EPA Reg. No. 34370-2

Hull-Sanders, Helen

From: Saunders, Jennifer
Sent: Wednesday, August 1, 2018 9:58 AM
To: Hull-Sanders, Helen
Subject: FW: Firebug Insect Repellant Spray (34370-2

Jennifer Urbanski Saunders, Ph.D.
Senior Biologist/Entomologist
Invertebrate & Vertebrate Branch 1, S7218
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0156

From: Fertich, Elizabeth
Sent: Wednesday, May 30, 2018 1:50 PM
To: Saunders, Jennifer <Saunders.Jennifer@epa.gov>
Subject: FW: Firebug Insect Repellant Spray (34370-2

Here is what Erin had to say about fire retardant claims. Do you have any concerns from an efficacy perspective? I'm pretty sure we already talked about this and you said no, but wanted to confirm.

Thanks!

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Invertebrate and Vertebrate Branch 1 (IVB1)
Product Manager 4
fertich.elizabeth@epa.gov
703-347-8560

From: Koch, Erin
Sent: Tuesday, May 29, 2018 9:14 AM
To: Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Subject: RE: Firebug Insect Repellant Spray (34370-2

Privileged attorney-client communication*

Privileged attorney-client communication*

From: Fertich, Elizabeth
Sent: Thursday, May 24, 2018 12:34 PM
To: Koch, Erin <Koch.Erin@epa.gov>
Subject: FW: Firebug Insect Repellant Spray (34370-2

Hi Erin,

Privileged attorney-client communication*

Thanks,
Beth

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Invertebrate and Vertebrate Branch 1 (IVB1)
Product Manager 4
fertich.elizabeth@epa.gov
703-347-8560

From: WALTER TALAREK [mailto:wtalarek@comcast.net]
Sent: Tuesday, May 22, 2018 8:32 AM
To: Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Cc: Ligia Hernandez <lhernandez@wechem.com>
Subject: RE: Firebug Insect Repellant Spray (34370-2

Good morning Beth,

Thank you for getting back to me on this inquiry so quickly.

There are quite a few registered picaridin products containing the active ingredients at 20%, which are insect repellents. Most of these products contain claims that the product will not damage various type of fabrics. See, for example, EPA Reg. Nos. 4822-556, 121-99 and 54287-22. Moreover, WECHEM's Firebug Insect Repellent Spray is already approved for application to clothing. Therefore, the only real issue is whether the new claims regarding application to clothing treated with fire retardant and not harming this type of clothing can be added by fast-track amendment or whether the Agency would like data supporting the claims, thus making the action a PRIA action.

May I have your guidance on this issue?

Thank you.

Walt

Walter G. Talarek P.C.

Authorized Agent

WECHEM, Inc.

540-935-2344

On May 22, 2018 at 7:25 AM "Fertich, Elizabeth" <fertich.elizabeth@epa.gov> wrote:

Hi Walt,

I got your voicemail. Thanks for following up with an email. Do you have the registration number/s for the products that contain the claims you'd like to add to 34370-2. Are the use patterns, directions for use and percent active ingredient the same as your product? If so, the claims can most likely be added as a fast track amendment.

Thanks,

Beth

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Invertebrate and Vertebrate Branch 1 (IVB1)

Product Manager 4

fertich.elizabeth@epa.gov
703-347-8560

From: WALTER TALAREK [mailto:wtalarek@comcast.net]
Sent: Thursday, May 17, 2018 2:37 PM
To: Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Cc: Ligia Hernandez <lhernandez@wechem.com>
Subject: Firebug Insect Repellant Spray (34370-2

Hello Beth,

This is a follow-up to the voice mail that I left for you today.

WECHEM would like to add some optional marketing claims to its registration for Firebug Insect Repellent Spray, EPA Reg. No. 34340-2. This product contains 20% picaridin as the sole active ingredient. Generally, the claims that WECHEM would like to add revolve around use of the product on clothes made of various materials, such as wool, cotton, synthetic fibers, and impregnated with fire retardants (FR). Many of these claims or similar claims have been already approved for competitors' products. Specifically, some of the claims that WECHEM would like to the product's label are:

-Insect repellent may be applied to clothing

-Can be applied to clothing

-Spray on: shorts, pants, socks, hats

-May be used on clothing protected with fire retardant

-Insect repellent may be used on fire resistant (FR) clothing

-Insect repellent that may be used on clothing, including clothing treated with fire retardant

-For clothing and gear

-For use by workers exposed to insects around electric and power utilities

-Will not damage cotton, wool, nylon, acetate or spandex

-Will not damage clothing protected with fire retardant (after 30-minte drying time)

-Will not affect the protection properties of FR (Flame Resistant) clothing (after 30 minute drying time)

-Will not damage fabrics and plastics

-Passes ASTM F2621-12 Standard Practice Method

-Passes IEC 61482-1-1:2009 Live Working Method

My question for you is whether the above claims may be added to the product's label by fast-track amendment? If the answer is no and the action is a PRIA action, what data will be needed to support the above claims?

Thank you,

Walt Talarek

Walter G. Talarek PC

Authorized Agent

WECHEM, Inc.

540-935-2344

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

July 23, 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. WALTER TALAREK
WALTER G. TALAREK, PC
WECHEM, INC.
5153 ALLISON MARSHALL DRIVE
WARRENTON, VA 20187-8980

PRODUCT NAME: FIREBUG INSECT REPELLENT SPRAY
COMPANY NAME: WECHEM, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 34370-2
EPA RECEIPT DATE: 07/19/18

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 Registration Division, Risk Management Team 4, at 703-347-8560.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service {1022557T~

This package includes the following

- ○ New Registration
- ◉ Amendment

for Division

- ○ AD
- ○ BPPD
- ◉ RD

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

Risk Mgr. 4

Receipt No.	S- 1022557
EPA File Symbol/Reg. No.	34370-2
Pin-Punch Date:	7/19/2018

✓ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: $ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Dee Colley Date: 23 July 2018

Remarks:

DOCUMENTUM

LAW OFFICES OF
WALTER G. TALAREK, PC
5153 Allison Marshall Drive
Warrenton, VA 20187-8980

PHONE: 540-935-2344
FAX: 540-935-2344
E-MAIL: wtalarek@comcast.net

July 19, 2018

DELIVERED ELECTRONICALLY TO
CENTRAL DATA EXCHANGE (CDX)
Elizabeth Fertich, PM 4
Registration Division
c/o Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Re: Application for Amendment to Registration of Firebug Insect Repellent Spray; EPA Reg. No. 34370-2

Dear Ms. Fertich:

On behalf of Wechem, Inc. ("Wechem"), I am submitting the enclosed application for an amendment to its registration for "Firebug Insect Repellent Spray", EPA Reg. No. 34370-2. In essence this amendment would revise the product's master labeling, as follows:

1. Adds an alternate brand name, i.e., "Extreme Insect Repellent";
2. Lists all the product's alternate brand names;
3. Amends existing optional marketing claim #45 by adding the words "camping equipment" after the words "Won't damage";
4. Adds twenty-one (21) optional marketing claims;
5. Adds three (3) optional graphics;
6. Adds the words "returning indoors" to the sentence beginning "Wash hands thoroughly ... " in the Hazards to Humans section of the second Precautionary Statements section. See page 4. This revision makes this section consistent with the Hazards to Humans section on page 2;
7. Deletes the words "and clothing" following the words "Avoid contact with eyes" in the Hazards to Humans sections. The product is approved for application to clothing, and these words contradict the approval for this use site; and
8. Inserts a statement regarding use of the product on flame resistant clothing in the Directions for Use.

You and I communicated previously with regard to the permissibility of adding to the product's label certain marketing claims on use of the product on various types of fabrics and clothing treated with fire

DOCUMENTUM

and flame retardants. Please see my e-mails to you dated May 17, 2018, May 22, 2018, and May 24, 2018, and your responsive e-mails to me dated May 22, 2018, May 24, 2018, and May 30, 2018.

Two electronic copies of the revised labeling for this product have been submitted through the Agency's Central Data Exchange. One of these labels has the revisions being made by this amendment highlighted in yellow.

Expedited review is requested under FIFRA section 3(c)(3)(B)(i).

If you have any questions about this application, please feel free to contact me.

Sincerely yours,

Walter G. Talarek
Authorized Agent

Enclosure – Application for Amendment

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

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 34370-2	2. EPA Product Manager Elizabeth Fertich	3. Proposed Classification ☒ None ☐ Restricted
4. Company/Product (Name) Firebug Insect Repellent Spray	PM# 4	
5. Name and Address of Applicant *(Include ZIP Code)* Wechem, Inc. c/o Walter G. Talarek PC 5153 Allison Marshall Drive Warrenton, VA 20187-8980 ☐ *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. 34370-2 Product Name Firebug Insect Repellent Spray	

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.)

Amendment to product's registration which adds an alternate brand name and revises the product's label. See the enclosed letter to Ms. Elizabeth Fertich, PM 4, for the alternate brand name and a detailed explanation of the revisions being made to the product's label.

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" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	6, 10, 12, 14 fl. oz.	☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☒ Lithograph ☐ 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)
Walter G. Talarek	Authorized Agent	540-935-2344

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	3. Title Walter G. Talarek
4. Typed Name Walter G. Talarek	5. Date July 19, 2018

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

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 34370-2	2. EPA Product Manager Elizabeth Fertich	3. Proposed Classification ☒ None ☐ Restricted
4. Company/Product (Name) Firebug Insect Repellent Spray	PM# 4	
5. Name and Address of Applicant *(Include ZIP Code)* Wechem, Inc. c/o Walter G. Talarek PC 5153 Allison Marshall Drive Warrenton, VA 20187-8980 ☐ *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. 34370-2 Product Name Firebug Insect Repellent Spray	

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.)

