21°C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage times (up to about 1 month), temperatures of up to 100 °F (37.8° C) can be tolerated but the preferred maximum storage temperature is about 80 °F (26.7 °C).
Handle in a well -ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.

PESTICIDE DISPOSAL: Open dumping is prohibited. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or your Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.
CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple or pressure rinse container (or equivalent) promptly after emptying.

(For containers 5 gallons or less)
Triple Rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times.

(For containers larger than 5 gallons) Clean container promptly after emptying. Triple Rinse as follows: Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times.

Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or other procedures approved by state and local authorities

PROCESSING REQUEST

Reg # 74712-8 **Decision #** 495702

Description: New product registration

Electronic Label & Letter (see PPLS):	OR	**Non Electronic Label & Letter** (Scanning required):
☒ Dated: 10/13/15		☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 8/12/15

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Terria Northern

Division: AD

Phone: 703-347-0265 **Date:** 10/13/15

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
__ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
74712-8	10/13/15

Term of Issuance:
Conditional

Name of Pesticide Product:
AVANCID GL 50M

Name and Address of Registrant (include ZIP Code):

Special Materials Company
70 West 40th Street, 2nd Floor
New York, NY 10018

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

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

Registration is in no way to be construed as an endorsement or recommendation of this product by the 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 section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Julie Chao, Product Manager 33
Regulatory Management Branch I, Antimicrobials Division (7510P)

Date:
10/13/15

EPA Form 8570-6

2. You are required to comply with the data requirements described in the DCI identified below:

    - Glutaraldehyde GDCI-043901-30859

    You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI a listed above, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division

3. The data requirement for storage stability (Guideline 830.6317) is not satisfied. A one year study is required to satisfy this data requirement. You have 18 months from the date of registration to provide the data.

4. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 74712-8."

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 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. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated August 12, 2015

If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,

Julie Chao, Product Manager 33
Regulatory Management Branch 1

Enclosure: Accepted Label

AVANCID® GL 50M

FOR MANUFACTURING USE ONLY FOR FORMULATING INDUSTRIAL BACTERICIDES AND PRESERVATIVES. FORMULATORS USING THIS PRODUCT ARE RESPONSIBLE FOR PROVIDING DATA FOR THE EPA REGISTRATION OF THEIR FORMULATED PRODUCTS.

Active Ingredient:
Glutaraldehyde..... 50.0%
Other Ingredients:..... 50.0%
Total:..... 100.0%

ACCEPTED
Oct 13, 2015
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 74712-8

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID	
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. • Call a poison control center or immediately for treatment advice
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 a doctor for further treatment advice
If Swallowed	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person.
If Inhaled	· Move person to fresh air. · If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. If breathing is difficult, oxygen should be administered by a qualified professional. · Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER

IN CASE OF EMERGENCY endangering life or property involving this product, call 800-424-9300. Have product container or label with you when calling a poison control center or doctor or going to treatment.

NOTE TO PHYSICIAN

Aspiration may cause lung damage. Probable mucosal damage may contraindicate the use of gastric lavage.

EPA Reg. No.74712-I

EPA Est. No. XXXXX-XX-XXX

Special Materials Company
70 West 40th Street
New York, New York 10018

Net Contents: _____

Lot Number: _____

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER

Corrosive. Causes irreversible eye damage. Causes skin burns. May be fatal if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes asthmatic signs and symptoms in hyper -reactive individuals.
Do not get in eyes, on skin, on clothing. Avoid breathing vapor. Do not swallow. Wear goggles, protective clothing, and butyl or nitrile gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

User Safety Recommendations

BEFORE HANDLING OR USING THIS PRODUCT, SEE YOUR EMPLOYER AND READ THE CURRENT SAFETY DATA SHEET. Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must wash hands before eating, drinking, chewing gum, or using the toilet. Users must remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

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

FOR FORMULATION OF INDUSTIAL BACTERICIDES AND PRESERVATIVES FOR USE IN:

- AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS, RECIRCULATING COOLING AND PROCESS WATER SYSTEMS INCLUDING THOSE THAT CONTAIN REVERSE OSMOSIS MEMBRANES, SERVICE WATER AND AUXILIARY SYSTEMS, HEAT TRANSFER SYSTEMS, WASTEWATER SYSTEMS INCLUDING WASTEWATER SLUDGE AND HOLDING TANKS.
- BEET SUGAR MILLS AND BEET SUGAR MILL PROCESS WATER SYSTEMS.
- PAPER MILLS AND PAPER MILL PROCESS WATER SYSTEMS, PIGMENTS AND FILLER SLURRIES FOR PAPER AND PAPERBOARD, WATER BASED COATINGS FOR PAPER AND PAPERBOARD

- FUNCTIONAL FLUIDS AND LUBRICANTS AND AQUEOUS METALWORKING FLUIDS AND IN INDUSTRIAL, INSTITUTIONAL AND CONSUMER PROCESSES AND PRODUCTS IN AQUEOUS-BASED SOLUTIONS, SLURRIES AND EMULSIONS.

