7444-158

07/08/2009



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

July 8, 2009

Ms. Cynthia L. Rohner, Registration Specialist Waterbury Companies, Inc. 129 Calhoun Street, P.O. Box 640 Independence, LA 70443-2735

## Subject: Amended Labeling, Review of Efficacy Data to Support Revised Label Dosage Claims CB<sup>®</sup> Purge<sup>®</sup> III, EPA Reg. No. 9444-158 Your Submission Dated February 17, 2009

Dear Ms. Rohner:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following label revision provision(s):

General Comment:

1. Delete all text throughout the label marked with "strikethrough."

<u>Efficacy Review comment(s)</u>: In response to EPA's review of the efficacy data (MRID 47689501) that you submitted on February 17, 2009, make the following revisions to this label:

- 2. Delete the 1<sup>st</sup> optional marketing claim that reads "LASTS 30 DAYS" since this product lasts for 3 applications, not 30 days.
- 3. Throughout this label, delete all references to "Flies," "Mosquitoes," "Flying Insects" and "Mosquitoes [including Culex species], which/that may carry/transmit the West Nile Virus." The submitted efficacy data do not support use of this product on these pests.
- 4. Throughout this label, delete all repellency claims, since pyrethrins is not considered a repellent.
- 5. Delete the 4<sup>th</sup> optional marketing claim for the reasons stated in Item #3 above.
- 6. Replace the 6<sup>th</sup> optional marketing claim that reads "REPELS with Pyrethrins from Chrysanthemum Flowers" with: "Contains Pyrethrins, A Botanical Insecticide."

Precautionary Statements, Hazards to Humans & Domestic Animals section comment(s):

7. To facilitate inclusion of language from the REDs for pyrethrins, piperonyl butoxide and MGK® 264 insecticide synergist, revise this section to read: "Harmful if swallowed or absorbed through the skin. Avoid breathing vapor or spray mist. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse."

## First Aid section comment(s):

 Revise the existing "HOT LINE NUMBER" subsection to read: "Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call (985) 878-6751, Monday through Friday, 8 a.m. to 4:30 p.m. CST. After 4:30 p.m. CST, call your poison control center. For product information, you may call (203) 597-1812, Monday through Friday, 8 a.m. to 5:00 p.m. EST."

## Environmental Hazards comment(s):

9. To facilitate inclusion of language from the REDs for pyrethrins, piperonyl butoxide and MGK® 264 insecticide synergist, insert the following new section immediately preceding the "Physical or Chemical Hazards" section as follows:

"This product is toxic to aquatic organisms, including fish and invertebrates. Drift and run-off may be hazardous to aquatic organisms in water adjacent to treated areas. This product may contaminate water through run-off. This water has a potential for run-off for several weeks after application. Poorly draining soils and soils with shallow water tables are more prone to produce run-off that contains this product.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

Do not apply to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash-waters or rinsate. See Directions for Use for additional precautions and restrictions."

#### Directions for Use section comment(s):

10. To facilitate inclusion of language from the REDs for pyrethrins, piperonyl butoxide and MGK® 264 insecticide synergist, add the following new subsection in its own text box immediately following the statement "It is a violation of Federal law ..." as follows:

# GENERAL PRECAUTIONS & USE RESTRICTIONS Apply this product only as specified on this label. Do not contaminate of food or feedstuffs. Do not enter or allow others to enter until vapors, mists and aerosols have dispersed, and the area has been thoroughly ventilated. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Do not remain in treated area. Exit area immediately and remain outside the treated area until aerosols, vapors and/or mists have dispersed. Remove or cover exposed food and drinking water before application. Remove or cover dishes, utensils, food processing equipment and food preparation surfaces, or wash them before use. For indoor food handling/processing facilities: Do not make space spray applications when facility is in operation. During space spray applications, cover food processing surfaces or clean after treatment with a suitable detergent, rinse with potable water before use. Do not apply more than 1 time per day.