Amendment to product's registration which adds an alternate brand name and revises the product's label. See the enclosed letter to Ms. Elizabeth Fertich, PM 4, for the alternate brand name and a detailed explanation of the revisions being made to the product's label.

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" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	6, 10, 12, 14 fl. oz.	☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☒ Lithograph ☐ 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)
Walter G. Talarek	Authorized Agent	540-935-2344

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	3. Title Walter G. Talarek
4. Typed Name Walter G. Talarek	5. Date July 19, 2018

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

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 3, 2017

G.K. (Ghona) Sangha, Ph.D.
Company Agent
WECHEM Inc.
5734 Susitna Drive
Harahan, LA 70123

Subject: Notification per PRN 98-10 – ABN
Product Name: FIREBUG INSECT REPELLENT SPRAY
EPA Registration Number: 34370-2
Application Date: 2/6/2017
Decision Number: 526001

Dear Dr. Sangha:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand name "*BUZZ UP Insect Repellent Spray*" has been added to the product record.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

For

Gene Benbow, Acting Product Manager 4
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

GKS International LLC

352 Via Sonador
Henderson, NV 89012

Mobile: 913-638-3968
Office/Fax: 702-444-0355

February 6, 2017

U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (RD) 7505P
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Kable (Bo) Davis (Product Manager 3)

Subject: **WECHEM Inc. (Company No. 34370) – "Notification for an Alternate Brand Name "BUZZ UP INSECT REPELLENT SPRAY" to the Master Label: FIREBUG Insect Repellent Spray (34370-2), Per PR Notice 98-10**

Dear Mr. Davis,

On behalf of **WECHEM Inc. (Company No. 34370)** of 5734 Susitna Drive, Harahan LA 70123, I am submitting this notification to add an additional brand name to the registered product FIREBUG Insect Repellent Spray (34370-2).

The Alternate Brand Name is: "**BUZZ UP INSECT REPELLENT SPRAY**". The product is identical to **FIREBUG Insect Repellent Spray (34370-2)**.

Per PR Notice 98-10." C "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

The notification includes the following:

1) Cover latter
2) Application for Notification: Form 8570-1
3) Brand Name 'BUZZ UP INSECT REPELLENT SPRAY' label ~~-5~~ 2 copies
4) Master Label (FIREBUG Insect Repellent Spray) with changes highlighted
5) Market Label for BUZZ UP MOSKITO REPELLENT SPRAY

We would appreciate an expedited review so that we can pursue state registrations and able to send the Market Label with our registration application.

Please feel free to call me if you have any questions.

Thanks you.

Sincerely,

G.K. (Ghona) Sangha, Ph.D.
GKS International, LLC
352 Via Sonador
Henderson, NV 89012
Phone: 913-638-3968; Fax: 702-444-0355
Email: sangha8@roadrunner.com

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 23, 2018

Walter Talarek, PC
WECHEM, INC.
5153 Allison Marshall Dr
Warrenton VA 20187-8980

Subject: Label Amendment – Adding an alternate brand name and marketing claims
Product Name: FIREBUG INSECT REPELLENT SPRAY
EPA Registration Number: 34370-2
Application Date: 07/19/2018
Decision Number: 543040

Dear Mr. Talarek:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Helen Hull-Sanders by phone at 703-347-0243, or via email at hull-sanders.helen@epa.gov.

The alternate brand name EXTREME INSECT REPELLENT has been added to the product record.

Sincerely,

Elizabeth Fertich
Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Text in braces { } is explanatory or informational and will not appear on the labeling
Text in brackets [ ] is optional and may or may not appear on the labeling
Text in parentheses ( ) will appear on the labeling

WECHEM® Engineered Chemistries SUPERIOR SOLUTIONS

Rev. 10/9/18

{Language for Front Panel of Label for Container and Peel Back Label}

FIREBUG INSECT REPELLENT SPRAY

[ABN: BUZZ UP INSECT REPELLENT SPRAY]
[ABN: FIREBUG™]
[ABN: FIREBUG ALL-FAMILY INSECT REPELLENT SPRAY]
[ABN: FIREBUG INSECT REPELLENT]
[ABN: FIREBUG MOSQUITO & TICK REPELLENT]
[FIREBUG TICK AND INSECT REPELLENT]
[ABN: EXTREME INSECT REPELLENT]

ACCEPTED
10/23/2018
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 34370-2

[Insect Repellent Spray] [All-Family Insect Repellent Spray] [Tick and Insect Repellent] [Mosquito & Tick Repellent] {if applicable} **[Continuous Spray] [Pump Spray]**
[Long-lasting Effective 12 hour Mosquito [& Tick] Protection]

ACTIVE INGREDIENTS:
Picaridin, 1-Methylpropyl-2-(2-hydroxyethyl)-1-piperidine carboxylate.....20%
OTHER INGREDIENTS:.....80%
TOTAL 100.0%

[Repels Mosquitoes that may transmit West Nile Virus [For up to 12 hours [of protection]]
[Repels Mosquitoes that may transmit Zika Virus [For up to 12 hours [of protection]]
[Repels Mosquitoes that may transmit Dengue Fever [For up to 12 hours [of protection]]
[Repels Mosquitoes that may spread Zika Virus, West Nile Virus, or Dengue Fever [For up to 12 hours [of protection]]

[And][&] [Repels Ticks that may carry Lyme Disease [For up to 12 hours [of protection]]

[REPELS] Biting flies, stable flies, black flies, gnats, chiggers; [&] sand flies and Scottish biting midges for up to 8 hours.]

[Long-lasting, 12 hour effective protection from mosquitoes]
[including mosquitoes that may be carrying [And] [&] [that may transmit] West Nile Virus.]
[including mosquitoes that may be carrying [And] [&] [that may transmit] Zika Virus.]
[including mosquitoes that may be spreading [And] [&] [that may transmit] =Dengue Fever]
[including mosquitoes that may be spreading [And] [&] [that may transmit] Zika, West Nile Virus, or Dengue Fever]
[including mosquitoes that may be carrying [And] [&] [that may transmit] Chikungunya, Dengue, and Zika]

[Long-lasting, 12 hour effective protection from ticks, including ticks carrying Lyme Disease]

[[Repels] [and protects against] Mosquitoes that may transmit Zika Virus, West Nile Virus, Dengue Fever, Chikungunya and Ticks that may carry Lyme Disease for up to 12 hours.]

KEEP OUT OF REACH OF CHILDREN.

CAUTION: Stop and read this entire label before use.

[See [card] [behind peel back] for additional precautionary statements.]
IN CASE OF EMERGENCY, CALL: 1-800-535-5053

Net Contents: [_] [fluid] oz. [_] ml

[Pump Spray] {or} [Continuous Spray]

[Contains Picaridin] [www.wechem.com/products/Firebug_Firebug.aspx] {Registrant may insert one or more graphics from page 7}

{Language for Back Panel of Label for Container, Card and Peel Back Label}

PRECAUTIONARY STATEMENTS
CAUTION. Hazards to Humans: Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash hands thoroughly with soap and water after handling, returning indoors, and before eating, drinking, chewing gum, using tobacco, or using the toilet.
{Note: First Aid grid format used if market label space permits: otherwise a paragraph format will be used}

FIRST AID
IF IN EYES:
- Hold eye open and rinse gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first five (5) minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:
- Call a physician or poison control center immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a Poison Control Center or a doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-535-5053 for emergency medical information.

Text in braces { } is explanatory or informational and will not appear on the labeling
Text in brackets [ ] is optional and may or may not appear on the labeling
Text in parentheses ( ) will appear on the labeling

WECHEM® Engineered Chemistries SUPERIOR SOLUTIONS

Rev. 10/9/18

STORAGE & DISPOSAL

Pesticide Storage: Store this product in a cool, dry (preferably locked) place, out of reach of children. Keep away from heat, sparks, and open flame.

Pesticide Disposal and Container Handling: Non-refillable container. Do not reuse or refill this container. Do not puncture or incinerate! **If Empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PHYSICAL HAZARDS

FLAMMABLE. Do not use or store near heat sources, sparks or open flame. [{container specific} Contents under pressure do not puncture or incinerate container.] [{container specific} Exposure to temperature above 130°F may cause bursting.] Do not smoke while applying.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on [this product label] {or} [all labels and packaging {where size requires peel-back}]. [Remove protective cap.] Hold [can] 4 to 6 inches from skin while spraying, keeping nozzle pointed away from face. Slightly moisten skin or clothing with a slow sweeping motion. **FOR USE ON: [FR] [Flame Resistant] [FRC] [clothing]: Allow product to dry for 30 minutes before being exposed to areas of energized equipment.** Use just enough repellent to cover exposed skin and/or clothing. Do not use under clothing. Do not spray directly on face [or enclosed areas]. [Do not inhale.] Do not apply near eyes and mouth. Spray on hands first, and then apply sparingly to face, neck and around ears, avoiding your eyes. Do not apply over cuts, wounds, or irritated skin, and do not apply to excessively sunburned skin. Do not apply to children's hands. Do not allow children to handle this product. When using on children, apply to your own hands and then put it on the child. Excessive amounts or frequent reapplication is unnecessary. Avoid over-application of this product. Do not exceed more than 2 applications per day. Apply sparingly around ears. After returning indoors, wash treated skin with soap and water [and double-check yourself and other family members for ticks.] Wash treated clothing before wearing it again. Use of this product may cause skin reactions in rare cases. If you suspect a reaction to this product, discontinue use, wash treated skin and call your Poison Control Center. If you go to a doctor, take this product with you.

WARRANTY DISCLAIMER: Buyer assumes all responsibility for safety and use not in accordance with directions.