- OIL WELL DRILLING, OIL FIELD PROCESSING APPLICATIONS, OIL FIELD WATER SYSTEMS, GAS PRODUCTION AND TRANSMISSION PIPELINES AND SYSTEMS AND GAS STORAGE FIELDS AND EQUIPMENT SUCH AS STEAM INJECTION WATER HOLDING TANKS, FLOOD WATER, INJECTION WATER, HOLDING POND WATER, DISPOSAL-WELL WATER, WATER HOLDING TANKS, FUEL STORAGE TANKS AND RELATED REFINERY AND OIL FIELD CLOSED, INDUSTRIAL RECIRCULATING WATER HANDLING SYSTEMS.

- ANIMAL PRODUCTION FACILITIES AND FARM EQUIPMENT SUCH AS: POULTRY & TURKEY HOUSES, SWINE HOUSING AND FARROWING AREAS, BARNS AND LARGE ANIMAL BUILDINGS, HATCHERS, SETTERS AND CHICK PROCESSING FACILITIES, CAGES AND TRANSPORT VEHICLES, AND HATCHING EGGS AND FOR SANITIZING INDUSTRIAL OR NON-FOOD CONTACT SURFACES SUCH AS EQUIPMENT FOR MIXING, PACKING, OR PACKAGING PRODUCTS, PRODUCT TRANSFER LINES, STORAGE TANKS, FLOORS, AND WALLS.

- USES NOT REGISTERED IN THE STATE OF CALIFORNIA: OIL PRODUCTION AND TRANSMISSION PIPELINES AND SYSTEMS, FRACTURING FLUIDS.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: This product is incompatible with many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc. The product can be stored and handled in baked phenolic -lined steel, polyethylene, stainless steel, or reinforced epoxy -plastic equipment. This product freezes at about -6°F (-21°C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage times (up to about 1 month), temperatures of up to 100 °F (37.8° C) can be tolerated but the preferred maximum storage temperature is about 80 °F (26.7 °C).
Handle in a well -ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.

PESTICIDE DISPOSAL: Open dumping is prohibited. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or your Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.
CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple or pressure rinse container (or equivalent) promptly after emptying.

(For containers 5 gallons or less)
Triple Rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times.

(For containers larger than 5 gallons) Clean container promptly after emptying. Triple Rinse as follows: Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times.

Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or other procedures approved by state and local authorities

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

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

August 26, 2015

DP BARCODE:	423412
MRID:	49475200 and 49475201
SUBJECT:	AVANCID GL 50M
REG. NO.:	74712-I
DOCUMENT TYPE:	Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
043901	111-30-8	Glutaraldehyde

TEST LAB:	Special Materials Company
SUBMITTER:	toXcel LLC
GUIDELINE:	Group A and B Product Chemistry
ORGANIZATION:	AD\PSB\CTT
REVIEWER:	Lynette T. Umez-Eronini
APPROVED BY:	Karen P. Hicks
APPROVED DATE:	August 26, 2015
COMMENT:	This product is for non-food use.

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

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

August 26, 2015

MEMORANDUM

SUBJECT:	Product Chemistry Review for EPA Reg. 74712-I Product Name: AVANCID GL 50M DP Barcode: 423412
FROM:	Lynette T. Umez-Eronini, Chemist Lynette T. Umez-Eronini Chemistry and Toxicology Team Product Science Branch Antimicrobials Division (7510P)
THRU:	Karen Hicks, Team Leader Chemistry and Toxicology Team Product Science Branch Antimicrobials Division (7510P)
TO:	John Hebert PM #33/Terria Northern Regulatory Management Branch I Antimicrobials Division (7510P)
Applicant:	Special Materials Company
CODE:	A560 Me-Too; New Manufacturing Use Product; Old AI; Selective Citation;
DATE DUE:	October 15, 2015

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Glutaraldehyde	50.0
Other Ingredients:	50.0
Total:	100.0

BACKGROUND:

The consultant, toXcel LLC, on behalf of the registrant, Special Materials Company has submitted an application for registration of an integrated manufacture-use product called AVANCID GL 50M. This product is used for formulating industrial bactericides and preservatives. The product is for non-food use.

