



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

January 10, 2008

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

**Subject: Label Amendment, Addition of Duration Claim, Various Insect-Borne Diseases & Marketing Claims  
INSECT GUARD "25-S" AEROSOL, EPA Reg. No. 54287-19  
Your Submission Dated October 11, 2007**

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 provision(s):

General Statement:

1. Delete all text throughout the label marked with "strikethrough."

Optional Marketing Claims section comment(s): <sup>1</sup>

2. Revise optional marketing claim #1 to read: "Up to 8 hours of mosquito protection."
3. Remove Eastern equine Encephalitis, Lacrosse Encephalitis, Cache Valley Encephalitis and Venezuelan equine Encephalitis from optional marketing claim #2. These diseases are not established in the U.S. or suitable vectors have not been tested.
4. Remove European Tick Borne Encephalitis from optional marketing claim #3. This disease is not established in the U.S. or suitable vectors have not been tested.
5. Delete optional marketing claim #4. This disease (Onchocerciasis) is not established in the U.S. or suitable vectors have not been tested.
6. Revise optional marketing claim #5 to read: "Protection [you can count on for up to 8 hours] [from mosquitoes that may carry West Nile Virus]."
7. Delete optional marketing claim #13. Long lasting is ambiguous.
8. Delete optional marketing claim #18. Claims against vectors of specific diseases are acceptable. For this claim, the vector(s) cannot be identified.

<sup>1</sup> For more detailed information, please refer to page 2 of 2 of the efficacy review for this product.

Directions for Use, General Precautions and Restrictions subsection comment(s):

- 9. As required by PR Notice 2001-3, replace the existing subsection with: "Apply this product only as specified on this label. Hold container 6 to 8 inches from exposed skin and/or clothing with a slow, sweeping motion. **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. Heavy application and saturation is unnecessary for effectiveness. For maximum protection, spread evenly with hand to moisten all exposed skin. 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. Wipe palms after applying. When using sprays, do not spray directly into face; spray on hands first and then apply to face. To apply to clothing, spray shirts, pants, socks and hats. For chiggers and ticks, also spray pant cuffs, socks and around openings in outer clothing. **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. 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. Will not damage cotton, wool or nylon. **DO NOT** apply on or near acetate, rayon, Spandex or other synthetic fabrics (other than 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."

Storage & Disposal section comment(s):

- 10. Replace the existing section with:

<p><b>Storage and Disposal</b></p> <p>Do not contaminate water, food, or feed by storage and disposal.</p> <p><b>Pesticide Storage:</b> Store this product dry in a cool, dry (preferably locked) area away from heat or open flame in an area inaccessible to children.</p> <p><b>Pesticide Disposal:</b> Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. <b>Container Disposal:</b> Do Not Puncture or Incinerate! <b>If empty:</b> Place in trash or offer for recycling if available. <b>If partly filled:</b> Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.</p>
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Precautionary Statements section, Hazards to Humans and Domestic Animals subsection comment(s):

- 11. As required by PR Notice 2001-3, replace the existing section with: "Causes substantial but temporary eye injury. Harmful if swallowed. Avoid contact with eyes and lips. **DO NOT** get in eyes. **DO NOT** apply to children's hands. **DO NOT** use on infants. 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."

First Aid Statement (table) comment(s):

12. Replace the existing 3<sup>rd</sup> line of this table with:

<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. <b>For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-940-4464 or the National Pesticide Information Center at 1-800-858-7378.</b><sup>2</sup></p> <p><b>Note to Physician:</b> Probable mucosal damage may contraindicate the use of gastric lavage.</p>
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As required by the Reregistration Eligibility Decision (RED) document for DEET, this product 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.

Associated Registrations, Inc. should also note that 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.

Copies of your label stamped "Accepted with Comments" and the efficacy review for this product are enclosed for your records. If you have any questions, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at [Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov).

*for* *Ann Sebold*  
 Richard J. Gebken  
 Product Manager (10)  
 Insecticide Branch  
 Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments"  
 054287-00019 D346658 & D385799

<sup>2</sup> Please note that the "1-800-940-4464" 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.