[EPA Reg. No.:_____] [EPA Est. No.:_____] [Batch Lot No.:_____]

Wechem, Inc. {5734 Susitna Dr.] Harahan, LA 70123 **{Registrant may insert one or more graphics from page 7}**

Text in braces { } is explanatory or informational and will not appear on the labeling
Text in brackets [ ] is optional and may or may not appear on the labeling
Text in parentheses ( ) will appear on the labeling

WECHEM® Engineered Chemistries SUPERIOR SOLUTIONS

Rev. 10/9/18

{For Very Small Packaging: When container size does not allow a peel back label, product will always be sold attached to a card with the complete "back panel" labeling from above, and these very small sizes will have the following language on the immediate container}

FIREBUG INSECT REPELLENT SPRAY

{Alternate Brand Name may be substituted} [BUZZ UP INSECT REPELLENT SPRAY] [FIREBUG] [FIREBUG INSECT REPELLENT] [FIREBUG ALL-FAMILY INSECT REPELLENT SPRAY] [FIREBUG TICK AND INSECT REPELLENT] [FIREBUG MOSQUITO & TICK REPELLENT] [EXTREME INSECT REPELLENT]

ACTIVE INGREDIENTS:

Picaridin, 1-Methylpropyl-2-(2-hydroxyethyl)-1-piperidine carboxylate.....20%

OTHER INGREDIENTS:.....80%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN.

CAUTION: Stop and read all information on card for additional important precautionary statements before use.

Net Contents: [_] [fluid] oz. [_] ml [Pump Spray] [Continuous Spray]
Wechem, Inc., Harahan, LA 70123
[Questions?] Call 504-733-1152
[EPA Reg. No.:_____] [EPA Est. No.:_____] **[Batch Lot No.:_____]**

PRECAUTIONARY STATEMENTS

CAUTION: Hazards to Humans: Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash hands thoroughly with soap and water after handling, returning indoors, and before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID: IF IN EYES: · Hold eye open and rinse gently with water for 15-20 minutes · Remove contact lenses, if present, after five minutes, and then continue rinsing. · Call a poison control center or doctor for treatment advice. **IF SWALLOWED:** · Call a physician or poison control center immediately for treatment advice. · Have person sip a glass of water if able to swallow. · Do not induce vomiting unless told to by Poison Control Center or doctor. · Do not give anything to an unconscious person. Have the product container or label with you when calling or going for treatment. You may also contact 1-800-535-5053 for emergency medical information.

STORAGE & DISPOSAL

Pesticide Storage: Store this product in a cool, dry (preferably locked) place, out of reach of children. Keep away from heat, sparks, and open flame.

Pesticide Disposal and Container Handling: Non-refillable container. Do not reuse or refill this container. Do not puncture or incinerate! **If Empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Text in braces { } is explanatory or informational and will not appear on the labeling
Text in brackets [ ] is optional and may or may not appear on the labeling
Text in parentheses ( ) will appear on the labeling

WECHEM® Engineered Chemistries Superior Solutions

Rev. 10/9/18

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on all labels and all packaging. [Remove protective cap.] [{Spray delivery} Hold 4 inches from skin while spraying keeping nozzle pointed away from face and slightly moisten area with a slow sweeping motion. Do not spray directly on face, spray on hands first and then rub on face.] Apply sparingly around ears. Do not apply to the hands of small children. Avoid contact with eyes, mouth, cuts, wounds, or irritated skin. Do not apply to excessively sunburned skin. Do not apply under clothing.

WARRANTY DISCLAIMER: Buyer assumes all responsibility for safety and use not in accordance with directions.

{Everything between the brackets below is Optional Selling Copy, and according to container size and type may or may not be placed on the front panel, back panel, card or peel back label}

[

{1.} Aerosol-like Spray
{2.} Continuous Spray
{3.} No Rubbing required
{4.} One Touch Pump
{5.} Easy Application
{6.} No Mess
{7.} Convenient, no mess, no rub protection
{8.} Spray Upside Down
{9.} Level {for packages with clear indicator of amount remaining}
{10.} Running Low {for packages with clear indicator of amount remaining}
{11.} Twist Close Cap
{12.} Airplane carry-on size
{13.} TSA {approved] travel size
{14.} TSA [approved] carry-on size
{15.} Convenient Travel Size
{16.} Convenient Airplane Travel Size
{17.} Airplane carry-on
{18.} Carry on size
{19.} Protects against ticks and mosquitoes for up to 12 hours, and biting flies, stable flies, black flies, gnats, chiggers, and sand flies for up to 8 hours
{20.} For up to 12 hours of protection against mosquitoes and ticks, and up to 8 hours of protection against biting flies, stable flies, black flies, gnats, chiggers, sand flies and Scottish biting midges.
{21.} Use with confidence on the whole family
{22.} And your family will want to use it, too
{23.} Not oily, greasy or sticky
{24.} Cool Spray

Text in braces { } is explanatory or informational and will not appear on the labeling
Text in brackets [ ] is optional and may or may not appear on the labeling
Text in parentheses ( ) will appear on the labeling

{25.} Spray (and) ('n) go
{26.} Non-oily
{27.} Does not damage plastic
{28.} Won't Damage Fishing Lines, Plastics or other Synthetic Materials [Fisherman's Formula]
{29.} [Won't Damage Fishing Lines, Plastics or other Synthetic Materials [Gear Safe]]
{30.} Unscented [Repels bug(s), not people]
{31.} Pocket Size
{32.} Repels [mosquitoes] [ticks] [mosquitoes and ticks] for up to 12 hours, and biting flies, stable fies, black flies, gnats, chiggers, sand flies, and Scottish biting midges for up to 8 hours.
{33.} Non-Staining
{34.} Quick Drying
{35.} Dye-Free
{36.} [Not your standard aerosol:]
a. Apply upside down without worry
b. Product delivery is the same regardless of the position the can is held during spraying
c. May be sprayed upright, inverted, or at any angle
d. Constant pressure of application – won't lose pressure as can empties
e. Same product delivery from the initial spray to the last spray
f. Continuous Spray [Insect Repellent] [Mosquito Repellent]
g. Quick and Even Coverage
h. No Rub, No Hassle
i. No chilling effect compared to a standard aerosol
j. No pumping motion needed
{37.} Pleasant [Fragrance] [Scent]
{38.} Unscented
{39.} Feels light and clean
{40.} No one will know you're wearing it
{41.} You won't smell it
{42.} You'll forget you're wearing it
{43.} Won't damage [fishing line, gun barrel, plastic lenses] [sporting equipment] [camping equipment]
{44.} Clean, dry feel
{45.} Light, Clean
{46.} Passes ASTM F2621-12 Standard Practice Method (Electric Arc Test)
{47.} Passes IEC 61482-1-1: 2009 Live Working Method (Electric Arc Test)
{48.} Insect repellent to be used on general clothing, [FR] [Flame Resistant] [FRC] clothing.
{49.} Will not affect the protection properties of FR (Flame Resistant) clothing (After 30 minute drying time).
{50.} For Clothing & Gear
{51.} For use on general clothing, [FR] [Flame Resistant] [FRC] clothing, and skin

Text in braces { } is explanatory or informational and will not appear on the labeling
Text in brackets [ ] is optional and may or may not appear on the labeling
Text in parentheses ( ) will appear on the labeling

WECHEM® Engineered Chemistries SUPERIOR SOLUTIONS

Rev. 10/9/18

{52.} For use by any worker exposed to insects around electric and power utilities.
{53.} Spray on: shirts, pants, socks, hats, boots and shoes.
{54.} Will not damage fabrics and plastics.
{55.} Patent Pending Formulation Application {Patent #_____ for use on FR clothing}
{56.} Will not adversely affect [Rubber Lineman's gloves] [Rubber Goods]
{57.} Passes ASTM D120 AC Electrical Proof Test
{58.} [Outdoor] [Worker] [Workman's] [Utility Worker] [Utility Worker's] formula.
{59.} [Sportman] [Sportman's] [Outdoor] formula.
{60.} [Outdoor] [12 Hour] protection.
{61.} 12 Hour protection for Mosquitoes and Ticks.
{62.} Performed ASTM D6413 (Vertical Flame Test) with 0 [Zero] Afterflame
]
{OPTIONAL GRAPHICS}
[

]

Hull-Sanders, Helen

From: WALTER TALAREK <wtalarek@comcast.net>
Sent: Thursday, October 11, 2018 8:53 AM
To: Hull-Sanders, Helen
Cc: Fertich, Elizabeth; IVB1; Ligia Hernandez
Subject: RE: label comments for 34370-2

Thank you, Helen. Enjoy your day.

Walt

On October 11, 2018 at 6:57 AM "Hull-Sanders, Helen" <hull-sanders.helen@epa.gov> wrote:

Good morning Walt,

I have submitted the label and the decision letter for Beth's final review. I do not know when she will be able to finalize her review.

Thank you,

Helen

Helen Hull-Sanders, Ph.D.

Environmental Protection Agency

Office of Pesticide Programs

Registration Division

Invertebrate & Vertebrate Branch

(703) 347-0243

hull-sanders.helen@epa.gov

From: WALTER TALAREK [mailto:wtalarek@comcast.net]
Sent: Tuesday, October 9, 2018 2:29 PM
To: Hull-Sanders, Helen <hull-sanders.helen@epa.gov>
Cc: Fertich, Elizabeth <fertich.elizabeth@epa.gov>; IVB1 <IVB1@epa.gov>; Ligia Hernandez <lhernandez@wechem.com>
Subject: RE: label comments for 34370-2

Hello Helen,

Thank you for the quick turnaround on your label review and your comments. All of revisions that your requested for the product's label have been made. Please see the attached label (both clean and highlighted copies).