The product chemist reviewed the following documents:

1. Cover letter from the registrant to EPA, September 22, 2014.
2. Basic Confidential Statement of Formula (CSF), September 12, 2014, July 15, 2015 and August 12, 2015.
3. Label, September 22, 2014.
4. Application for Pesticide Registration, September 22, 2014
5. Certification with Respect to Citation of Data, September 22, 2014.
6. Confidential Data Matrix, September 22, 2014, page 1/7 -3/7 pages.
7.

MRID	Citation
49485200	Special Materials Company (2014) Submission of Product Chemistry Data in Support of the Application for Registration of Avancid® GL 50M. Transmittal of 1 Study.
49475201	Goad, E. (2014) Avancid® GL 50M: Product Chemistry. Project Number: 38456, P801, 140108/4H. Unpublished study prepared by ToXcel, LLC. 162p.

FINDINGS:

1. Basic CSF, September 12, 2014 and July 15, 2015 are obsolete.
2. Basic CSF, August 12, 2015 supersedes all previous Basic CSFs.
3. The nominal concentration of the active ingredient on the Basic CSF, dated August 12, 2015 is consistent with the label.
4. All ingredients in this formulation are approved for use in pesticide formulations.
5. Certified limits of all the ingredients are within the EPA Standard Certified Limits.
6. Group A product chemistry data requirements applicable to end-use products have been met (see MRID 49475201 and Table A below).
7. Group B product chemistry data requirements applicable to end-use products have been met (see MRID 49475201 and Table B below), with the exception of the 830.6317 Storage Stability guideline.
8. MRIDs 41071401, 41070301, 41070501, and 41168703 fail to satisfy the 830.6317 Storage Stability guideline for the proposed product, which has a nominal concentration of 50% for the active ingredient. MRIDs 41071401,

41070301, and 41070501 address the said guideline for products having a nominal concentration of 45% for the active ingredient, which differ from the proposed product, and which thereby make it unacceptable for satisfying the 830.6317 Storage Stability guideline for the proposed product.

9. MRID 41168703 addresses a physical and chemical characteristics summary for AQUCAR 545 Water Treatment Microbiocide and fails to address the 830.6317 Storage Stability guideline.

CONCLUSION:

Product Science Branch of Antimicrobials Division finds the Basic CSF, dated August 12, 2015 to be acceptable and to supersede all previous Basic CSFs. Group A and Group B Product Chemistry data requirements have been met, with the exception of the 830.6317 Storage Stability guideline. The unmet data requirement must be submitted upon completion.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system Yes [X] No [ ]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system Yes [ ] No [X]
- If "ME-TOO," specify EPA Reg. No. of existing product:

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §180.940 and §180.950.

Yes [ ] No [X]

c. Physical state of product: Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient	NC(%)	LCL(%)	UCL(%)
Hypochlorous acid	50.0	48.5	51.5

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [X]

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	49475201
830.1600 Description of Materials	A	49475201
830.1620 Production Process[2]	NA	
830.1650 Formulation Process[3]	A	49475201
830.1670 Formation of Impurities[4]	A	49475201
830.1700 Preliminary Analysis[5]	A	49475201
830.1750 Certified Limits[6]	A	49475201
830.1800 Enforcement Analytical Method[7]	A	49475201
830.1900 Submittal of Samples	A	49475201

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA		
830.6303 Physical State	A	Liquid	49475201
830.6304 Odor	N/A		
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Not applicable, product does not contain any oxidizing or reducing agent.	49475201
830.6315 Flammability/ Flame Extension	A	Not applicable, does not contain any combustible liquids.	49475201
830.6316 Explodability	A	Not applicable, does not contain explosive materials.	49475201
830.6317 Storage Stability	N	The MRIDs are not applicable for this product, which has a nominal concentration of 50%.	41071401,41070301, 41070501; and 41168703
830.6319 Miscibility[1]	A	Not applicable, not to be diluted with petroleum solvents.	49475201
830.6320 Corrosion Characteristics	A	Not corrosive to product containers: EPA Glutaraldehyde RED (2007) indicates not applicable.	49475201
830.6321 Dielectric Breakdown Voltage	A	Cite MRID 44263601	49475201

