

58007-7

12/14/2004

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## United States Environmental Protection Agency

Susan M. Price, Sr. Regulatory Affairs Specialist  
 3M  
 3M Center, Building 220-2E-02  
 St. Paul, MN 55144-1000

DEC 14 2004

Subject: Application to Amend the efficacy claim for Ultrathon Insect Repellent 8 (EPA Reg. No. 58007-7) from 8 hours to 12 hours, and to change the name of the product to Ultrathon insect Repellent 12 to reflect this change.

Registration No: 58007-7

Date of Submission: May 27, 2004

OPP Identifier No. (form 8570-1): none

Dear Ms. Price.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable subject to the comments listed below.

1. Based on the Efficacy review (copy enclosed)

- the 12 hour claim is applicable only to mosquitoes. No such claim may be made in a association with any other taxa (pests) included on the label,
- and the product name change is acceptable provided that corroborating field data are submitted or cited for at least two genera of mosquitoes. *Culex sp.* and *Aedes sp.*. 3M must submit field data within 12 months or provide cited data with an updated data matrix (EPA form 8570-35) within 6 months.

2. Revise the label by moving the statement "developed by 3M for the U.S. Military" from all marketing claims and adding it to the back panel. This statement, moved to the back panel, must be stated as follows: "Developed by 3M for the U.S. Military." This statement cannot not be used in conjunction with any marketing claims (either directly, or indirectly (i.e. footnoting)). In addition, the statement must maintain the same font size, color, background, and text orientation as the smallest font size on the back panel. The preferred location for this verbiage is outside of the Directions for Use, and either directly above or below the company name and address.

3. Revise the following "Hazards to Humans" section from "HAZARDS TO HUMANS — WARNINGS: Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes. Use of this product may cause skin reactions in rare cases. Wash treated clothing before wearing it again. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet." to the following: "HAZARDS TO HUMANS **WARNING:** Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Remove and

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wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco."

Five copies of the finished labeling must be submitted prior to releasing the product for shipment. If you have any questions, you may contact Richard J. Gebken, at (703) 305-6701.

Sincerely,



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

Enclosure

cc: M. Novak (Keller & Heckman LLP)

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3M ULTRATHON INSECT REPELLENT 12

Front:

UP TO 12 HOURS of protection against mosquitoes.

CONTAINS DEET

ACTIVE INGREDIENTS:

DEET .....25%  
Other Ingredients .....75%

KEEP OUT OF REACH OF CHILDREN  
WARNING

See back panel for additional precautions

NOTICE: Extremely Flammable

REPELS MOSQUITOES, BITING FLIES, TICKS, CHIGGERS, GNATS AND FLEAS

REPELS MOSQUITOES THAT MAY CARRY WEST NILE VIRUS

REPELS DEER TICKS THAT MAY CARRY LYME DISEASE

CONTROLLED RELEASE FORMULA

Advanced 3M Controlled Release Technology -  
Developed for the U.S. Military.

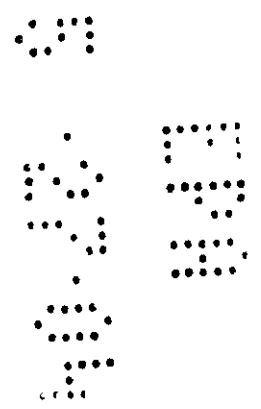
Fresh Outdoor Scent  
Outdoor Scent  
Pine Scent

NET WT. (6oz or 170g)

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:

DEC 14 2004

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
58007-7



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3M ULTRATHON INSECT REPELLENT 12 (back)

Ultrathon's proprietary 3M Controlled Release Technology provides a continuous shield of protection that lasts up to 12 hours against mosquitoes. This Controlled Release Technology was developed by 3M for the U.S. Military for use in challenging situations requiring long lasting protection. Ultrathon™ Insect Repellent 12 also repels ticks, biting flies, chiggers, gnats, fleas and deerflies by creating an effective barrier that repels insects hour after hour. Ultrathon™ resists rain, perspiration and water splashes.

**THIS CAN IS DESIGNED TO SPRAY RIGHT SIDE UP OR UPSIDE DOWN FOR CONVENIENT APPLICATION.**

**PRECAUTIONARY STATEMENTS:**

**HAZARDS TO HUMANS – WARNINGS:** Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes. Use of this product may cause skin reactions in rare cases. Wash treated clothing before wearing it again. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

**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 five minutes, then continue rinsing.

Call a poison control center or doctor for treatment advice.

**IF SWALLOWED:**

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 by a poison control center or a doctor.

**Do not give anything by mouth to an unconscious person.**

**IF YOU SUSPECT A REACTION TO THIS PRODUCT:**

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.

**HOT LINE NUMBER:**

In case of emergency call toll free 800-364-3577. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

**PHYSICAL & CHEMICAL HAZARDS: FLAMMABLE.** Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

**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 and spray with a slow sweeping motion. **TO APPLY TO FACE,** spray into palm of hand and spread evenly on face and neck. For best protection spread evenly with hand to moisten all exposed skin. **WORKS ON CLOTHING, TOO.** Spray shirts, pants, cuffs, socks and around other openings in outer clothing. **WILL NOT DAMAGE** nylon, cotton or wool fabrics.

**MAY DAMAGE** other synthetic fabrics, plastics, watch crystals, leather, painted, or varnished surfaces.

**GENERAL PRECAUTIONS AND RESTRICTIONS:**

Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply over cuts, wounds or irritated skin. Do not allow children to handle this product. Do not apply to children's hands. 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 over application of this product. After returning indoors, wash treated skin with soap and water. Do not spray in enclosed areas.

**PESTICIDE STORAGE:** Store the product in a cool and dry place. Keep out of reach of children.

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**CONTAINER 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 1-800-253-2687 for disposal instructions.  
Never place unused product down any indoor or outdoor drain.

Refer to Material Safety Data Sheet (16-4412-9) for more information.

**3M**

3M Center

St. Paul, MN 55144-1000

EPA Reg. No. 58007-7

EPA Est. No. 3657-WI-2

Made in USA

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Insert UPC

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REMEMBER TO HELP KEEP OUR WORLD CLEAN!

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