Please let me know if any further revisions are needed. Also, would you please provide an estimate (non-binding) on when you think that Beth will make a decision on this action?

Best wishes,

Walt

Walter G. Talarek

Authorized Agent

WECHEM, Inc.

On October 9, 2018 at 12:33 PM "Hull-Sanders, Helen" <hull-sanders.helen@epa.gov> wrote:

Good afternoon Walter,

Yes, I did get your email and met with Beth late last week to discuss the label. Attached are the label comments from that meeting. Please let me know if you have any questions.

Sincerely,

Helen

From: WALTER TALAREK [mailto:wtalarek@comcast.net]
Sent: Monday, October 8, 2018 4:52 PM
To: Hull-Sanders, Helen <hull-sanders.helen@epa.gov>
Cc: Fertich, Elizabeth <fertich.elizabeth@epa.gov>; IVB1 <IVB1@epa.gov>; Ligia Hernandez <lhernandez@wechem.com>
Subject: Re: label comments for 34370-2

Hello Helen,

I would like to confirm that you have received my e-mail of September 28th (please see below), and if so, whether you have any questions or comments? Also, would you please let me know when you anticipate that Beth will make a decision on this action.

Thank you.

Walt Talarek

Walter G. Talarek PC
Authorized Agent

WECHEM, Inc.

540-935-2344

On September 28, 2018 at 2:29 PM WALTER TALAREK <wtalarek@comcast.net> wrote:

Hello Helen,

Please find attached, a revised label (both highlighted and clean copies) which responds to your comments. The revisions that have been made in response to your comments are highlighted in yellow. Please note that several revisions have been made in braces to explain the structure for the product's labeling, particularly for small containers. Two of the revisions that you requested have not been made, as follows:

1. Both the optional claims "[Pump Spray]" and" [Continuous Spray]" have been retained. Although the original application for registration was based on the product being a me-too to EPA Reg. No. 39967-53, during the application process, WECHEM submitted data for a bag-on valve (BOV) container, and the Agency approved both pump spray and BOV containers for this product. Please see MRID 49933801; and

2. The claim "DEET Alternative" claim has been retained. This claim is not a direct claim about the absence of an ingredient.

Also, although you did not request any revisions to the fire retardant (FR) claims, you did highlight them for some reason. Please note that prior to submitting this amendment, WECHEM contacted Beth Fertich, and she did indicate that FR claims would be acceptable, data supporting the claims would not need to be submitted, and the amendment would be a fast-track amendment.

When do you anticipate that a decision will be made on this action?

If you need further information to complete your review of the action, please feel free to contact me.

Thank you.

Walt Talarek

Walter G. Talarek PC
Authorized Agent

WECHEM, Inc.

540-935-2344

On September 27, 2018 at 7:41 AM "Hull-Sanders, Helen" <hull-sanders.helen@epa.gov> wrote:

Good morning,

Attached please find label comments for 34370-2. Please let me know if you have any questions.

Sincerely,

Helen

Helen Hull-Sanders, Ph.D.

Environmental Protection Agency

Office of Pesticide Programs

Registration Division

Invertebrate & Vertebrate Branch

(703) 347-0243

hull-sanders.helen@epa.gov

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 34370/34370-2	2. EPA Product Manager Kable Bo Davis	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name) WECHEM Inc./BUZZ UP Insect Repellent Spray	PM# 3	
5. Name and Address of Applicant *(Include ZIP Code)* 5734 Susitna Drive Harahan , LA 70123 ☐ *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. 34370-2 Product Name FIREBUG Insect Repellent Spray	

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.)

WECHEM Inc. would like to use an Alternate Brand Name for their registered product FIREBUG Insect Repellent Spray (34370-2). The proposed Alternate Brand Name is 'BUZZ UP INSECT REPELLENT SPRAY'.

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" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☒ Container	0.5-16 Fl. Oz.	☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☒ Lithograph ☒ 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)
G K (Ghona) Sangha	Company Agent	913-638-3968

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 GKSangha	3. Title Company Agent
4. Typed Name G K (Ghona) Sangha	5. Date February 6, 2017

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

PROCESSING REQUEST

Reg # 34370-2 **Decision #517811**

Description: New product with new CSF.

Electronic Label & Letter (see PPLS):	OR	**Non Electronic Label & Letter** (Scanning required):
☐ Dated: 10/5/2016		☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

X New CSF(s) Dated: 6/23/2016

☐ 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: Jen Gaines

Division: RD

Phone: 305-5967 **Date: 10/6/2016**

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
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:
34370-2	10/5/16

Term of Issuance:
Unconditional

Name of Pesticide Product:
Firebug Insect Repellent Spray

Name and Address of Registrant (include ZIP Code):

Ghona Sangha, Ph.D.
Agent for WeChem Inc.
5734 Susitna Dr.
Harahan, LA 70123

Note: Changes in labeling 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 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 unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

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

Signature of Approving Official:

Laura Bacon, Acting Product Manager 4
Invertebrate & Vertebrate Branch, Registration Division (7505P)

Date: 10/5/16

EPA Form 8570-6

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

    - Revise the EPA Registration Number to read, "EPA Reg. No. 34370-2."

3. Submit one copy of the revised 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 these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. 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 06/23/2016
- Alternate CSF 1 dated 06/23/2016
- Alternate CSF 2 dated 06/23/2016

If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

Laura N. Bacon, Acting Product Manager 4
Invertebrate & Vertebrate Branch 1 (IVB1)
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

WECHEM® Engineered Chemistries
SUPERIOR SOLUTIONS

Rev. 10/5/16

{Front Panel Container Labels and Cards}

FIREBUG™

[Insect Repellent Spray]{or} [All-Family Insect Repellent Spray][Tick and Insect Repellent] [Mosquito & Tick Repellent] {if applicable}[**[Continuous Spray][Pump Spray]**
[Long-lasting Effective Mosquito[& Tick] Protection]

ACTIVE INGREDIENTS:
Picaridin, 1-Methylpropyl-2-(2-hydroxyethyl)-1-piperidine carboxylate.....20%
OTHER INGREDIENTS:.....80%
TOTAL 100.0%

[Repels Mosquitoes that may transmit West Nile Virus [For up to 12 hours [of protection]]
[Repels Mosquitoes that may transmit Zika Virus [For up to 12 hours [of protection]]
[Repels Mosquitoes that may transmit Dengue Fever [For up to 12 hours [of protection]]
[Repels Mosquitoes that may spread Zika Virus, West Nile Virus, or Dengue Fever [For up to 12 hours [of protection]]

[And][&] [Repels Ticks that may carry Lyme Disease [For up to 12 hours [of protection]]

[REPELS] Biting flies, stable flies, black flies, gnats, chiggers; [&] sand flies and Scottish biting midges for up to 8 hours.]

[Long-lasting, 12 hour effective protection from mosquitoes]
[including mosquitoes that may be carrying [And] [&][that may transmit] West Nile Virus.]
[including mosquitoes that may be carrying [And] [&][that may transmit] Zika Virus.]
[including mosquitoes that may be spreading [And] [&][that may transmit] Dengue Fever]
[including mosquitoes that may be spreading [And] [&][that may transmit] Zika, West Nile Virus, or Dengue Fever]
[including mosquitoes that may be carrying [And] [&][that may transmit] Chikungunya, Dengue, and Zika]

[Long-lasting, 12 hour effective protection from ticks, including ticks carrying Lyme Disease]

KEEP OUT OF REACH OF CHILDREN.
CAUTION: Stop and read this entire label before use.
[See[card] [behind peel back] for additional precautionary statements.]
IN CASE OF EMERGENCY, CALL: 1-800-535-5053

Net Contents: [_] [fluid] oz. [_] ml

[Pump Spray] {or} [Continuous Spray]

[Contains Picaridin] [www.wechem.com/products/Firebug_Firebug.aspx] {icons}

ACCEPTED
10/05/2016
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under
EPA Reg. No. 34370-2

{Back Panel Container Labels and Cards and Peel Backs}

PRECAUTIONARY STATEMENTS

CAUTION. Hazards to Humans: Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash hands thoroughly with soap and water after handling, returning indoors, and before eating, drinking, chewing gum, using tobacco, or using the toilet.

{Note: First Aid grid format used if market label space permits: otherwise a paragraph format will be used}

FIRST AID

IF IN EYES:

- Hold eye open and rinse gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first five (5) minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a physician or poison control center immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a Poison Control Center or a doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-535-5053 for emergency medical information.

STORAGE & DISPOSAL

Pesticide Storage: Store this product in a cool, dry (preferably locked) place, out of reach of children. Keep away from heat, sparks, and open flame.

Pesticide Disposal and Container Handling: Non-refillable container. Do not reuse or refill this container. Do not puncture or incinerate! **If Empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PHYSICAL HAZARDS

FLAMMABLE. Do not use or store near heat sources, sparks or open flame. [{container specific} Contents under pressure do not puncture or incinerate container.] [{container specific} Exposure to temperature above 130°F may cause bursting.] Do not smoke while applying.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on [this product label] {or} [all labels and packaging {where size requires peel-back}]. [Remove protective cap.] Hold [can] 4 to 6 inches from skin while spraying, keeping nozzle pointed away from face. Slightly moisten skin or clothing with a slow sweeping motion. Use just enough repellent to cover exposed skin and/or clothing. Do not use under clothing. Do not spray directly on face [or enclosed areas]. [Do not inhale.] Do not apply near eyes and mouth. Spray on hands first, and then apply sparingly to face, neck and around ears, avoiding your eyes. Do not apply over cuts, wounds, or irritated skin, and do not apply to excessively sunburned skin. Do not apply to

children's hands. Do not allow children to handle this product. When using on children, apply to your own hands and then put it on the child. Excessive amounts or frequent reapplication is unnecessary. Avoid over-application of this product. Do not exceed more than 2 applications per day. Apply sparingly around ears. After returning indoors, wash treated skin with soap and water [and double-check yourself and other family members for ticks.] Wash treated clothing before wearing it again. Use of this product may cause skin reactions in rare cases. If you suspect a reaction to this product, discontinue use, wash treated skin and call your Poison Control Center. If you go to a doctor, take this product with you.

