

# U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460 EPA Registration No.

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38811-5

Date of Issuance:

APR 0 3 2008

NOTICE OF PESTICIDE: 

Registration

☐ Registration ☐ Reregistration

(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

Term of Issuance:

**Conditional** 

Name of Pesticide Product:

**Muskol Insect Repellent** 

Name and Address of Registrant (include ZIP Code): Schering-Plough HealthCare Products Canada, a Division of Schering Canada, Inc. c/o RegWest Company, LLC 30856 Rocky Road Greeley, CO 80631-9375

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This action is taken under the authority of section 4(g)(2)(c) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

Based on your response to the Reregistration Eligibility Document(s), EPA has reregistered the product listed above provided that the following change is made to the label:

### 1. Marketing Claims:

Remove "100% DEET" from the label.

This product contains less than 100% DEET and related isomers.

Remove the claim "Odorless"

This is a false and misleading statement.

Revise the following statement "Works on skin and outer surfaces of clothing." This insertion is necessary to clarify that this product is intended to be applied to the outer surfaces of clothing only. (Page 2 of label).

2. Change the Ingredient Statement to read:

"Active Ingredient

DEET ..... 98.11%

Other Ingredients ...... 1.89%"

Note: Only Morflex (51147-1) and MGK (1021-891) can be used as suppliers for this

product. A revised Confidential Statement of Formula(CSF) showing only Morflex (51147-1) and MGK 1021-891 as suppliers must be submitted and approved by the Agency.

3. Change the Precautionary Statements to read:

"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."

4. 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."

You may refer to PR Notice 2001-1 for guidance.

- 5. Add the following "Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage." to bottom of the First Aid statements.
- 6. Within the Directions for Use section, revise as follows:

"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.

For Outdoor Use Only. Do not spray in enclosed areas. Never use repellents over cuts, wounds, or irritated skin. Do not apply near eyes and mouth. Apply sparingly around ears. 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 apply to children's hands. Do not allow children to handle this product, and do not apply to children's hands. When using on children, apply to your own hands and then put it on the child. Apply only to exposed skin and/or clothing (as directed on the product label). Do not use under clothing. Use just enough repellent to cover exposed skin. Heavy application and saturation is unnecessary for effectiveness; if biting insects do not respond to a thin film of repellent, apply a bit more. 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. Also, wash treated clothing before wearing it again.

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.

For application to exposed skin to repel mosquitoes, biting flies, gnats, and fleas: Squeeze a few drops into hand and apply to exposed skin.

For application to outer surfaces of clothing to repel chiggers and ticks, apply around all clothing openings.

Will not damage nylon, cotton, wool or polyester. Avoid contact with plastic and fabric such as acetate and rayon. May damage some plastics, furniture finishes, painted surfaces and linoleum."

7. Revise the Storage and Disposal Section as follows:

"Storage and Disposal

Store in a cool, dry locked place inaccessible to children and pets.

**Pesticide Storage:** Store in a cool dry place away from heat or open flame and inaccessible to children.

Pesticide Disposal: If empty: 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."

- 8. 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.
- 9. With the next submission of the label, Schering-Plough Health Care Products Canada, should clearly identify <u>all</u> labeling components for the complete package that accompanies the pesticidal product (i.e. display card, label front panel, back panel, etc.).

  Refer to Chapter 3 Section VII. "Label Format" at the following Agency internet site for guidance: <a href="http://www.epa.gov/oppfead1/labeling/lrm/chap-03.htm">http://www.epa.gov/oppfead1/labeling/lrm/chap-03.htm</a>
- 10. 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.
- 11. 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.

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.

Signature of Approving Official:

Date:

APR 0 3 2008

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

38811-5 New Label: Page 1 of 3

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

#### **INSECT REPELLENT**

Insect Repellent [Lotion] [Pump Spray]
100% DEET

Up to 10 Hours Protection!

Up to 10 Hours Protection against mosquitos, biting flies and ticks

Protects Against Mosquitos and Ticks for up to 10 Hours!

Odorless Unscented Starts to Work Quickly
Sprays on Skin or Clothing
A Canadian Tradition Since 1951 . . . From Col. C. Coll, Muskol® Inventor

Active Ing	redient:	•
DEET	***************************************	100%

Keep Out of Reach of Children
WARNING
See precautionary statements on back panel.

\_\_ fl. oz. (\_\_ mL)

ACCEPTED with COMMENTS In EPA Letter Dated

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

{Back Panel - Lotion}

[Retain for Complete Directions]

[Read and Retain Outer Package for Complete Directions]

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

- Provides up to 10 hours protection against mosquitos, ticks, biting flies, chiggers, fleas and gnats.
- Easy to apply.
- Resists water, perspiration and wear.
- For those who prefer aerosol sprays, try Muskol Insect Repellent Spray.

## 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

	1 list Ald	
If Swallowed	Immediately call a poison control center or doctor for treatment advice.	1
	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.	
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.	
Have the produc	ct 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.}

8811-5 New Label: Page 2 of 3 08/18/03

#### **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.

Squeeze a few drops into hand and apply to 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. Wipe palms after applying. For chiggers and ticks, apply around all clothing openings. Use just enough repellent to cover exposed skin. 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 nylon, cotton, wool or polyester. Avoid contact with plastic and fabric such as acetate and rayon. May damage some plastics, furniture finishes, painted surfaces and linoleum.

[Storage and Disposal]

Storage: Store in a cool, dry (preferably locked) place inaccessible to children and pets. 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-CLEANUP] for disposal instructions. Never place unused product down any indoor or outdoor drain.

{Back Panel - Pump Spray}

[Retain for Complete Directions]

[Read and Retain Outer Package for Complete Directions]

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

- Provides up to 10 hours protection against mosquitos, ticks, biting flies, chiggers, fleas and gnats.
- Easy to apply.
- · Resists water, perspiration and wear.
- · Works on skin and clothing.

#### 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 repellent with you.

#### First Aid

If Swallowed	Immediately call a poison control center or doctor 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.
If in Eyes	Hold eye open and rinse slowly and gently with water for 15-20 minutes.
ľ	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
1	Call a poison control center or doctor for treatment advice.
Have the produc	ct 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.}

#### **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 4 to 6 inches from skin or clothing and spray. Keep upright. 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. For chiggers and ticks, apply around all clothing openings. 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 nylon, cotton, wool or polyester. Avoid contact with plastic and fabric such as acetate and rayon. May damage some plastics, furniture finishes, painted surfaces and linoleum.

676

38811-5 New Label: Page 3 of 3

[Storage and Disposal]

Storage: Store in a cool, dry (preferably locked) place inaccessible to children and pets. 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-CLEANUP] for disposal instructions. Never place unused product down any indoor or outdoor drain.

(Lotion and Pump Spray)

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6400 Northam Drive

Mississauga, Ontario, Canada L4V 1J1

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Questions or Comments? {toll free number}

[] Denotes alternate/optional language

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