

JUL 30 2003

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

Subject: Revised Label For:
Coppertone Bug & Sun Sunscreen with
Insect Repellent Adult Formula
EPA Registration No. 6148-11
Application dated March 26, 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 accordance with PR Notices 2001-1 and 2001-6 is acceptable subject to the comment listed below:

The Ingredient Statement must be revised as shown below:

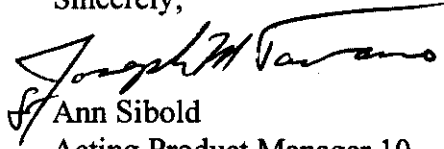
Active Ingredient:	
DEET.....	10%
Other Ingredients.....	90%
Total.....	100%

Note: You should check with your supplier of DEET. Since your supplier no longer claims that their product is 100% active, you will have to amend your formula to bring the active up to 10 percent or lower the amount claimed on your label. A revised Confidential Statement Of Formula(CSF) must be submitted.

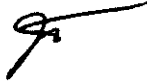
A stamped copy of the revised label is enclosed for your records. Submit two copies of the final label before the product is released for shipment under this revised label.

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

Sincerely,



Ann Sibold
Acting Product Manager 10
Insecticide Branch
Registration Division(7505C)



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Coppertone® Bug & Sun Sunscreen with Insect Repellent Adult Formula

INSECT REPELLENT

Waterproof ❖ SPF 15

Active Ingredient:

*DEET (CAS No. 134-62-3) 10%

Other Ingredients 90%

Total 100%

*N,N-diethyl-m-toluamide (m-DEET) + Related Isomers

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

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUL 30 2003

*Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
6148-11*

_____ fl. oz. (118 ml)
{2 through 16 fl. oz.}

{Back Panel}

Coppertone® Bug & Sun Sunscreen with Insect Repellent Adult Formula is specifically formulated to provide protection for over two hours against mosquitoes, gnats and biting flies (sand flies, black flies and deer flies), as it protects you from the sun. Coppertone® Bug & Sun Sunscreen with Insect Repellent Adult Formula offers convenient dual protection in one bottle, for total outdoor skin protection. It is water-resistant and provides protection from UVA and UVB rays. This waterproof SPF 15 sunscreen protects from harmful UVA and UVB rays, while it also repels mosquitos, gnats, deer flies, stable flies and black flies on exposed skin surfaces. This pleasantly-fragranced, PABA-free, non-greasy lotion also moisturizes dry skin with soothing Aloe Vera. Regular use may help reduce the chance of long-term sun damage such as premature aging, wrinkling and skin cancer.

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. Apply evenly before exposure to sun and insects. Reapply after prolonged swimming or excessive perspiration. Use just enough product to cover exposed skin. Do not use under clothing. Frequent reapplication and saturation is unnecessary for effectiveness. 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. Wipe palms after applying. Avoid over-application of this product. After returning indoors, wash treated skin with soap and water. **Consult a physician before use on children under 6 months of age.**

Storage and Disposal

Storage: Store in a cool, dry place inaccessible to children. **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 for disposal instructions. Never place unused product down any indoor or outdoor drain.

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PRECAUTIONARY STATEMENTS
Hazards to Humans

CAUTION: Harmful if swallowed. Do not apply over cuts, wounds or irritated skin. Avoid contact with eyes and lips. Causes moderate eye irritation. Avoid contact with plastic and fabric such as acetate, rayon and dyneel. May damage some plastics, furniture finishes, painted surfaces and linoleum. Will not damage nylon, cotton, wool or polyester.

First Aid

If Swallowed:	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • 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 on Skin or Clothing:	<ul style="list-style-type: none"> • Use of this product may cause skin reactions in rare cases. • If you suspect that you or your child is reacting to this product, wash treated skin and call your local poison control center.

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 permits; otherwise a paragraph format will be used.}

Active sunscreen ingredients: Ethylhexyl p-methoxycinnamate, oxybenzone, 2-Ethylhexyl salicylate, homosalate.

EPA Reg. No. 6148-11

EPA Est. 10744-IL-1

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} Denotes language that does not appear on market labeling

