

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JAN 16 2009

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

Subject: Amended Reregistration Label For: Insect Guard II EPA Registration No. 54287-8

Dear Dr. Dickens;

The Agency in accordance with the Federal Fungicide and Rodenticide Act as Amended (FIFRA) has completed reviewing all of the information submitted with your application to support the reregistration of the aforementioned product in connection the MGK 326 RED, and have concluded that your submission is acceptable with the following label revision provisions:

1. Page 1:

a. Revise the marketing claim as follows: "Repels Mosquitoes that may carry Encephalitis (St. Louis, Eastern equine, Western equine, LaCrosse, Cache Valley) and Dengue 1

2. Page 2:

- a. Remove the statement from the Directions for use, "(Instruct older children in the proper use of this product.)"
- b. Revise the statement "Do not apply to children's hands" with ""Do not allow children to handle this product, and do not apply to children's hands"
- c. Storage and Disposal section comment(s), page 2 of 2:

Replace the existing section with the following:

"STORAGE AND DISPOSAL

Pesticide Storage: Store this product ma cool, dry place inaccessible to 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 toll-free number or website which meets the criteria in paragraph II.E, PR Notice 2007-1] for disposal' instructions. Never place unused product down any indoor or outdoor drain."

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

¹ The Agency is currently permitting only those diseases that occur within the United States.

permanent and readable for the reasonable life of the product. 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.

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.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act 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) list 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 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 the EPA's Office of Enforcement and Compliance Assurance. As an alternative, you may refer consumers to the company's phone number or email address.

NOTE: This product is not being re-registered under FIFRA Sec. 4(g) at this time.

You must submit two copies of the final printed label revised in accordance with the comments listed above before the product is released for shipment under this label. If you have any questions, you may contact Carmen Rodia at (703)-306-0327 or rodia.carmen@epa.gov.

A copy of your label stamped "Accepted with Comments" is enclosed for your records.

Sincerely,

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

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INSECT GUARD II INSECT REPELLENT

~ OPTIONAL LANGUAGE ~

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

Contains DEET [and] [plus] MGK® 326 to Repel Mosquitoes and Flies Lotion

INSECT REPELLENT

Repels mosquitoes that may carry West Nile Virus

Repels mosquitoes that may carry (St. Louis) (Eastern equine) (Western equine) (Lacrosse) (Cache Valley) (Venezuelan equine) encephalitis and (Dengue Fever)

ACTIVE INGREDIENTS:	
DEET	
*N-octyl bicycloheptene dicarboximide	5.0%
**Di-n-propyl isocinchomeronate	
OTHER INGREDIENTS:	
TOTAL:	100.0%
*MGK-264, Insecticide Synergist, **MGK® 326	

KEEP OUT OF REACH OF CHILDREN WARNING

See Back Panel For Additional Precautionary Statements

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[] Optional/Alternate text

ACCEPTED with COMMENTS In EPA Letter Dated JAN 16 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 54287-8



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 place inaccessible to children. 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 toll free number or website which meets the criteria in paragraph II.E., PR Notice 2007-1] 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. 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.

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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.
	ct container with you when calling a poison control center or doctor, or going for treatment. For information in case of emergency call toll free 1-800-940-4464, Weekdays from 9-5 EST.

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, Inc.

P.O. Box 188, Safety Harbor, FL 34695 EPA Reg. No. 54287-8 EPA Est. No. 58188-FL-1 MGK® - Reg'd TM McLaughlin Gormley King Co. 54287-BREVISEDFINAL20007