WARRANTY DISCLAIMER: Buyer assumes all responsibility for safety and use not in accordance with directions.

[EPA Reg. No.:_____] [EPA Est. No.:_____] [Batch Lot No.:_____]

Wechem, Inc. {5734 Susitna Dr.] Harahan, LA 70123 **{ICONS}**

{Very Small Packaging: When size does not allow a peel back, product will <u>always be sold attached to a card with the complete "back panel" labeling</u> from above and these very small sizes will have the following on the immediate packaging--- Please see Draft Label enclosed as representative of the "very small packaging"}

FIREBUG

{Alternate Brand Names}[FIREBUG]{FIREBUG INSECT REPELLENT][FIREBUG TICK AND INSECT REPELLENT][FIREBUG MOSQUITO & TICK REPELLENT]

ACTIVE INGREDIENTS:

Picaridin, 1-Methylpropyl-2-(2-hydroxyethyl)-1-piperidine carboxylate.....20%

OTHER INGREDIENTS:.....80%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN.

CAUTION: Stop and read all information on card for additional important precautionary statements before use.

Net Contents: [_] [fluid] oz. [_] ml [Lotion] {or} {Pump Spray} [Continuous Spray]

Wechem, Inc., Harahan, LA 70123

[Questions?] Call 504-733-1152

[EPA Reg. No.:_____] [EPA Est. No.:_____] **[Batch Lot No.:_____]**

PRECAUTIONARY STATEMENTS

CAUTION: Hazards to Humans: Causes moderate eye irritation. Avoid contact with eyes. Wash hands thoroughly with soap and water after handling, and before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID: IF IN EYES: · Hold eye open and rinse gently with water for 15-20 minutes · Remove contact lenses, if present, after five minutes, and then continue rinsing. · Call a poison control center or doctor for treatment advice. **IF SWALLOWED:** · Call a physician or poison control center immediately for treatment advice. · Have person sip a glass of water if able to swallow. · Do not induce vomiting unless told to by Poison Control Center or doctor. · Do not give anything to an unconscious person. Have the product container or label with you when calling or going for treatment. You may also contact 1-800-535-5053 for emergency medical information.

STORAGE & DISPOSAL

Pesticide Storage: Store this product in a cool, dry (preferably locked) place, out of reach of children. Keep away from heat, sparks, and open flame.

Pesticide Disposal and Container Handling: Non-refillable container. Do not reuse or refill this container. Do not puncture or incinerate! **If Empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

DIRECTIONS FOR USE It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on all labels and all packaging. [Remove protective cap.] [{Spray delivery} Hold 4 inches from skin while spraying keeping nozzle pointed away from face and slightly moisten area with a slow sweeping motion. Do not spray directly on face, spray on hands first and then rub on face.] Apply sparingly around ears. Do not apply to the hands of small children. Avoid contact with eyes, mouth, cuts, wounds, or irritated skin. Do not apply to excessively sunburned skin. Do not apply under clothing.

WARRANTY DISCLAIMER: Buyer assumes all responsibility for safety and use not in accordance with directions.

{Everything below is Optional Selling Copy and according to container size and type}

{1.} Aerosol-like Spray
{2.} Continuous Spray
{3.} No Rubbing required
{4.} One Touch Pump
{5.} Easy Application
{6.} No Mess
{7.} Convenient, no mess, no rub protection
{8.} Spray Upside Down
{9.} Level {for packages with clear indicator of amount remaining}
{10.} Running Low {for packages with clear indicator of amount remaining}
{11.} Twist Close Cap
{12.} Airplane carry-on size
{13.} TSA {approved] travel size
{14.} TSA [approved] carry-on size
{15.} Convenient Travel Size
{16.} Convenient Airplane Travel Size
{17.} Airplane carry-on
{18.} Carry on size
{19.} Protects against ticks and mosquitoes for up to 12 hours, and biting flies, stable flies, black flies, gnats, chiggers, and sand flies for up to 8 hours
{20.} For up to 12 hours of protection against mosquitoes and ticks, and up to 8 hours of protection against biting flies, stable flies, black flies, gnats, chiggers, sand flies and Scottish biting midges.
{21.} Use with confidence on the whole family
{22.} And your family will want to use it, too

{23.} Not oily, greasy or sticky
{24.} Cool Spray
{25.} Spray (and) ('n) go
{26.} Non-oily
{27.} Does not damage plastic
{28.} Won't Damage Fishing Lines, Plastics or other Synthetic Materials [Fisherman's Formula]
{29.} [Won't Damage Fishing Lines, Plastics or other Synthetic Materials [Gear Safe]]
{30.} Unscented [Repels bug(s), not people]
{31.} Pocket Size
{32.} Repels [mosquitoes] [ticks] [mosquitoes and ticks] for up to 12 hours, and biting flies, stable fies, black flies, gnats, chiggers, sand flies, and Scottish biting midges for up to 8 hours.
{33.} Non-Staining
{34.} Quick Drying
{35.} Dye-Free
{36.} [Not your standard aerosol:]
   a. Apply upside down without worry
   b. Product delivery is the same regardless of the position the can is held during spraying
   c. May be sprayed upright, inverted, or at any angle
   d. Constant pressure of application – won't lose pressure as can empties
   e. Same product delivery from the initial spray to the last spray
   f. Continuous Spray [Insect Repellent] [Mosquito Repellent]
   g. Quick and Even Coverage
   h. No Rub, No Hassle
   i. No chilling effect compared to a standard aerosol
   j. No pumping motion needed
{37.} Pleasant [Fragrance] [Scent]
{38.} Unscented
{39.} DEET Alternative
{40.} Does Not Contain DEET
{41.} Feels light and clean
{42.} No one will know you're wearing it
{43.} You won't smell it
{44.} You'll forget you're wearing it
{45.} Won't damage [fishing line, gun barrel, plastic lenses][sporting equipment]
{46.} Clean, dry feel
{47.} Light, Clean

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

FEE

DOCUMENT CONTAINS CONFIDENTIAL INFORMATION

DPBAR CODE NO.: 434261 **EPA File Symbol NO.: 34370-E** **DECISION NO.: 517811**
PC Code: 070705 **ACTION CODE: R300**
FOOD Use: No

DATE OUT: June 22, 2016

SUBJECT: End Use Product Chemistry Review
Product Name: Firebug Insect Repellent

FROM: Hari Mukhoty, DVM, PhD.
Product Chemistry Team
CITAB / Registration Division (7505P)

7/6/16

TO: Jennifer Gaines, RMR / Meridith Fry, RM 04
Invertebrate & Vertebrate Branch 1 / Registration Division (7505P)

Company Name: Wechem, Inc.

INTRODUCTION:

The registrant has submitted a basic CSF (Dated: 06/23/2016), two alternate formulations (CSFs Dated: 06/23/2016 - Alt. # 1 & 2) to the aforesaid basic and has also proposed a product specific label for registration of the aforesaid products under EPA File Symbol No: 34370-E. Product chemistry data have been submitted under MRID: 444087-47.

The aforesaid products were manufactured by the Wechem Inc. Harahan, LA, USA.

CITAB has been requested to evaluate the product chemistry data required for registration of the aforesaid products.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Picaridin (20% also called KBR 3023).

2. Has the registrant claimed substantial similarity to registered product?

   [X] Yes [ ] No [ ] NA If yes: EPA Reg. No. 39967-53. The registrant claimed that the proposed product is identical in composition the cited product.

3. The source materials of the active ingredients are registered with the Agency [Yes].

4. The CSFs have been screened by inert group and they found that inerts are approved for non-food use.

DPBAR CODE NO.: 434261 EPA File Symbol NO.: 34370-E DECISION NO.: 517811
PC Code: 070705 ACTION CODE: R300
FOOD Use: No

5. Confidential Statement of Formula(s):

[X] Basic - Dated: 06/23/2016 Re-submitted: NA
[X] Alternate # 1 & 2 Dated: " Re-submitted: NA

Alternate CSF(s) complies with 40CFR §152.43: [X] Yes [ ] No NA [ ]

6. Product label

a. Ingredient statement: Nominal concentrations of AI listed on CSF(s) concur with product label (PR Notice 91-2).

[Yes]

Is the sub statement in compliance with PR Notice 97-6?

[X] Yes [ ] No - Uses the term "Other Ingredients"

, if not, explain below:

Metallic equivalent: [ ] Yes [X] NA
Soluble arsenic: [ ] Yes [X] NA
Isomeric ratios: [ ] Yes [X] NA
Acid equivalent: [ ] Yes [X] NA

b. Health related sub statements:

Petroleum distillate at > 10%: [ ] Yes [ ] No [X] NA
Methanol at > 4%: [ ] Yes [ ] No [X] NA
Sodium Nitrate / Sodium Nitrite [ ] Yes [ ] No [X] NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: **flammability**, explosive potential or electric insulator breakdown?

[X] Yes [ ] No

Total Release Fogger PR Notice 98-6 (40 CFR 156.78 d): [ ] Yes [X] No [ ] NA

d. Label requires an additional Storage and Disposal statement: [X] Yes [ ] No

Final decision of overall label acceptance will be made by the PM.