 For metered release devices: Not for use in residential areas. Do not use in nurseries or rooms where infants, ill or aged persons are confined. Do not place metering device directly over or within 8 feet of exposed food, dishes, utensils, food processing equipment and food handling or preparation. Do not install within 3 feet of air vents. Carefully follow directions for the dispenser unit and when replacing cans or conducting maintenance.

- For agricultural premises, and commercial animal housing and equipment: Do not apply more than 1 time per day.
  When used in dairy barns or facilities: Close milk bulk tank lids to prevent contamination from spray and from dead or falling insects. Remove or cover milking utensils before application. Wash teats of animals before milking.
- Remove pets, birds and cover fish aquariums before application.

11. On the 2<sup>nd</sup> line of the 1<sup>st</sup> paragraph starting with "**FOR USE IN [ON]** Food handling and ...," replace the words "(cargo area)" with the words "(cargo area only)" and delete the following use sites: "schools," "hospitals," "nursing homes" and "day-care centers," since the RED for pyrethrins prohibits the use of metered release devices on these use sites.

#### Directions for Use section comment(s), continued:

12. In the last sentence of the 2<sup>nd</sup> paragraph starting with "This product is engineered ...," replace the word "control" with the word "kill."

#### Storage & Disposal section comment(s):

13. Revise the subsection title currently labeled as "Storage:" to read: "Pesticide Storage:"

14. To facilitate inclusion of language from PR Notice 2007-4, replace the "Disposal:" subsection with: "Container Disposal: Do Not Puncture or Incinerate! If empty: Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions."

Waterbury Companies, Inc. should note that a notice of availability of EPA's RED for products containing pyrethrins was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42387-42389). In addition, EPA's RED for products containing piperonyl butoxide was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42385-42386). Further, EPA's RED for products containing MGK® 264 insecticide synergist was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42381-42383). As a result, additional data and/or labeling changes may be required for products containing pyrethrins, piperonyl butoxide and MGK® 264 insecticide synergist.

Should Waterbury Companies, Inc. wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA 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 section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists 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 be 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 EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, Waterbury Companies, Inc. may refer consumers to the company's phone number or e-mail address.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at <u>Rodia.Carmen@epa.gov</u>.

Sincerely Yours,

Richard J. Gebken Product Manager (10) Insecticide Branch Registration Division (7505P)

Enclosures: Copy of label stamped "Accepted with Comments" Copy of efficacy review, dated June 11, 2009



[For Reviewer: Optional - Country Vet logo]

(For Reviewer: Optional - CB® logo] **Purge<sup>®</sup>** 

# -LASTS 30 DAYS

# **Fresh Outdoor Scent**

# Kills & Repels: Flice, Mosquitoes, Gnats and Small Flying Moths.

-Kills & Repels Flying Insects-

Kills fand repets] Flies, Mosquitoes [including Culex species] which/that may carry/transmit — the West Nile Virus, Gnats and Small Flying Moths.

# **REPELS with Pyrethrins from Chrysanthemum Flowers**

**Active Ingredients:** 

Pyrethrins	0.975%
* Piperonyl Butoxide, technical	
N-octyl bicycloheptene dicarboximide	
[Inert] [Other] Ingredients	94.025%
	100 000%

ACCEPTED With COMMENTS In EPA Letter Dated: July 8, 2009 Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

9444-158

\*Equivalent to 1.56% (butylcarbityl) (6-propylpiperonyl) ether and 0.39% of related compounds.

**Contains Petroleum Distillates** 

Contains no CFCs or Other Ozone Depleting Substances. Federal regulations prohibit CFC propellants in aerosols.

# KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel for Additional Precautionary Statements.

EPA Reg. No. 9444-158

EPA Est. No. 9444-LA-1

# NET WEIGHT 6.4 oz./181 g

#### PRECAUTIONARY STATEMENTS Hazards to Humans & Domestic Animals CAUTION

Do not use in nurseries or rooms where infants, ill or aged people are confined. Do not install directly above or within 12 feet of any food handling or dispersing area. Metering device must be timed so that it does not dispense while food processing is underway. Foods should be removed or covered in such a way as to prevent contamination. All food processing surfaces should be covered during treatment or washed with an effective cleaning compound followed by potable water rinse.