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7000 pH[2]	A	Cite 3.76, PSL Study No. 38456 - Appendix	49475201
830.7050 UV/Visible Absorption	NA		
830.7100 Viscosity	A	20.15 cps @20°C 2 cps@ 20°C, Cited: EPA Glutaraldehyde RED (2007), pp. 3-4	49475201
830.7200 Melting Point/Melting Range	NA		
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	A	17 mm Hg @20°C, 11.5 mm Hg 20 mm Hg, Cited: EPA Glutaraldehyde RED (2007), pp. 3-4	
830.7370 Dissociation Constants in Water	NA		
830.7550/830.7560/830.7570 Partition Coefficient	NA		
830.7840/830.7860 Water Solubility	NA		
830.7950 Vapor Pressure	NA		

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water

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DATA MATRIX

Date **September 16, 2015**	EPA Reg. No./File Symbol: **74712-I**	**Page 1 of 7**
Applicant's/Registrant's Name & Address: **Special Materials Company 70 West 40th Street, 2nd Floor, New York, NY 10018**	Product **AVANCID® GL 50M**	

Active Ingredient: **GLUTARALDEHYDE**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY:					
830.1550	Product Identity and Composition	49475001	Special Materials Company	OWN	
830.1600	Description of Materials Used to Produce the Product	49475001	Special Materials Company	OWN	
830.1620	Description of Production Process	49475001	Special Materials Company	OWN	
830.1650	Description of Formulation Process	49475001	Not Formulated; see Production Process	N/A	
830.1670	Discussion of Formation of Impurities	49475001	Special Materials Company	OWN	
830.1700	Preliminary Analysis (TGAI; EP if by integrated production process)	49475001	Special Materials Company	OWN	
830.1750	Certification of Limits	49475001	Special Materials Company	OWN	
830.1800	Analytical Methods to Verify Certified Limits	49475001	Special Materials Company	OWN	
830.1900	Submittal of Samples (EP, TGAI, PAI)	49475001	Special Materials Company	OWN	
830.6302	Color (EP and TGAI)	49475001	Special Materials Company	OWN	
830.6303	Physical State (EP and TGAI)	49475001	Special Materials Company	OWN	
830.6304	Odor (EP and TGAI)	49475001	Special Materials Company	OWN	

Signature JMKelley	**Name and Title** J. Michael Kelley Authorized Representative	Date **September 16, 2015**

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Applicant's/Registrant's Name & Address: **Special Materials Company 70 West 40th Street, 2nd Floor, New York, NY 10018**	Product **AVANCID® GL 50M**	
Active Ingredient: **GLUTARALDEHYDE**		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY (Cont.)					
830.6313	Stability to temperature, metals, and metal ions (TGAI)	49475001		N/A	
830.6314	Oxidizing or Reducing Action (EP)	49475001		N/A	
830.6315	Flammability (EP)	49475001		N/A	
830.6316	Explodability (EP)	49475001		N/A	
830.6317	Storage Stability (EP)	41071401;41070301; 41070501;41168703	DOW (Formerly Union Carbide Corporation)	OLD	
830.6319	Miscibility (TGAI)	49475001		N/A	
830.6320	Corrosion Characteristics (EP)	41071401;41070301; 41070501;41168703	DOW (Formerly Union Carbide Corporation)	OLD	
830.6321	Dielectric Breakdown Voltage	44263601	DOW (Formerly Union Carbide Corporation)	OLD	
830.7000	pH (EP and TGAI)	49475001	Special Materials Company	OWN	
830.7050	UV / Visible Light Absorption (TGAI)	49475001		N/A	

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Applicant's/Registrant's Name & Address: **Special Materials Company** **70 West 40th Street, 2nd Floor, New York, NY 10018**	Product **AVANCID® GL 50M**	

Active Ingredient: **GLUTARALDEHYDE**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY (Cont.)					
830.7100	Viscosity (MUP and EP)			PL	** EPA Glutaraldehyde RED
830.7200	Melting Point (TGAI)	49475001		N/A	
830.7220	Boiling Point (TGAI)			PL	** EPA Glutaraldehyde RED
830.7300	Density, Bulk Density or Specific Gravity (EP and TGAI)	49475001	Special Materials Company	OWN	
830.7370	Dissociation Constant (TGAI or PAI)	49475001		N/A	
830.7520	Particle Size, Fiber Length, and Diameter Distribution	49475001		N/A	
830.7550; 830.7560; 830.7570	Octanol-Water Partition Coefficient (PAI)	40833301; 44210101	DOW (Formerly Union Carbide Corporation)	OLD	
830.7840	Water Solubility: Column Elution Method; Shake Flask Method (TGAI)	43151401	DOW (Formerly Union Carbide Corporation)	OLD	
830.7950	Vapor Pressure (TGAI or PAI)			PL	** EPA Glutaraldehyde RED

**Physical Chemical Properties from Glutaraldehyde RED (2007) page 3 and 4 were from public literature or derived using EPIsuite.