7. The composition of the basic proposed product (34370-E / CSF dated 06/23/2016)) is identical to the cited product EPA Reg. No. 39967-53 (CSF dated 5/7/10). Therefore, to support the registration of the proposed product, the product chemistry data (MRID: 444087-47) used for registration of the cited product can be used.

DPBAR CODE NO.: 434261 EPA File Symbol NO.: 34370-E DECISION NO.: 517811
PC Code: 070705 ACTION CODE: R300
FOOD Use: No

CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted/cited for the end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. No. 39967-53) from Product chemistry view point
[ ] Similar
[ ] Not similar, give reasons
[X] Identical
[ ] Not identical
[ ] Not applicable

B. Confidential Statement of formula

1. Basic CSF (dated: 06/23/2016)
[X] Acceptable
[ ] Not Acceptable
[ ] Not Applicable

If not acceptable provide the reasons

2. Alternate CSFs (Alt. # 1 & 2) / dated: 06/23/2016)
[X] Acceptable -
[ ] Not Acceptable -
[ ] Not Applicable

If not acceptable give reasons

C. Group A Product Chemistry Data
[X] Acceptable
[ ] Not acceptable
[ ] Acceptable with the exception of Guideline(s): (provide the guideline number & explain)
[ ] Not required
[X] Data cited

D. Group B Product chemistry data
[X] Acceptable
[ ] Not acceptable
[ ] Acceptable with the exception of Guideline(s): (830.6317 & 830.6320 Tests are In Progress)
[ ] Not required
[X] Data cited

E. Product Label/Draft Label

Recommendations – Yes [ ]; No [X]

If yes, give recommendations below:

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WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OFPESTICIDE PROGRAMS
REGISTRATION DIVISION

14/JUN/2016

SIMILARITY CLINIC MEMORANDUM

Subject:	Name of Pesticide Product:	Firebug Insect Repellent
	EPA Reg. No. /File Symbol:	34370-E
	DP Barcode:	D434121
	Decision No:	517811
	Action Code:	R300
	PC Code:	070705 (picaridin)
From:	Eugenia McAndrew, Biologist	Eugenia McAndrew 3CR
Through:	John C. Redden, M.S., Senior Risk Assessor Chemistry, Inerts and Toxicology Assessment Branch Registration Division (7505P)	
To:	Meridith Fry, Risk Manager Team 04 Invertebrate and Vertebrate Branch 1 Registration Division (7505P)	
Applicant:	Wechem Inc. 57343 Susitna Drive Harahan, LA 70123	

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Picaridin	20
Other ingredients:	80
Total:	100

ACTION REQUESTED: Similarity determination for 34370-E, proposed product, and 39967-53, cited product.

BACKGROUND: Wechem Inc. has applied for registration of Firebug Insect Repellent, EPA File Symbol 34370-E, claiming to be substantially similar to KBR 3023 All-Family Insect Repellent Spray, EPA Reg. No. 39967-53. Both products contain 20% picaridin. The submission includes a basic CSF, alternate CSFs #1 and #2 dated May 11, 2016, label, data matrix and company letter.

The registrant is using the selective method of data support to satisfy the acute toxicity data requirements. The data matrix cites acute toxicity studies with MRIDs 444087-48, -49, -51, -52, 45035002 and 46885001. A search of the OPP electronic databases shows that these studies were cited/submitted to support the registration of 39967-53 in a 2006 Technical Review Branch/Registration Division memo (Backus; D331863; EPA File Symbol 39967-LG; 22/AUG/2006).

RECOMMENDATIONS:

1. We compared the basic CSFs and labels of the proposed product, 34370-E, and the cited product, 39967-53, and determined that the two products are substantially similar. The cited acute toxicity data may be used to support this registration.

2. The acute toxicity profile for the proposed product, Firebug Insect Repellent, EPA File Symbol 34370-E, is as follows:

acute oral toxicity	IV	cited	MRID 44408748
acute dermal toxicity	IV	cited	MRID 44408749
acute inhalation toxicity	IV	cited	MRID 45034002
primary eye irritation	III	cited	MRID 46885001
primary skin irritation	IV	cited	MRID 44408751
dermal sensitization	negative	cited	MRID 44408752

3. The proposed basic CSF and alternate CSFs #1 and #2 submitted for 34370-E must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 34370-E

PRODUCT NAME: Firebug Insect Repellent

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

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 doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

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DATA MATRIX

Date July 28, 2016	EPA Reg No./File Symbol 34370	Page 1 of 5
Applicant's/Registrant's Name & Address Nechem Inc. 5734 Susitna Drive Harahan, LA 70123	Product FIREBUG Insect Repellent Spray	

Ingredient

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.1550 (OPP 61-1)	Product Chemistry Identity of ingredients	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.1600 OPPTS 830.1650 (OPP 61-2)	Statement of Composition and Formulation Process	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.1620	Description of Production Process	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.1670 (OPP 61-3)	Discussion of formation of impurities	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.1700 (OPP 62-1)	Preliminary analysis	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.1750 (OPP 62-2)	Certification of Limits	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.1800 (OPP 62-3)	Analytical method for enforcement limits	44408747 47364201	LANXESS 34370 BRN 2039 (Formulation) BRN 2039 (TGAI)	PER	

Signature	Name and Title:	Date:
GKSangha	G.K. Sangha / Company Agent	July 28, 2016

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DATA MATRIX

Date July 28, 2016	EPA Reg No./File Symbol 34370	Page 2 of 5
Applicant's/Registrant's Name & Address 'chem Inc. 34 Susitna Drive Harahan, LA 70123	Product FIREBUG Insect Repellent Spray	

Ingredient

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.6302 (OPP 63-2)	Appearance (Color)	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.6303 (OPP 63-3)	Physical State	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.6304 (OPP 63-4)	Odor	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.7100 (OPP 63-18)	Viscosity	N/A	N/A	N/A	
OPPTS 830.7300 (OPP 63-7)	Density, bulk-density, or specific gravity	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.7000 (OPP 63-12)	pH	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.6314 (OPP 63-14)	Oxidation/Reduction	N/A	N/A	N/A	
OPPTS 830.6315 (OPP 63-15)	Flammability	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	

Signature	Name and Title:	Date:
GKSangha	G.K. Sangha / Company Agent	July 28, 2016

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DATA MATRIX

Date July 28, 2016	EPA Reg No./File Symbol 34370	Page 3 of 5
Applicant's/Registrant's Name & Address Wechem Inc. 5734 Susitna Drive Harahan, LA 70123	Product FIREBUG Insect Repellent Spray	

Ingredient

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.6316 (OPP 63-16)	Explodability	N/A	N/A	N/A	
OPPTS 830.6317 (OPP 63-17)	Storage stability of product	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.6319 (OPP 63-19)	Miscibility	N/A	N/A	N/A	
OPPTS 830.6320 (OPP 63-20)	Corrosion characteristics	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.6321 (OPP 63-21)	Dielectric Breakdown Voltage	N/A	N/A	N/A	
Section 158.340	Toxicology				
OPPTS 870.1100 (81-1)	Acute oral toxicity - rat	44408748	LANXESS 34370 BRN 107487 (Formulation)	PER	
OPPTS 870.1200 (81-2)	Acute dermal toxicity - rat	44408749	LANXESS 34370 BRN 107470 (Formulation)	PER	

Signature	Name and Title:	Date:
GKSangha	G.K. Sangha / Company Agent	July 28, 2016

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DATA MATRIX

Date July 28, 2016	EPA Reg No./File Symbol 34370	Page 3 of 5
Applicant's/Registrant's Name & Address Wechem Inc. 7734 Susitna Drive Harahan, LA 70123	Product FIREBUG Insect Repellent Spray	

Ingredient

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.6316 (OPP 63-16)	Explodability	N/A	N/A	N/A	
OPPTS 830.6317 (OPP 63-17)	Storage stability of product	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.6319 (OPP 63-19)	Miscibility	N/A	N/A	N/A	
OPPTS 830.6320 (OPP 63-20)	Corrosion characteristics	44408747	LANXESS 34370 BRN 2039 (Formulation)	PER	
OPPTS 830.6321 (OPP 63-21)	Dielectric Breakdown Voltage	N/A	N/A	N/A	
Section 158.340	Toxicology				
OPPTS 870.1100 (81-1)	Acute oral toxicity - rat	44408748	LANXESS 34370 BRN 107487 (Formulation)	PER	
OPPTS 870.1200 (81-2)	Acute dermal toxicity - rat	44408749	LANXESS 34370 BRN 107470 (Formulation)	PER	

Signature	Name and Title:	Date:
GKSangha	G.K. Sangha / Company Agent	July 28, 2016

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DATA MATRIX

Date July 28, 2016	EPA Reg No./File Symbol 34370	Page 4 of 5
Applicant's/Registrant's Name & Address ɜchem Inc. ɔ734 Susitna Drive Harahan, LA 70123	Product FIREBUG Insect Repellent Spray	

Ingredient

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 870.1300 (81-3)	Acute Inhalation toxicity - rat	45034002	LANXESS 34370 BRN 109513 (Formulation)	PER	
OPPTS 870.2400 (81-4)	Primary eye irritation - rabbit	46885001	LANXESS 34370 BRN 19555 (Formulation)	PER	
OPPTS 870.2500 (81-5)	Primary dermal irritation - rabbit	44408751	LANXESS 34370 BRN 107629 (Formulation)	PER	
OPPTS 870.2600 (81-6)	Dermal sensitization - guinea pig	44408752	LANXESS 34370 BRN 107490 (Formulation)	PER	
Section 158.640 OPPTS 810.3300 95-5	Product Performance Efficacy	44408744 44408745 44426704 44728901 45040601 45040602 45040603; 47732701 47734901 48053801 48215902 48230901	LANXESS 34370 BR 1948 BR 1949	PER	

Signature	Name and Title:	Date:
GKSangha	G.K. Sangha / Company Agent	July 28, 2016

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DATA MATRIX

Date July 28, 2016	EPA Reg No./File Symbol 34370	Page 5 of 5
Applicant's/Registrant's Name & Address Wechem Inc. 5734 Susitna Drive Harahan, LA 70123	Product FIREBUG Insect Repellent Spray	

Ingredient

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 810.3700 95-9, 95-10	Insect Repellents for human skin and outdoor premises	47506401 47571901 48053802 48071301 48117601	LANXESS 34370 LNX-001 LNX-001-1 LNX-002 LNX-002-1 LNX-002-2	PER	
OCSPP SUPP	Supplemental		Wechem Wechem-16-01	PER	

Signature	Name and Title	Date
GKSangha	G.K. Sangha / Company Agent	July 28, 2016

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Fee for Service

{986899É~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 4

Receipt No.	S- 986899
EPA File Symbol/Reg. No.	34370-E
Pin-Punch Date:	5/27/2016

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R300

Granted: R300

Amount Due: $ 1582

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: [illegible] Date: 5/31/16

Remarks:

Decision #: 517811
DP #: (434121)
PRIA
Parent DP #:
Submission #: 986899
E-Sub #:

DATA PACKAGE BEAN SHEET

Date: 14-Jun-2016

* * * Registration Information * * *

Registration: 34370-E - FIREBUG INSECT REPELLENT

Company: 34370 - WECHEM, INC.