[For Reviewer: Boxed and "bulleted" format will be used if label space permits; otherwise a paragraph format will be used.] FIRST AID

If Swallowed: Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice

If on Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

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

HOT LINE NUMBER- Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information, call (985) 878-6751, Monday through Friday, 8:00 am to 4:30 pm CST. After 4:30pm call your poison control center. For product information call (203) 597-1812, Monday-Friday, 8:00 am to 5:00 pm EST.

NOTE TO PHYSICIAN- Contains petroleum distillate - vomiting may cause aspiration pneumonia.

[For Reviewer: Note to Physician- will be used for formulations containing >10% petroleum distillates]

#### PHYSICAL OR CHEMICAL HAZARDS

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Do not allow spray to contact plastic, painted or varnished surfaces.

#### **DIRECTIONS FOR USE**

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

FOR USE IN [ON] Food handling and food preparation areas of restaurants and food processing plants, stores, farms, dairies, bams, kennels, factories, schools, hotels, motels, offices, ships, planes (cargo area), supermarkets food warehouses, bottling plants, hospitals, nursing homes, day-care centers, [porch] [&] [patio], homes, milk and egg handling areas of dairies and chicken houses.

This product contains a highly effective insecticide designed especially FOR USE IN automatic dispensers. The dispenser activates the metered valve every 15 minutes. Usually the effectiveness of this product will be noticeable within one hour after the Dispenser is activated. If less than 24 hour control is required, the Dispenser should [be set to] start one hour before control is desired and run one hour after control is no longer needed. Keep in mind that factors such as airflow rate, size of space treated, humidity and room temperature affect insect activity and control. Therefore, one unit per 6,000 cubic feet of unobstructed space should be considered as an average with adjustments made depending on specific conditions at usage site. As with any method of insect control, best results are achieved when sanitation and other positive insect prevention practices are followed.

Do not use in aircraft cabins. It is suggested that the container be changed once a month.

OUTDOORS: This product can be used to treat dog kennels, dog runs, side yards, patios, decks & [and] residential landscapes. Set the dispenser to treat at dawn & [and] dusk & [and] use when humans are not in the area. When heavy pest infestations are present the dispenser may be set to treat at [15], [30], [45] [15 – 45] minute intervals. Place the dispensers out of the reach of pets & [and] children & [and] use the prevailing wind to assist in carrying the spray throughout the area to be treated. This product can be used to <del>control [aid - in controlling] Flics, Mosquitoes, [including the Culex species] [which may carry] [that may carry] [that carry] [which carry] [and transmit] -- [the West Nile Virus] [including those that [carry] West Nile Virus], gnats & [and] small flying moths. Each dispenser will treat up to 650 square feet. Use enough dispensers to treat the entire area you want protected.</del>

> Kill

OPERATION: Remove protective cap from top of can & [and] insert can in dispenser. Secure dispenser at least 7 feet from floor or ground & [and] at a point where air flow or wind will carry the particles throughout the area to be protected.

# STORAGE & DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Storage: Do not store near heat or open flame. Store in cool dry area away from children. Disposal: 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 or 1800-CLEANUP for disposal instructions. [For Reviewer: The Steel graphics symbol is optional if label space allows it.]

For Additional Products and Information Visit Us At www.Country-Vet.com [For Reviewer: Optional text]

Manufactured by



WATERBURY COMPANIES, INC. P. O. Box 1812 Waterbury, CT 06722 985-878-6751[For Reviewer: Optional text] Made in USA www.CBProProducts.com [For Reviewer: Optional text]



[For Reviewer: Optional - Premium Pyrethrum logo]

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[For Reviewer: Optional - CFCs logo]