Signature	**Name and Title** J. Michael Kelley Authorized Representative	Date **September 16, 2015**

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Applicant's/Registrant's Name & Address: **Special Materials Company 70 West 40th Street, 2nd Floor, New York, NY 10018**	Product **AVANCID® GL 50M**	

Active Ingredient: **GLUTARALDEHYDE**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
TOXICITY:					
870.1100	Acute Oral Toxicity: Rat (EP and TGAI)	; 00164370	BASF Corporation	OLD	
870.1200	Acute Dermal Toxicity: Rat (EP and TGAI)	44691606	BASF Corporation	OLD	
870.1300	Acute Inhalation Toxicity: Rat (EP and TGAI)	164188; 164365	DOW (Formerly Union Carbide Corporation)	OLD	
870.2400	Primary Eye Irritation: Rabbit (EP)	117066	BASF	OLD	
870.2500	Primary Dermal Irritation (EP)	117063; 164460:	BASF; DOW (Formerly Union Carbide Corporation)	OLD	
870.2600	Dermal Sensitization (EP)	43330201	DOW (Formerly Union Carbide Corporation)	OLD	

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Applicant's/Registrant's Name & Address: **Special Materials Company** **70 West 40th Street, 2nd Floor, New York, NY 10018**	Product **AVANCID® GL 50M**	

Active Ingredient: **GLUTARALDEHYDE**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
TOXICITY (Cont.):					
870.3100	90-Day Sub-chronic Oral Toxicity – rodent (TGAI)	40908101 41089601 41773601	DOW (Formerly Union Carbide Corporation)	OLD	
870.3100	90-Day Sub-chronic Oral Toxicity – non-rodent (TGAI)	41480501	DOW (Formerly Union Carbide Corporation)	OLD	
870.3200	28-Day Dermal Toxicity	43259101	DOW (Formerly Union Carbide Corporation)	OLD	
870.3700	Teratogenicity - two species (TGAI)	42154101; 42154001	DOW (Formerly Union Carbide Corporation)	OLD	
870.3800	Reproduction, 2-generation (TGAI)	43189701	DOW (Formerly Union Carbide Corporation)	OLD	
870.5100; 870.5300; 870.5375; 870.5385; 870.5395	Genotoxicity (TGAI)	42035301; 42707301; 42851701; 43010201; 43211601; 43213401	DOW (Formerly Union Carbide Corporation)	OLD	Cited in the Risk Assessment: [Note: Varied results but EPA concluded that glutaraldehyde is not mutagenic or genotoxic.]

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Applicant's/Registrant's Name & Address: **Special Materials Company 70 West 40th Street, 2nd Floor, New York, NY 10018**	Product **AVANCID® GL 50M**	

Active Ingredient: **GLUTARALDEHYDE**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
ECOTOXICITY:					
850.2100	Avian acute oral (quail or mallard) (TGAI)	117070; 147584	BASF	OLD	
850.2200	Avian dietary LC_{50} (mallard and quail) (TGAI)	125519; 125520	DOW (Formerly Union Carbide Corporation)	OLD	
850.1075	Freshwater fish LC_{50} (trout and bluegill) (TGAI)	117076; 117077	BASF	OLD	
850.1010	Acute freshwater invertebrates (Daphnia) (TGAI)	125516; 43645701	DOW (Formerly Union Carbide Corporation)	OLD	
850.1730	Bioaccumulation in Fish (TGAI)			N/R	
850.1075; 850.1025 or 1055; and 850.1035 or 1045	Acute LC_{50} or EC_{50} with estuarine/marine fish, bivalve, and shrimp species (TGAI)	42753201; 42952101; 42952301; 43640301; 117074	DOW (Formerly Union Carbide Corporation); BASF	OLD	
850.1400	Fish early life stage study (TGAI)			N/R	Require to support all outdoor end-uses, but are generally not required to support highly corrosive end-use products
850.1300	Invertebrate life cycle study (TGAI)			N/R	
850.4400	Aquatic plant growth (TGAI)			N/R	
850.5400	Algal toxicity (TGAI or EP)			N/R	

