

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

February 3, 2009

Mr. Mitch Whitney, Vice-President Quest Chemical Corporation 12255 FM 529 Road Northwoods Industrial Park Houston, TX 77041-2805

Subject:

Amended Reregistration Label for BUG BAN PLUS Personal Insect Repellent

EPA Registration No. 44446-48

Dear Mr. Whitney:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act, as amended, has completed reviewing all of the information submitted with your application to support the reregistration of BUG BAN PLUS Personal Insect Repellent (EPA Reg. No. 44446-48) in connection with the MGK® Repellent 326 RED, and have concluded that your submission is acceptable with the following label revision provision(s):

General Comment(s):

- Delete all text throughout the label marked with "strikethrough."
- 2. Delete the statement (top of page 3 of 3): "[CONTAINS (CAS#): Isopropyl Alcohol (67-63-0), Propane/n-Butane (68476-86-8), Diethyltoluamide (134-62-3), N-octyl bicycloheptene dicarboximide (113-48-4), Acetone (67-64-1).]" since this information is incorrect and/or incomplete. As explained in Chapter 5, Section X.B. of the Agency's Label Review Manual: "If a registrant wants to list a particular active ingredient (in the ingredient statement), the registrant must list **all** inert ingredients directly below the ingredient statement."

<u>Precautionary Statements, Hazards to Humans and Domestic Animals section comment(s)</u>:

3. Revise this section heading to read: "HAZARDS TO HUMANS" since this product is not registered for application to domestic animals.

First Aid Statement comment(s):

4. Replace the statement starting with "For additional information..." with: "For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-255-3924."

Directions for Use section comment(s):

- 5. To facilitate inclusion of language from the MGK[®] Repellent 326 RED, insert the following text immediately preceding the 6th sentence as follows: "Do not apply more than 3 times per day to children ages twelve (12) and under."
- 6. In the 12th sentence, replace the word "rate" with the word "rare."

¹ Please note that the "1-800-255-3924" number listed must be available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

<u>Directions for Use section comment(s), continued:</u>

7. Revise the subsection title "FOR CLOTHING:" read "FOR OUTER SURFACES OF CLOTHING:"

The Agency determined in the DEET RED document that all aerosol and pump spray formulations must be packaged in containers utilizing a concave trigger to help aim product or other comparable mechanism that will ensure that the product will not be inadvertently sprayed in the eyes. In addition, current labels on DEET repellent products tend to dissolve from contact with the repellent (usually liquids). All reregistered DEET product labels must use materials that remain permanent and readable for the reasonable life of the product.

The Agency is also in the process of developing and improving the current Efficacy Assessment Guidelines for repellent products. The Agency intends to defer the determination of any related efficacy data requirements supporting the claims that may appear on this label until these Efficacy Assessment Guidelines are complete. When the guidelines are finalized, the Agency expects to issue a Data Call-In to address the revised guidelines to all registrants with registrations for personal repellent products that have not previously submitted efficacy data sufficiently consistent with the revised guidelines.

Quest Chemical Corporation should also note that a notice of availability of EPA's RED for products containing MGK® Repellent 326 was published in the *Federal Register* on May 23, 2003 (Volume 68, Number 100, Pages 28216-28218). In addition, EPA's RED for products containing products containing MGK® 264 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 MGK® Repellent 326 and MGK® 264.

Should you 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 FIFRA section 12(a)(1)(E). 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, you may refer consumers to the company's phone number or e-mail address.

NOTE: This product is not being reregistered under Section 4(g) of FIFRA at this time.

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 FIFRA section 6(e). 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)

Enclosure: Copy of label stamped "Accepted with Comments" 044446-00048 D404841

BUG BAN PLUS

Personal Insect Repellent

Repels Mosquitoes, Biting Flies, Chiggers, Ticks & Other Small Flying Insects Including Fleas on Exposed Skin Surfaces

Repels Mosquitoes Which May Carry Diseases
Such as West Nile Virus and Encephalitis
(St. Louis, Eastern equine, Western equine, LaCrosse, Cache Valley)

ACTIVE INGREDIENTS:

DEET 22.56%

*N-Octyl Bicycloheptene Dicarboximide 5.00%

**Di-n-propyl isocinchomeronate 2.50%

OTHER INGREDIENTS: 69.94%

TOTAL: 100.00%

With COMMENTS In EPA Letter Dated

*MGK® 264, Insecticide Synergist

**MGK® Repellent 326

MGK: Registered trademark of McLaughlin Gormley King Co.

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

EPA Reg. No. 44446-48 EPA Est. No. 44446-TX-1
KEEP OUT OF REACH OF CHILDREN

CAUTION:

See Additional Precautionary Statements on Back Panel NET WT. 6.5 OZ. (184 g)

SPRAYS RIGHT SIDE UP/UPSIDE DOWN

PRECAUTIONARY STATEMENTS *HAZARDS TO HUMANS & DOMESTIC ANIMALS

Delete

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

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 eye.
- · Call a poison control center or doctor for treatment advice.

If swallowed:

- Call poison control center or doctor immediately for treatment advice.
- · Have person sip a glass of water if able to swallow.

- Do not induce vomiting unless told to do so by the poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

If you suspect a reaction to this product:

- · Discontinue use.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- •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.

For additional information in case of emergency call toll free 800-255-3924.

PHYSICAL & CHEMICAL HAZARDS

EXTREMELY FLAMMABLE: Contents under pressure. Do not use near fire, heated surface, sparks or flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Do not expose treated skin or clothing to fire, sparks or flame until liquid has evaporated.

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.

Do not apply over cuts, wounds or irritated skin. Do not apply near eyes and mouth. Apply sparingly around ears. 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. Use just enough repellent to cover exposed skin and/or clothing. Do not use under clothing. Avoid overapplication of this product. After returning indoors, wash treated skin with soap and water. Wash treated clothing before wearing it again. Use of this product may cause skin reactions in rate cases. If you suspect a reaction to this product, discontinue use, wash treated skin, and call your local poison control center. If you go to a doctor, take this product with you. Do not spray in enclosed areas. If used on the face, spray on hands first and then apply sparingly and avoid eyes. Do not spray directly onto face.

Remove protective cap, and spray from a distance of 8–12 inches from surface to be protected. Slightly moisten surface—saturation is not necessary. Use slow sweeping motion.

FOR EXPOSED SKIN AREAS, to repel flies, gnats and mosquitoes: Use as directed above.

FOR CLOTHING, to repel ticks, fleas and chiggers—Apply along all openings of clothing, such as around the neck band, the fly and cuffs of trousers, tops of socks, eyelets of shoes and areas of clothing which may contact the ground, weeds or other growth.

Avoid contact with plastics, such as eyeglass frames, and such fabric as acetate rayon. Exposure to temperatures above 130°F may cause bursting. May damage some plastics, varnished or painted surfaces. May be used on Nylon, Orlon, Wool, Cotton. **DO NOT USE** on Rayon, Spandex or Dynel.

STORAGE AND DISPOSAL

STORAGE: Store in a cool dry area away from heat or open flame. 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 1-800-CLEANUP for disposal instructions.

grasé

-	[CONTAINS (CAS#): Isoprepyl Alcohol (67-63-0), Propanc/n Butene (68476-86-8), Diothylteluamide (134-62-3), N octyl bicyclohoptene dicarboximide (113-48-4), Acctone (67-64	
	HMIS RATINGS: HEALTH-1, FLAMMABILITY-2, REACTIVITY-1, PERSONAL-1	
	- For MSDS or additional product information:	

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