

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

June 10, 2008

Ms. Jean Killoren, Authorized Agent for K-G Packaging, Inc. c/o Killoren Regulatory Consulting 316 Highland Avenue Hartford, WI 53027-1318

Subject:

Acceptance of Amended Labeling

Personal Insect Repellent II, EPA Reg. No. 46813-22

Your Submission Dated March 4, 2008

Dear Mr. Whitney:

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 provision(s):

General Comment(s):

- 1. Delete all text throughout the label marked with "strikethrough."
- 2. The words "INSECT REPELLENT" <u>must</u> be displayed prominently on the front panel of this product label as well as on the alternate brand name(s), immediately after the brand name in capital lettering, with large, contrasting, bold-faced type.

Marketing Claims section comment(s):

- 3. In the 8th marketing claim, expand on the term "encephalitis", only to include those that occur within the continental United States and/or its territories or remove the term "encephalitis."
- 4. In the 8th marketing claim, delete "dengue" since this insect-borne disease does not occur within the continental United States and/or its territories.

Directions for Use section comment(s):

- 5. Replace the 1st bulleted statement with: "Apply this product only to exposed skin and/or clothing as directed on this label."
- 6. In the 4th bulleted statement, replace the 3rd sentence with: "Avoid over-application of this product." and delete the 4th sentence.
- 7. Delete the 7th bulleted statement.
- 8. In the 9th bulleted statement, delete the 2nd sentence.

Directions for Use section comment(s), continued:

- 9. In the 11th bulleted statement, replace the words "... synthetic fabrics, nylon furniture, ..." with "... synthetic fabrics (other than nylon), furniture, ..."
- 10. The 3 sentences in the 12th bulleted statement should be **bolded** in order to increase the prominence of these label statements.

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

11. Replace the 3rd and 4th sentences with: "Harmful if swallowed. Avoid contact with eyes." and delete the 4th, 5th and 6th sentences.

To be eligible for reregistration, 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.

K-G Packaging, Inc. 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 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 MGK® Repellent 326 and MGK® 264 Insecticide Synergist.

The Agency is 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.

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 *Rodia.Carmen@epa.gov*.

Sincerely yours,

Richard J. Gebken, Product Manager (10)

Insecticide Branch,

Registration Division (7505P)

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Enclosure: Copy of label stamped "Accepted with Comments" 046813-00022 D390666

Personal Insect Repellent II

Insect Repellent 25% DEET 25% DEET Insect Repellent

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

Repels Biting Flies Repels Mosquitoes and Other Biting Insects Repels Mosquitoes up to 8 Hours Repels Mosquitoes that may carry diseases such as West Nile virus, encephalitis and dengue...

Unscented **Unscented Insect Repellent**

Active Ingredients:

DEET	25.00%
*N-octyl bicycloheptene dicarboximide	5.00%
**Di-n-propyl isocinchomeronate	2.50%
Other Ingredients	67.50%
Total	100.00%
*MCK® 264 Insecticide Synarcist	

MGK® - Registered trademark of McLaughlin Gormley King Company CCEPTED

with COMMENTS In EPA Letter Dated

Keep Out of Reach of Children CAUTION

See back [side] panel for first aid and additional precautionary states needs for the pesticide

Net Weight

{Back/Side Panel}

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

- Apply this product only as specified on this label.
- DO NOT spray in enclosed areas. Avoid breathing a spray product, and DO NOT use it near food.
- Repellents should be applied only to exposed skin and/or clothing (as directed on this product label). DO NOT use under clothing.
- Never use repellents over cuts, wounds or irritated skin. Use just enough of this product to cover exposed skin and/or clothing. Avoid overexposure. Heavy application-and-saturation is unnecessary for effectiveness. If biting insects do not respond to a thin film of repellent, apply a bit more.
- DO NOT apply near eyes and mouth, and apply sparingly around ears. When using sprays, do not spray directly into face; spray on hands first and then apply to face.
- DO NOT allow children to handle this product, and DO NOT apply to children's hands. When using on children, apply product to your own hands and then put it on the child. **DO NOT** use on infants.
- -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.

^{**}MGK® Repellent 326

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- After returning indoors, wash treated skin with soap and water or bathe. This is particularly important when repellents are used repeatedly in a day or on consecutive days.
- Wash treated clothing before wearing it again.
- **DO NOT** apply on or near acetate, rayon, Spandex or other synthetic fabrics, nylon furniture, plastics (such as eyeglasses and watch crystals), leather and painted or varnished surfaces (including automobiles).
- 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 local poison control center. If you go to a doctor, take this repellent product with you.

To Repel the Listed Insects

[First, remove protective cap.] Hold can at least 12 inches away, point valve in desired direction and press button to spray. Apply to clothing and all exposed skin areas. Repeat as needed. For ticks and chiggers, apply to shoe tops, socks and around openings in clothing.

Storage and Disposal

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

Pesticide Storage: Store this product in a cool, dry (preferably locked) area away from heat or open flame. Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Container 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 for disposal instructions [or toll free number or website, which meets the criteria in paragraph II. E. of PR Notice 2007-1]

PRECAUTIONARY STATEMENTS Hazards to Humans CAUTION

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes or clothing. Do not get in eyes. Do not apply to children's hands. Do not using the toilet. Remove and wash contaminated clothing before reuse.

First Aid
 Call a 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.
 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.

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 pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-xxx-xxxx¹ or the National Pesticide Information Center at 1-800-858-7378.

{Note: The first aid statements' grid format will be used if market label space permits; otherwise a paragraph format will be used.}

Physical or Chemical Hazards

Flammable. Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperature above 130°F may cause bursting.

[In case of medical emergencies or health and safety inquiries, or in case of fire, leaking or damaged containers, information may be obtained by calling 1-800-{phone number}.]
[For product information call toll-free: 1-800-{phone number}.]
[Questions? Call {phone number}]

{Logo²}
Contains no CFCs or other ozone depleting substances.
Federal regulations prohibit CFC propellants in aerosols.

Manufactured by [for]

K-G Packaging, Inc.
8001 Keele Street
Concord, Ontario K4K 1Y8
[{phone, fax numbers}]
Made in [Product of] Canada

{¹Please note that the "1-800-xxx-xxxx" 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.}

{2The "{Logo}" placed on this page must be a logo to indicate absence of chlorofluorocarbons (CFCs) in this product. The logo must consist of the universal nonverbal symbol for negation – a red circle with diagonal red slash through the circle – with: (a) wording as discussed in PR Notice 92-2 immediately next to the logo; and (b) text set in type size of at least 6 points (the minimum type size permitted by regulation).}

L] Denotes alternate/optional language
{	} Denotes descriptive language that does not appear on the market labeling