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Applicant's/Registrant's Name & Address: **Special Materials Company 70 West 40th Street, 2nd Floor, New York, NY 10018**	Product **AVANCID® GL 50M**	
Active Ingredient **GLUTARALDEHYDE**		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
ENVIRONMENTAL FATE:					
835.2120	Hydrolysis (TGAI)	42691201; 42691701; 164374; 41906201	DOW (Formerly Union Carbide Corporation); BASF	OLD	
835.2240	Photodegradation in Water (TGAI)	164375; 42462601	BASF; Safe Materials Inc.	OLD	
835.1230	Leaching and Adsorption/Desorption or Soil Column Leaching (TGAI)	43195801	DOW (Formerly Union Carbide Corporation)	OLD	
835.1240	Soil Column Leaching (TGAI)	43195801	DOW (Formerly Union Carbide Corporation)	OLD	
835.4100	Aerobic Soil Metabolism (TGAI)			N/A	
835.4200	Anaerobic Soil Metabolism (TGAI)			N/A	
835.4300	Aerobic Aquatic Metabolism (TGAI)	43209601 43256101	DOW (Formerly Union Carbide Corporation)	OLD	
835.4400	Anaerobic Aquatic Metabolism (TGAI)	43266201	DOW (Formerly Union Carbide Corporation)	OLD	

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Applicant's/Registrant's Name & Address: **Special Materials Company 70 West 40th Street, 2nd Floor, New York, NY 10018**	Product **AVANCID® GL 50M**	

Active Ingredient: **GLUTARALDEHYDE**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			Special Materials Company	OWN	
			Special Materials Company	OWN	
			Special Materials Company	OWN	
			Not Formulated; see Production Process	N/A	
			Special Materials Company	OWN	
			Special Materials Company	OWN	
			Special Materials Company	OWN	
			Special Materials Company	OWN	
			Special Materials Company	OWN	
			Special Materials Company	OWN	
			Special Materials Company	OWN	
			Special Materials Company	OWN	

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Applicant's/Registrant's Name & Address: **Special Materials Company** **70 West 40th Street, 2nd Floor, New York, NY 10018**	Product **AVANCID® GL 50M**	
Active Ingredient: **GLUTARALDEHYDE**		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
				N/A	
				N/A	
				N/A	
				N/A	
			DOW (Formerly Union Carbide Corporation)	OLD	
				N/A	
			DOW (Formerly Union Carbide Corporation)	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	
			Special Materials Company	OWN	
				N/A	

Signature	**Name and Title** J. Michael Kelley Authorized Representative	Date **September 16, 2015**

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Date **September 16, 2015**

EPA Reg. No./File Symbol **74712-I**

Applicant's/Registrant's Name & Address: **Special Materials Company**
70 West 40th Street, 2nd Floor, New York, NY 10018

Product
AVANCID® GL 50M

Active Ingredient: **GLUTARALDEHYDE**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
				PL	** EPA Glutaraldehyde RED
				N/A	
				PL	** EPA Glutaraldehyde RED
			Special Materials Company	OWN	
				N/A	
				N/A	
			DOW (Formerly Union Carbide Corporation)	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	
				PL	** EPA Glutaraldehyde RED
[redacted]					

Signature	Name and Title	Date
J Kelley	J. Michael Kelley Authorized Representative	**September 16, 2015**

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DATA MATRIX

Date **September 16, 2015**	EPA Reg. No./File Symbol: **74712-I**	**Page 4 of 7**
Applicant's/Registrant's Name & Address: **Special Materials Company** **70 West 40th Street, 2nd Floor, New York, NY 10018**	Product **AVANCID® GL 50M**	
Active Ingredient: **GLUTARALDEHYDE**		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	
			BASF	OLD	
			BASF; DOW (Formerly Union Carbide Corporation)	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	

Signature	**Name and Title** J. Michael Kelley Authorized Representative	Date **September 16, 2015**

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date **September 16, 2015**	EPA Reg. No./File Symbol **74712-I**	**Page 5 of 7**
Applicant's/Registrant's Name & Address: **Special Materials Company** **70 West 40th Street, 2nd Floor, New York, NY 10018**	Product **AVANCID® GL 50M**	
Active Ingredient: **GLUTARALDEHYDE**		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			DOW (Formerly Union Carbide Corporation)	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	[redacted]

