

54287-8

05-09-2007

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



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 9, 2007

Mr. Timothy H. Dickens, Ph.D.
Registered Agent
Associated Registrations
c/o Scientific Coordination, Inc.
4629 Cherry Valley Drive
Rockville, MD 20853-1110

**Subject: EXPEDITED REVIEW -- Amended Labeling, Addition of Various Insect-Borne Diseases
INSECT GUARD II INSECT REPELLENT, EPA Registration No. 54287-8
Your Submission Dated September 19, 2006**

Dear Mr. Dickens:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following provisions:

Marketing Claims section comment(s), page 1 of 2:

1. The words "insect repellent" must be revised in the product title. Specifically, the words "**INSECT REPELLENT**" must be displayed prominently on the front panel of this product label, immediately after the brand name in capital lettering with large, contrasting bold-face type.
2. Revise all references to "R-326" and "MGK Repellent 326" to read as follows: "MGK® 326."
3. Modify the 2nd optional marketing claim to read as follows:

"Contains DEET and MGK® 326 to repel mosquitoes and flies."
4. Delete the following insect-borne diseases from the label: (1) Japanese encephalitis; (2) Murray Valley encephalitis; (3) Ross River Fever; (4) Barmah Forest Disease; (5) Yellow Fever; and (6) Rift Valley Fever. These insect-borne diseases currently do not occur within the continental United States and/or its territories.

Ingredient Statement section comment(s), page 1 of 2:

5. Relocate the CAS number listed for DEET as a footnote on the first page of the label.
6. Delete the word "INERT" from the ingredient legend. ¹

¹ For more detailed information, please refer to PR Notice 97-6.

Directions for Use section comment(s), page 2 of 2:

7. Revise the introduction to this section by relocating the first two (2) sentence to their own lines for more prominence as follows:

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.

Shake well before using. Rub a thin uniform layer

Storage and Disposal section comment(s), page 2 of 2:

8. Replace the existing section with the following:

STORAGE AND DISPOSAL

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

Pesticide Storage: Store this product in a cool and dry area. Keep out of reach of children.

Pesticide Disposal: If empty: Do not reuse this container. 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. Never place unused product down any indoor or outdoor drain.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling, or puncture and dispose of in a sanitary landfill, or incineration, etc., or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Precautionary Statements, Hazards to Humans and Domestic Animals section comment(s), page 2 of 2:

9. Insert the following text after the existing 5th sentence: "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." ²

First Aid section comment(s), page 2 of 2:

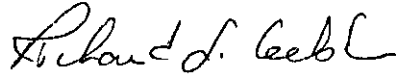
10. Delete the 3rd row from this table that starts with "If you suspect a reaction to this product." For a more detailed explanation, please refer to the footnote #1 below and the comment on item #7 above.

The optional marketing claim "Repels mosquitoes that may carry West Nile virus" requires in part the submission of product-specific efficacy data. In accordance with the Agency's January 5, 2004 letter, this data requirement remains applicable. Once the efficacy performance guidelines for repellents are in place, you will be notified of all efficacy data requirements.

² PR Notice 2001-1 is very specific about which sections are applicable for the various routes of exposure. The "If you suspect....." comment is not a part of this PR Notice, but is specifically addressed as a requirement in the DEET Reregistration Eligibility Decision (RED) document, dated April 1998, page 40 of 118, and should be placed in the Precautionary Statements, Hazards to Humans and Domestic Animals section and NOT in the First Aid section.

A stamped copy is attached for your records. Please submit two (2) final printed copies of the referenced label, incorporating the above changes, before releasing the product for shipment. If you have any questions regarding the label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,



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

Attachment

INSECT GUARD II
Insect Repellent (either in name or stated separately)

~ OPTIONAL LANGUAGE ~

Repels Mosquitoes, Chiggers, Ticks, Black Flies Also Jecrflies, Gnats, Stable Flies and Fleas on Exposed Skin Surfaces

Contains DEET to Repel Mosquitoes Plus R-326 to Repel Flies
Lotion

Repels mosquitoes that may carry West Nile Virus

Repels mosquitoes that may carry (St. Louis) (Eastern equine) (Western equine) (Lacrosse) (~~Japanese~~) (Cache Valley) (Venezuelan equine) (~~Murray Valley~~) encephalitis and (~~Ross River Fever~~) (~~Barmah Forest Disease~~) (~~Dengue Fever~~) (~~Yellow Fever~~) (~~Rift Valley Fever~~)

ACTIVE INGREDIENTS:

DEET (CAS No. 134-62-3).....	17.5%
*N-octyl bicycloheptene dicarboximide	5.0%
**Di-n-propyl isocinchomeronate	2.5%
INERT {OTHER} INGREDIENTS:	75.0%
TOTAL:	100.0%

*MGK-264, Insecticide Synergist, **MGK Repellent 326
MGK® - Reg'd TM McLaughlin Gormley King Co.

KEEP OUT OF REACH OF CHILDREN
WARNING
See Back Panel For Additional Precautionary Statements

NET CONTENTS _____ fl. oz.

[] Optional/Alternate text

ACCEPTED
with COMMENTS
In EPA Letter Dated
May 9, 2007
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
54287-B

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.** Shake well before using.

Rub a thin uniform layer on exposed skin. Use just enough repellent to cover exposed skin and/or clothing. Do not use under clothing. Avoid over-application of this product. Do not apply near eyes and mouth and 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. (Instruct older children in the proper use of this product.) Do not apply more than 3 times per day to children ages twelve (12) and under. Do not apply over cuts, wounds or irritated skin. After returning indoors, wash treated skin with soap and water. Wash treated clothing before wearing it again. May damage certain synthetic fabrics; acetate, spandex, rayon and leather and plastics such as eyeglasses and watch crystals. [Will not damage cotton, wool, or nylon.][Do not apply on or near acetate, rayon, spandex, or other synthetics, furniture, plastics, watch crystals, leather and painted or varnished surfaces including automobiles.]

STORAGE & DISPOSAL

Storage: Store in a cool, dry area away from heat or open flame. If empty: Do not reuse this container. 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. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS
Hazard to Humans and Domestic Animals

WARNING: Causes substantial but temporary eye injury. Do not get in eyes. Due to irritating nature, may be harmful if swallowed. Use of this product may cause skin reactions in rare cases. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID
<p>If In Eyes:</p> <ul style="list-style-type: none"> • 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.
<p>If Swallowed:</p> <ul style="list-style-type: none"> • 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 a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
<p>If you suspect a reaction to this product:</p> <ul style="list-style-type: none"> • Discontinue use; • 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.
<p>Have the product container with you when calling a poison control center or doctor, or going for treatment. For additional information in case of emergency call toll free 1-800-940-4464, Weekdays from 9-5 EST.</p>

NOTE: The First Aid statement's grid format will be used if market label space permits; otherwise a paragraph format will be used.

Associated Registrations
P.O. Box 188
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EPA Reg. No. 54287-8 EPA Est. No. 54287-FL-1