Risk Manager: RM 04 - Meridith Fry - (703) 347-0128 Room# PY1 S-7213

Risk Manager Reviewer: John Redden JREDDEN

Sent Date: PRIA Due Date: 17-Oct-2016 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R300) NEW PRODUCT;OR SIMILAR COMBINATION PRODUCT (ALREADY REGISTERED)

Ingredients: 070705, Picaridin(20%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 14-Jun-2016 Due Back:

DP Ingredient: 070705, Picaridin

DP Title:

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #:

Assigned To		Date In	Date Out		
Organization:	RD / CITAB			Last Possible Science Due Date:	18-Aug-2016
Team Name:				Science Due Date:	
Reviewer Name:	McAndrew, Eugenia			Sub Data Package Due Date:	
Contractor Name:					

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Jeanie
Is the proposed (34370-E) similar to the cited (39967-53)?

34370-E

Memorandum

Date: 6/3/16

To: PM 04, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

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

June 02, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

GKS International, LLC
11411 Porter Ranch Drive #105
Porter Ranch, CA 91326

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 27-MAY-16. 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 11-03. 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.

GKS International LLC

11411 Porter Ranch Dr. #105
Porter Ranch, CA 91326

Mobile: 913 638 3968
Office/Fax: 818 277 5811

May 25, 2016

49933800

U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (RD) 7504P
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Meridith Fry
Product Manager 4

Subject: **WECHEM Inc. (Company No. 34370) – Application for Picaridin (KBR 3023) Based New Product 'Me-Too' Registration**
Brand Names: FIREBUG Insect Repellent

Dear Ms. Fry,

On behalf of **WECHEM Inc., (Company No. 34370)** of 5734 Susitna Drive, Harahan, LA 70123, I am submitting an application for registration of a new end-use product with brand name "FIREBUG Insect Repellent" similar to the LANXESS' KBR 3023 All-Family Insect Repellent Spray (EPA Reg. No. 39967-53) where some of the other ingredients have been replaced with alternatives. The FIREBUG product of WECHEM Inc. contains 20% active ingredient Picaridin [redacted]

To satisfy the requirements for registration of the end-use product the following are submitted:

1) Transmittal document
2) Form 8570-1, 8570-4, 8570-27, 8570-34 and 8570-35
3) Master Brand Label, 5 copies each
4) Letter of Authorization – LANXESS Corporation and for company agent
5) 1 – BOV devise report
6) SDSs for alternate inert ingredient
7) Application fee –$ 1,582 according to R 300

Product ingredient source information may be entitled to confidential treatment
Inert ingredient information may be entitled to confidential treatment

GKS International LLC

11411 Porter Ranch Dr. #105
Porter Ranch, CA 91326

Mobile: 913 638 3968
Office/Fax: 818 277 5811

Registration should be issued in the name of Ligia Hernandez of WECHEM Inc. and all correspondence, questions and communications should be directed to me (Company Agent). by phone (913-638-3968) or e-mail sangha8@roadrunner.com

Sincerely Yours,

GK Sangha

G.K. (Ghona) Sangha, Ph.D.
GKS International, Inc.
11411 Porter Ranch Drive #105
Northridge, CA 91326
Phone: 913-638-3968
Fax: 818-812-9123
Email: sangha8@roadrunner.com

Volume 1

TRANSMITTAL DOCUMENT

Name and Address of Submitter: WECHEM Inc.
5734 Susitna Drive
Harahan, LA 70123

Regulatory action in support of which this package is submitted: **Application for Registration of 'Insect Repellent'**

Product Name: **'FIREBUG' Insect Repellent**

EPA Reg. No./File Symbol: 34370

Transmittal Date: May 25, 2016

Volume No.	Citation	Guideline No.	MRID Number
1	Administrative Materials:		
	Transmittal Document		
	Cover Letter		
	Application for Pesticide Registration	EPA Form 8570-1	
	Confidential Statement of Formula (Basic)	EPA Form 8570-4	
	Confidential Statement of Formula (Alt1)	EPA Form 8570-4	
	Confidential Statement of Formula (Alt2)	EPA Form 8570-4	
	Formulator's Exemption	EPA Form 8570-27	
	Citation of Data	EPA Form 8570-34	
	Data Matrix	EPA Form 8570-35	
	Master Label (5 copies)		
	LOA from WECHEM to Company Agent		
	LOA from LANXESS to WECHEM		
	Pay.gov Acknowledgement – Tracking IDs: 25RQ7MUO; 75021803715 & 25RQ06HD;75022245296		
2	Sangha, G. K., 2016. FIREBUG Insect Repellent, Bag On Valve (BOV) Continuous Spray. Unpublished Report of WECHEM Inc. Report No. WECHEM-16-01. 6 pages	Supplemental	**49933801**
3	SDS for Ethyl Alcohol SDA-409-40B 190 Pf		

Company Official: G.K.Sangha (Company Agent)

Signature: GK Sangha

Company Name: GKS International LLC
Company Contact: Phone: 913-638-3968
Fax: 818-812-9123
E-mail: sangha8@roadrunner.com

gurcharan sangha

From: notification@pay.gov
Sent: Wednesday, May 25, 2016 9:09 AM
To: sangha8@roadrunner.com
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25RQO6HD
Agency Tracking ID: 75022245296
Transaction Type: Sale
Transaction Date: 05/25/2016 12:08:59 PM EDT

Account Holder Name: gurcharan sangha

Transaction Amount: $217.00
Card Type: AmericanExpress
Card Number: **********1009

Registration Number:
Company Name: WECHEM Inc.
Company Number: 34370
Action Code: R-300

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Paid 2015 Fee
Added this amount to Cover
the difference.

gurcharan sangha

From: notification@pay.gov
Sent: Tuesday, May 24, 2016 2:07 PM
To: sangha8@roadrunner.com
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25RQ7MUO
Agency Tracking ID: 75021803715
Transaction Type: Sale
Transaction Date: 05/24/2016 05:06:45 PM EDT

Account Holder Name: gurcharan sangha

Transaction Amount: $1,365.00
Card Type: AmericanExpress
Card Number: **********1009

Registration Number:
Company Name: WECHEM Inc.
Company Number: 34370
Action Code: R-300

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Receipt for Section 3

S: 986899 Milestone Email:

Regulatory Type: Product Registration - Section 3

Application Type: New Registration

Company: 34370 WECHEM, INC.

Resubmission: Yes No

Fee For Service: Yes No

Billable: Yes No

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 4

Product #: 34370-E Product Name: FIREBUG

Override#

Me Too Section3: 39967-53 Me Too Product Name:

Application Date: 25-May-2016 OPP Rec'vd Date: 27-May-2016

Front End Date: 27-May-2016 Risk Manager Send Date:

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Content

Study

CSF

View/Edit

Fast Track: New Ingredient:

Receipt Description:

NEW REGISTRATION WITH STUDIES

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

Please read instructions on reverse before comp' form. Form Approved. 1B No. 2070-0060 Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 34370
2. EPA Product Manager: Meridith Fry
3. Proposed Classification: [X] None [ ] Restricted
4. Company/Product (Name): WECHEM Inc. / FIREBUG Insect Repellent
PM# 4
5. Name and Address of Applicant *(Include ZIP Code)*
5734 Susitna Drive
Harahan, LA 70123
[ ] *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. 39967-53
Product Name All-Family Insect Repellent Spray

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] 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.)

Insect Repellent FIREBUG is identical to the LANXESS KBR 3023 All-Family Insect Repellent Spray (39967-53)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: [ ] Yes* [X] 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: [X] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____

3. Location of Net Contents Information: [ ] Label [X] Container
4. Size(s) Retail Container: 0.5-16 Oz
5. Location of Label Directions: [X] On Label [ ] On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] 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)
G K (Ghona) Sangha	Consultant	913-638-3968

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
3. Title: Toxicology & Reg. AffairsLab manger
4. Typed Name: Ligia Hernandez
5. Date: May 25, 2015

Daily for data
Kim
6/7

21-Day Screen Completed by Contractor

21-Day Expires on 6-17-16

Jacket # 34370-E
MRID# 499338

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN SCHAIBLE

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 5-27-16

Experts In-Processing Signature: B.B. Date 6-1-16 Fee Paid: Yes ✓

Division management contacted on issues No____ Yes____ Date____

EPA Reg. Number: 34370 -E	EPA Receipt Date: 5-27-16

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	yes: X	no:			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes:	no:			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	yes: X	no:			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**			X		
7	**Is the data package consistent with PR Notice 86-5**			X		
8	**Notice of Filing included with petitions**					X

9	**If applicable for conventional applications, reduced risk rationale**			X
10	**Required Data and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

Documentation: PASS
- All required forms are complete.

