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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 21, 2010

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

Subject:

Amended Labeling; Response to EPA Letter of July 8, 2009 & Meeting of September 30, 2009

CB[®] Country Vet Purge[®] 3, EPA Reg. No. 9444-237

Your Submission Dated June 11, 2010

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(s):

- 1. The efficacy data originally submitted for EPA Reg. No. 9444-158, were found inadequate to support the product. Confirmatory data were required to be submitted for EPA Reg. No. 9444-158 by July 26, 2006. To date, these data have not been submitted, and were subsequently reclassified as being "deficient." As discussed in a meeting with the Agency on September 30, 2009, Waterbury Companies, Inc. (Waterbury) and FMC Corporation (FMC) have agreed to redo the efficacy study using the correct product. In addition, Waterbury and FMC have agreed to conduct studies with flies as well as to redo the mosquito study.
- 2. Waterbury and FMC must submit the referenced new acceptable efficacy study within twelve (12) from the date of this letter, that is, on or before September 21, 2011.
- 3. Throughout the subject label, replace all instances of the word "control" with the word "kill."
- 4. Throughout the subject label, delete all repellency claims, since pyrethrins is not considered a repellent.

Optional Marketing Claims section comment(s):

- 5. Revise the existing 1st optional marketing claim "LASTS 30 DAYS" to read "When used according to the label directions, 6.4 oz can will dispense for 30 days."
- 6. Revise the existing 5th optional marketing claim "REPELS with Pyrethrins from Chrysanthemum Flowers" to read "Contains Pyrethrins, A Botanical Insecticide."

Ingredient Statement section comment(s):

7. Revise "Inert Ingredients" to read "Other Ingredients."

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

8. To facilitate inclusion of missing/required language required as part of the acute toxicity review completed for this product, insert the words "Contains Petroleum Distillates." immediately preceding the word "Harmful" in the 1st sentence of this subsection.

First Aid Statement section comment(s):

9. The subject label must include a "NOTE TO PHYSICIAN:" as was originally included in the label stamped as part of the Notice of Registration for this product, dated April 7, 2009. To facilitate inclusion of missing language required as part of the acute toxicity review completed for this product, insert the following statement at the end of this section as follows: "NOTE TO PHYSICIAN: Contains petroleum distillate. Vomiting may cause aspiration pneumonia."

Directions for Use section comment(s):

- 10. In the last sentence of the paragraph starting with "This product contains a highly effective ...," replace the word "control" with the word "kill."
- 11. In the 5th sentence of the paragraph starting with "OUTDOORS: This product can be ...," replace the words "control [aid in controlling]" with the word "kill."

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. Ğebken

Product Manager (10)

Insecticide Branch

Registration Division (7504P)

Enclosure: Copy of label stamped "Accepted with Comments"

Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

9444-237



[For Reviewer: Optional - Country Vet logo]

CB[®] Country Vet Purge[®] 3

Kills: Flies, Mosquitoes, and Small Flying Moths.

Kills Flying Insects

Kills Mosquitoes, including Culex species which may carry the West Nile Virus.

REPELS with Pyrethrins from Chrysanthemum Flowers

Active Ingredients:	
Pyrethrins	0.975%
* Piperonyl Butoxide	1.950%
N-octyl bicycloheptene dicarboximide	
Inert Ingredients	94.025%
	100.000%

*butyl carbityl) (6-propylpiperonyl) ether and 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. 9444-237

EPA Est. No. 9444-LA-1

NET WEIGHT 6.4 oz./181 g

PRECAUTIONARY STATEMENTS Hazards to Humans & Domestic Animals CAUTION

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.

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

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 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.

[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.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Spray drift may be hazardous to aquatic organisms in water adjacent to treated areas. This product is highly toxic to bees exposed to spray drift on to blooming plants. Place product so spray will not drift onto blooming plants visited by bees.

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, barns, kennels, factories, schools, hotels, motels, offices, ships, planes (cargo area only), 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 control [aid in controlling] Flies, 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.

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.

PESTICIDE STORAGE: Do not store near heat or open flame. Store in cool dry area away from children.

CONTAINER DISPOSAL: Do not Puncture or Incinerate! If empty: Offer for recycling, if available. If partly filled: Call your local

solid waste agency 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 - CFCs logo]

9444-237PDCI&FMCAmend.Ju10

[For Reviewer: Optional - Premium Pyrethrum logo]