

SEP 10 2003

Kim Davis  
Schering-Plough HealthCare Products Canada,  
a Division of Schering Canada, Inc.  
c/o RegWest Company, LLC  
30856 Rocky Road  
Greeley, CO 80631-9375

Subject: Muskol Insect Repellent Spray  
EPA Registration No. 38811-6  
Application dated December 18, 2002  
Application dated August 18, 2003

Dear Ms. Davis:

The proposed amendment to the registration for the product cited above under The Federal Insecticide, Fungicide And Rodenticide Act, as amended revising the label in response to the DEET RED, PR Notices 2001-1, 2001-6, 97-6, 97-5, 97-4 and 83-3 is acceptable subject to the comments listed below:

1) Change the Precautionary Statements to read:

“May cause eye injury.Harmful if swallowed Do not get in eyes. Avoid contact with lips and mouth.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.”.

2) Add the following to the First Aid section:

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.

3) Add the following statements to the First Aid section:

"For additional information in case of emergency call toll free( insert telephone number)."

"Have the product container or label with you when calling a poison control center or doctor or going for treatment."

4) Change the Ingredient Statement to read:

Active Ingredient	
DEET xxxxxxxxxxxxxxxxxxx	%(insert proper percentage)
Other Ingredients xxxxxxxx	%(insert proper percentage)

Note: Your suppliers are no longer claiming that their products are 100% active. Therefore you must adjust the amount of the supplier's product that you use. This will differ depending on which supplier you use.

A revised Confidential Statement Of Formula(CSF) must be submitted.

5) Add the following Note To Physician: "Probable mucosal damage may contraindicate the use of gastric lavage."

This product is not being re-registered at this time. Product specific efficacy data will be required. Once the efficacy guidelines are in place, you will be notified of the efficacy requirements.

Also, to meet the requirement of the DEET RED, the product, must be packaged in containers utilizing a concave trigger to help aim the product or other comparable mechanism that will ensure that the product will not be inadvertently sprayed in the eyes.

A stamped copy of the amended label submitted on August 18, 2003 is enclosed for your records. Submit two copies of the final label before the product is released for shipment under this revised label.

If you have any questions or comments please contact Joseph Tavano at (703) 305-6411.

Sincerely

*Joseph M. Tavano*  
 Linda Arrington  
 Acting Product Manager 10  
 Insecticide Branch  
 Registration Division (7505C)  
*JA*

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# Muskol<sup>®</sup> Insect Repellent Spray

## INSECT REPELLENT

Aerosol

25% Deet

Keeps Mosquitoes Away

Also Repels Ticks

Repels Biting Flies and Other Insects

Will Spray Upside Down

A Canadian Tradition Since 1951 ... From Col. C. Coll, Muskol<sup>®</sup> Inventor

### Active Ingredient:

DEET .....	25%
Other Ingredients .....	75%
Total .....	100%

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated:**  
**SEP 10 2003**

Keep Out of Reach of Children

### WARNING

See precautionary statements on back panel.

Net Wt. \_\_\_ oz. (\_\_\_ g)

**Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
38811-6**

{Back Panel}

## Muskol<sup>®</sup> Insect Repellent Spray

Muskol<sup>®</sup> Insect Repellent was originally developed in 1951 by Col. C. Coll, an avid Canadian outdoorsman. Since its introduction, Muskol<sup>®</sup> Insect Repellent has been repelling flying and crawling pests during outdoor activities ranging from fishing and camping trips to gardening.

Muskol<sup>®</sup> Insect Repellent Spray provides effective protection against mosquitoes, biting flies, chiggers, gnats, sand flies, black flies and deer flies. Also repels fleas and ticks. For especially vulnerable areas or severe conditions, try Muskol<sup>®</sup> insect Repellent products in lotion or pump spray.

This aerosol product has a special valve that will spray upside down, for easy use on legs and feet.

### PRECAUTIONARY STATEMENTS

#### Hazards to Humans

**WARNING:** Harmful if swallowed. May cause eye injury. Keep out of eyes, lips and mouth. 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 product with you.

#### First Aid

<b>If Swallowed</b>	<ul style="list-style-type: none"> <li>Immediately call a poison control center or doctor 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>
<b>If in Eyes</b>	<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>

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

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

#### Physical and 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.

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**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. Do not spray in enclosed areas. Spread by hand if necessary for complete coverage. 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, stockings and hat. 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. Safe to use on cotton or wool. Do not apply to synthetic fabrics other than nylon or polyester. May damage furniture finishes, plastics, linoleum, painted surfaces and watch crystals.

**[Storage and Disposal]**

**Storage:** Store in a cool, dry (preferably locked) place, inaccessible to children and pets, and away from sources of heat or ignition. **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 1-800-CLEANUP] for disposal instructions.

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EPA Reg. No. 38811-6      EPA Est. \_\_\_\_\_

{Code}

Questions or Comments? {toll free number}

[ ] Denotes alternate/optional language

{ } Denotes language that does not appear on the market label