Inerts: PASS
- Inerts approved for non-food use

II-3: PASS
- MRID 499338

Status: PASS
- MS 06/06/16

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

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

May 31, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-517811
EPA File Symbol or Registration Number: 34370-E
Product Name: FIREBUG INSECT REPELLENT
EPA Receipt Date: 27-May-2016
EPA Company Number: 34370
Company Name: WECHEM, INC.

G.K. SANGHA
AGENT FOR: WECHEM, INC.
GKS INTERNATIONAL LLC
11411 PORTER RANCH DRIVE
PORTER RANCH, CA 91326

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application 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: R300
NEW PRODUCT;OR SIMILAR COMBINATION PRODUCT (ALREADY REGISTERED) TO AN IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;REGISTERED SOURCE OF ACTIVE INGREDIENT;NO DATA REVIEW ON ACUTE TOXICITY, EFFICACY OR CRP - ONLY PRODUCT CHEMISTRY DATA;CITE-ALL DATA CITATION, OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA, OR APPLICANT SUBMITS SPECIFIC AUTHORIZATION LETTER FROM DATA OWNER;CATEGORY ALSO INCLUDES 100% RE-PACKAGE OF REGISTERED END-USE OR MANUFACTURING-USE PRODUCT THAT REQUIRES NO DATA SUBMISSION NOR DATA MATRIX;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,
Teresa Downs
Front End Processing Staff
Information Technology & Resources Management Division

GKS International LLC

11411 Porter Ranch Dr. #105
Porter Ranch, CA 91326

Mobile: 913 638 3968
Office/Fax: 818 277 5811

May 25, 2016

U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (RD) 7504P
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Meridith Fry
Product Manager 4

Subject: WECHEM Inc. (Company No. 34370) – Application for Picaridin (KBR 3023) Based New Product 'Me-Too' Registration
Brand Names: FIREBUG Insect Repellent

Dear Ms. Fry,

On behalf of **WECHEM Inc., (Company No. 34370)** of 5734 Susitna Drive, Harahan, LA 70123, I am submitting an application for registration of a new end-use product with brand name "FIREBUG Insect Repellent" similar to the LANXESS' KBR 3023 All-Family Insect Repellent Spray (EPA Reg. No. 39967-53) where some of the other ingredients have been replaced with alternatives. The FIREBUG product of WECHEM Inc. contains 20% active ingredient Picaridin (KBR 3023, Icaridin, Saltidin®) which is purchased from LANXESS Corporation.

WECHEM Inc. may use alternative suppliers for inert ingredients. SDS of the supplier (BRENNTAG) for ethyl alcohol is included in this submission. However, the alternative supplier (BRENNTAG) for Polyethylene glycol gets their product from DOW Chemical Company, which is also the supplier of LANXESS Corp. as reflected in the Basic CSF.

To satisfy the requirements for registration of the end-use product the following are submitted:

1) Transmittal document
2) Form 8570-1, 8570-4, 8570-27, 8570-34 and 8570-35
3) Master Brand Label, 5 copies each
4) Letter of Authorization – LANXESS Corporation and for company agent
5) 1 – BOV devise report
6) SDSs for alternate inert ingredient
7) Application fee –$ 1,582 according to R 300

Product ingredient source information may be entitled to confidential treatment
*Inert ingredient information may be entitled to confidential

Registration should be issued in the name of Ligia Hernandez of WECHEM Inc. and all correspondence, questions and communications should be directed to me (Company Agent). by phone (913-638-3968) or e-mail sangha8@roadrunner.com

Sincerely Yours,

GK Sangha

G.K. (Ghona) Sangha, Ph.D.
GKS International, Inc.
11411 Porter Ranch Drive #105
Northridge, CA 91326
Phone: 913-638-3968
Fax: 818-812-9123
Email: sangha8@roadrunner.com

Volume 1

TRANSMITTAL DOCUMENT

Name and Address of Submitter: WECHEM Inc.
5734 Susitna Drive
Harahan, LA 70123

Regulatory action in support of which this package is submitted: **Application for Registration of 'Insect Repellent'**

Product Name: **'FIREBUG' Insect Repellent**

EPA Reg. No./File Symbol: 34370

Transmittal Date: May 25, 2016

Volume No.	Citation	Guideline No.	MRID Number
1	Administrative Materials: Transmittal Document Cover Letter Application for Pesticide Registration Confidential Statement of Formula (Basic) Confidential Statement of Formula (Alt1) Confidential Statement of Formula (Alt2) Formulator's Exemption Citation of Data Data Matrix Master Label (5 copies) LOA from WECHEM to Company Agent LOA from LANXESS to WECHEM Pay.gov Acknowledgement – Tracking IDs: 25RQ7MUO; 75021803715 & 25RQ06HD;75022245296	 EPA Form 8570-1 EPA Form 8570-4 EPA Form 8570-4 EPA Form 8570-4 EPA Form 8570-27 EPA Form 8570-34 EPA Form 8570-35	
2	Sangha, G. K., 2016. FIREBUG Insect Repellent, Bag On Valve (BOV) Continuous Spray. Unpublished Report of WECHEM Inc. Report No. WECHEM-16-01. 6 pages	Supplemental	
3	SDS for Ethyl Alcohol SDA-409-40B 190 Pf		

Company Official: G.K.Sangha (Company Agent)

Signature: GK Sangha

Company Name: GKS International LLC
Company Contact: Phone: 913-638-3968
Fax: 818-812-9123
E-mail: sangha8@roadrunner.com

WECHEM®

Engineered Chemistries
SUPERIOR SOLUTIONS

May 6, 2016

Document Processing Desk
Office of Pesticide Programs (7504 P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501
Room S-4900, One Potomac Yard

Attention: Meridith Fry (PM4)

Re: Letter of Authorization for GKS International LLC For Wechem, Inc. (EPA Company No. 34370)

Dear Ms. Saunders,

I am writing this letter to authorize Dr. G.K. Sangha of GKS International LLC, as Wechem's Agent and as the regulatory contact for Wechem's application to register Picaridin (Saltidin) based products. Please direct any and all correspondence, e-mails and telephone calls regarding the application to Dr. Sangha at:

GKS International, LLC
11411 Porter Ranch Drive # 105
Northridge, CA 91326
M: 913-638-3968
Fax: 818-812-9123
sangha8@roadrunner.com

Wechem, Inc. reserves the right to withdraw this letter of authorization at any time upon written notification to the EPA.

Thank you.

Sincerely,

Ligia Hernandez
Lab Manager
Wechem, Inc. (EPA Company No. 34370)
5734 Susitna Drive
Harahan, LA 70123

Product ingredient source information may be entitled to confidential treatment

Form approved. OMB No. 2070-0060, 2070-0057, 0-0107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
WECHEM Inc. 5734 Susitna Drive Harahan, LA70123	34370
	Product Name FIREBUG INsect Repellent
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 05/11/2016

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

[redacted]

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☑ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. *That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in* paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
[redacted]	[redacted]	[redacted]

Signature	Name and Title	Date
	Ligia Hernandez, Lab Manager	05/25/2016

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number WECHEM Inc., 5734 Susitna Drive, Harahan , LA 70123; 504-733-1152	EPA Registration Number/File Symbol 34370
Active Ingredient(s) and/or representative test compound(s) Picaridin (Saltidine, KBR 3023)	Date May 25, 2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Dermally applied INsect Repellent	Product Name FIREBUG

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
	May 25, 2016	Ligia Hernandez

R 300 and 301

100% identical (repack): YES or NO (circle one)
{If **yes**, it's a 100% repack - then product chemistry, acute toxicity and efficacy data are not required}

Data on Group A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition	✓	
830.1600	Description of materials used to produce the product	✓	
830.1650	Description of formulation process	✓	
830.1670	Discussion on the formation of impurities	✓	
830.1700	Preliminary analysis	✓	
830.1750	Certified limits (158.345)	✓	
830.1800	Enforcement analytical method	✓	

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color	✓	
830.6303	Physical State	✓	
830.6304	Odor	✓	
830.6314	Oxidation/Reduction (Chemical incompatibility)	N/A	
830.6315	Flammability	✓	
830.6316	Explodability	N/A	
830.6317	Storage stability	✓	
830.6319	Miscibility	N/A	
830.6320	Corrosion Characteristics	✓	
830.6321	Dielectric Breakdown voltage	N/A	
830.7000	pH	✓	
830.7100	Viscosity	N/A	
830.7300	Density	✓	

R 300 and 301

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
870.1100	Acute Oral (LD50)	✓	
870.1200	Acute Dermal (LD50)	✓	
870.1300	Acute Inhalation (LC50)	✓	
870.2400	Acute Eye Irritation	✓	
870.2500	Acute Dermal Irritation	✓	
870.2600	Dermal Sensitization	✓	

Efficacy – which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

Guideline No.	Efficacy Study Titles	Cited		Comments
		Yes	No	
810.3100	Soil Treatments for Imported Fire Ants		✓	
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments		✓	
810.3300	Treatments to Control Pests of Humans and Pets	✓		
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments		✓	
810.3500	Premises Treatments		✓	
810.3600	Structural Treatments		✓	
810.3800	Methods for Efficacy Testing of Termite Baits		✓	

Pages 80-84 - *Confidential Statements of Formula may be entitled to confidential treatment*

MS 06-06-16