# INSECT GUARD "25-S" AEROSOL

## Optional Marketing Claims

- Mosquito Protection [for up to 8 hours]
- Repels mosquitoes that may carry (St. Louis) (~~Eastern equine~~) (~~Western equine~~) (~~Lacrosse~~) (~~Cache Valley~~) (~~Venezuelan equine~~) encephalitis and (Dengue Fever) [for up to 8 hours]
- Repels ticks that may carry (Lyme disease) (Rocky Mountain Spotted Fever) (Tick Paralysis) (Ehrlichiosis) (~~European Tick Borne Encephalitis~~) (Powassan Encephalitis) [for up to 8 hours]
- ~~• Repels black flies that may carry Onchocerciasis.~~
- ~~• [Proven][Effective] Protection [you can count on for up to 8 hours][from mosquitoes that may carry West Nile Virus][from mosquitoes that may carry disease(s)].~~
- Provides up to 8 hours of protection from mosquitoes and biting flies: gnats, sand flies, stable flies, black flies. Also repels ticks, chiggers and fleas from treated skin.
- Lasts up to 8 hours
- Repels Mosquitoes [for up to 8 hours]
- Mosquito Repellent
- Repels mosquitoes that may carry West Nile virus.
- Repels Mosquitoes, Chiggers, Ticks, Biting Flies, Black Flies, Deerflies, Stable Flies, Sand Flies Gnats, No-See-Ums, and Fleas on Exposed Skin Surfaces [for up to 8 hours]
- Contains 25% DEET
- Contains DEET
- ~~• Long Lasting Protection.~~
- Unscented
- Aerosol Spray
- Use on skin and clothing for maximum protection:
- Repels mosquitoes that may carry West Nile Virus [for up to 8 hours]
- ~~• Repels mosquitoes that may carry diseases [for up to 8 hours].~~

### ACTIVE INGREDIENTS:

DEET .....	25.0 %
OTHER INGREDIENTS .....	75.0 %
Total	100.0 %

KEEP OUT OF REACH OF CHILDREN

WARNING

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS (PRECAUTIONS).

[SEE ADDITIONAL PRECAUTIONS ON BACK PANEL]

NET CONTENTS: \_\_\_\_ oz.

[ ] Indicates alternative text

ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
*January 10, 2008*  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
54287-19

**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.** Hold container 6 to 8 inches from skin or clothing with a slow sweeping motion. Do not spray in enclosed areas. For maximum protection, spread evenly with hand to moisten all exposed 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. Do not apply over cuts, wounds or irritated skin. Do not spray directly on face. If used on the face, spray on hands first then apply sparingly and avoid eyes. Wipe palms after applying. To apply to clothing, spray shirts, pants, socks and hats. For chiggers and ticks, also spray pant cuffs, socks and around opening in outer clothing. Use just enough repellent to cover exposed skin and/or clothing. Do not use under clothing. Avoid over application of this product as frequent reapplication and saturation is unnecessary for effectiveness. After returning indoors, wash treated skin with soap and water. Wash treated clothing before wearing it again. Will not damage cotton, wool or nylon. Do not apply on or near: acetate, rayon, spandex or other synthetics (other than nylon), furniture, plastics, watch crystals, leather and painted or varnished surfaces including automobiles.

**STORAGE AND DISPOSAL**

**Pesticide Storage:** Store away from heat or flame in an area inaccessible to children. **Pesticide Disposal:** Do not puncture or incinerate! 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.

**PRECAUTIONARY STATEMENTS**

**Hazard to Humans - WARNING:** Harmful if swallowed. May cause eye injury. Avoid contact with eyes and lips. May cause skin reaction in rare cases. If you suspect a reaction to this product, discontinue use, take off contaminated clothing, wash treated skin, and call your local poison control center or doctor for treatment advice. If you go to a doctor, take this product with you. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

<i>FIRST AID</i>
<p><b>If in eyes:</b></p> <ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<p><b>If swallowed:</b></p> <ul style="list-style-type: none"> <li>• Call poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<p>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 1-800-940-4464.] <b>Note To Physician:</b> Probable mucosal damage may contraindicate the use of gastric lavage.</p>

NOTE: The First Aid statement's 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 or open flame. Do not puncture or incinerate container. Exposure to temperatures above 120°F may cause bursting.