Signature	**Name and Title** J. Michael Kelley Authorized Representative	Date **September 16, 2015**

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DATA MATRIX

Date **September 16, 2015**	EPA Reg. No./File Symbol: **74712-I**	**Page 6 of 7**
Applicant's/Registrant's Name & Address: **Special Materials Company** **70 West 40th Street, 2nd Floor, New York, NY 10018**	Product **AVANCID® GL 50M**	
Active Ingredient: **GLUTARALDEHYDE**		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			BASF	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	
			BASF	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	
				N/R	
			DOW (Formerly Union Carbide Corporation); BASF	OLD	
				N/R	[redacted]
				N/R	
				N/R	
				N/R	

Signature	**Name and Title** J. Michael Kelley Authorized Representative	Date **September 16, 2015**

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DATA MATRIX

Date **September 16, 2015**	EPA Reg. No./File Symbol **74712-I**	**Page 7 of 7**
Applicant's/Registrant's Name & Address: **Special Materials Company** **70 West 40th Street, 2nd Floor, New York, NY 10018**	Product **AVANCID® GL 50M**	
Active Ingredient **GLUTARALDEHYDE**		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			DOW (Formerly Union Carbide Corporation); BASF	OLD	
			BASF; Safe Materials Inc.	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	
				N/A	
				N/A	
			DOW (Formerly Union Carbide Corporation)	OLD	
			DOW (Formerly Union Carbide Corporation)	OLD	

Signature	**Name and Title** J. Michael Kelley Authorized Representative	Date **September 16, 2015**

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

toXcel

Toxicology & Regulatory Affairs
7140 Heritage Village Plaza
Gainesville, VA 20155-3061
USA

Phone: (703) 754-0248 **Fax: (703) 310-6950**

49475000

September 22, 2014

Mr. Eric Miederhoff (PM #33)
c/o Document Processing Desk (REGFEE)
Antimicrobial Division (7510P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: Application for a New Manufacturing Use Product: ADVANCID® GL 50M
EPA File Symbol 74712-I

Dear Mr. Miederhoff

On behalf of the Special Materials Company, please find enclosed an application for the new manufacture use product, **ADVANCID® GL 50M** (EPA File Symbol 74712-I.). Along with this application package we have submitted separate application packages for five additional new glutaraldehyde products, one is identical, and the four others are each simple aqueous dilutions of this new source product. All registrations of these formulations are dependent upon this new source. The additional dependent products are:

EPA File Symbol	Product Name	Use	Glutaraldehyde
74712-O	ADVANCID® GL 50	EP	50% (undiluted)
74712-L	ADVANCID® GL 45M	MP	45%
74712-T	ADVANCID® GL 45	EP	45%
74712-A	ADVANCID® GL 25	EP	25%
74712-RN	ADVANCID® GL 15	EP	15%

To this end, we have included with this registration application package the following administrative and supporting product chemistry documentation:

- Cover Letter, EPA Form 8570-1, Transmittal Document,
- Confidential Statement of Formula (2 Copies)
- Public and Confidential Data Matrices
- EPA Form 8570-34 Certification with Respect to Citation of Data
- Label (5 hard copies) and one digital copy with Certification of Label Integrity Form
- Small Business Waiver Documentation
- PRIA Payment Receipt
- Product Chemistry Volume.

It is anticipated that this registration will be categorized for this product as a PRIA A560, "New manufacture use product, registered active ingredient, selective data citation" with a decision review time of one year. The dependent products would be coded to be associated with the same decision time.

If you have any questions or require additional information, please contact me by e-mail at Mike.Kelley@toxcel.com or by phone at (703) 754-0248 x 112.

Regards,

J. Michael Kelley, Ph.D.
Vice President
Authorized Representative

TRANSMITTAL DOCUMENT

1. **Name and Address of Submitter**

Special Materials Company
70 West 40th Street, 2nd Floor
New York, NY 10018

Authorized Representative
toXcel, LLC
7140 Heritage Village Plaza
Gainesville, VA 20155

2. **Regulatory Action**
Submission of Application for Registration for AVANCID® GL 50M
EPA Reg. No. (File Symbol) 74712-1

3. **Transmittal Date**
22 September 2014

4. **List of Submitted Studies/Documents**

MRID _____	**Admin**	Cover Letter, EPA Form 8570-1, Transmittal Document, Confidential Statement of Formula (2 Copies), Public and Confidential Data Matrices, EPA Form 8570-34 Certification with Respect to Citation of Data, Label (5 hard copies) and one digital copy with Certification of Label Integrity Form, Small Business Waiver Documentation, PRIA Payment Receipt
MRID **49475001**	**Volume 1**	Product Chemistry for AVANCID® GL 50M. OCSPP Guideline 830 series. Prepared by toXcel, LLC (2014).

Company Name/Representative:

Company Name: Special Materials Company

Authorized Representative: _____ 22 September 2014
J. Michael Kelley, PhD — Date
toXcel LLC
7140 Heritage Village Plaza
Gainesville, VA 20155
Email: Mike.Kelley@toxcel.com
Telephone: (703) 754-0248 x112
Fax: (703) 310-6950

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, DC 20460

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Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, And Telephone Number **Special Materials Company** **70 West 40th Street, 2nd Floor** **New York NY 10018**	EPA Registration Number/File Symbol **74712-~~K~~ I**
Active Ingredient(s) and/or representative test compound(s) **Glutaraldehyde**	Date **22 September 2014**
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) — **Antimicrobial**	Product Name **AVANCID® GL 50M**

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ 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.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it 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.

Signature	Date	Typed or Printed Name and Title
JMKelley	**22 Sept 2014**	**J. Michael Kelley** **Authorized Representative**

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version

Pay.gov

Receipt

Your payment is complete

Pay.gov Tracking ID: 25HMU3UD
Agency Tracking ID: 74682673012
Form Name: Pesticide Registration Improvement Act - Prepayment
Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card
Payment Amount: $4559.00
Transaction Date: 09/23/2014 02:08:13 PM EDT
Payment Date: 09/23/2014
Registration Number: 74712-L
Company Name: Special Materials Company
Company Number: 74712
Action Code: A560

Account Information

Card Holder Name: Adam Feldman
Billing Address: 70 West 40th Street
Billing Address 2:
City: New York
Country: United States
State/Province: NY
ZIP/Postal Code: 10018
Card Type: American Express
Card Number: **********2011

Email Confirmation Receipt

Confirmation Receipts have been emailed to:
irosenzweig@smc-global.com
Mike.Kelley@toxcel.com

Please read instructions on reverse si... before com... ng form. ... orm Appr... d. OMB No. 2070-0060. Approval expires 05-31-98

EPA	United States Environmental Protection Agency Washington, DC 20460	☒ Registration ☐ Amendment ☐ Other	OPP Identifier Number

Application for Pesticide – Section 1

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
74712-~~K~~ I	Eric Miederhoff	☒ None ☐ Restricted
4. Company/Product (Name) **Special Materials Company/ AVANCID® GL 50M**	PM# **PM-33**	

5. Name And Address Of Applicant *(Include ZIP Code)*
Special Materials Company
70 West 40th Street, 2nd Floor,
New York, NY 10018
☐ *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

☐ 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.)
Submission of new manufacturing-use product registration application.

Section III

1. Material This Product Will Be Packaged In:

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

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☒ Container	**55 gal**	☒ On Label ☒ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
☐ Lithographed
☒ 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)
J. Michael Kelley	**Authorized Representative for Special Materials Company**	**(703) 754-0248 x112**

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

2. Signature	3. Title
J. Kelley	**Authorized Representative for Special Materials Company**
4. Typed Name **J. Michael Kelley**	5. Date **September 22, 2014**

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

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

September 26, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-495702
EPA File Symbol or Registration Number: 74712-I
Product Name: AVANCID GL 50M
EPA Receipt Date: 24-Sep-2014
EPA Company Number: 74712
Company Name: SPECIAL MATERIALS COMPANY

J. MICHAEL KELLEY
TOXCEL, LLC
SPECIAL MATERIALS COMPANY
7140 HERITAGE VILLAGE PLAZA
GAINESVILLE, VA 20156-

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A560

NEW MANUFACTURING USE PRODUCT;OLD AI;SELECTIVE CITATION;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-0228.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL

EPA Registration #	Date Submitted to EPA	Electronic file name
74712-~~x~~ I	22 September 2014	074712-xxxxx.20140922.AVANCID GL50M.pdf

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

Signature

22 September 2014
Date

J. Michael Kelley, PhD
Name (typed)

Authorized Representative for Special Materials Company
Title

FOR OFFICIAL USE ONLY

FILE SYMBOL
REGISTRATION NO. 74712-I

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
09/25/14		

Do Not Write Comments, Formula, or Parts of Formula on This Envelope

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

Pages 47-49 - *Confidential Statements of Formula may be entitled to confidential treatment*