

121-97

10/29/2008

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (H7505C)  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

EPA Reg. Number:  
121-97

Date of Issuance:  
OCT 29 2008

Term of Issuance:  
Conditional

Name of Pesticide Product:  
Cutter Insect Repellent SS

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):

Spectrum  
Division of United Industries  
2150 Schuetz Road  
St. Louis, MO 63146

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 product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided:

1. You will submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. You will make the following label changes before you release the product for shipment:
  - a) Revise the EPA Registration Number to read "EPA Reg. No.121-97".
  - b) Remove claim #10 Next generation insect repellent formula to be used for 6 months from the first date of shipment.
  - c) Remove 'PABA Free'
  - d) Remove 'Hypoallergenic'
  - e) Remove "Very water resistant; water/sweat resistant; and water/perspiration resistant."
  - f) Remove "Retains SPF after 80 minutes of activity in water or sweating or perspiring."
  - g) Remove "Remove "This fragrance free formula is hypoallergenic, PABA free and non-greasy."
  - h) Remove "Higher SPF gives more sunburn protection."
  - i) Remove "Provides high protection against sunburn, sunburn and tanning, or for skin highly sensitive to sunburn."
  - j) Remove "Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun."
  - k) Change: Do no apply to children under 6 months of age: ask a doctor." to "Do not apply to children under 6 months of age."

Signature of Approving Official

Date:

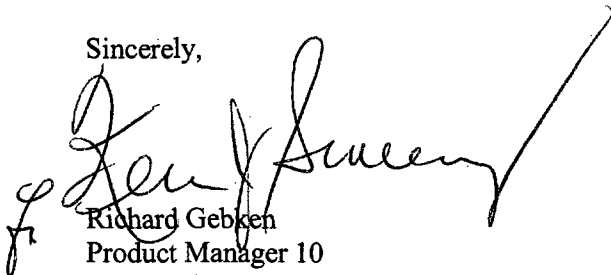
OCT 29 2008

Richard Gebken, Product Manager (10), RD/IB (7505P)

3. Submit the results of one year storage stability (830.6317) and corrosion characteristics (830.6320) to the Agency on completion. It is recommended that the observations be made at 0, 3, 6, 9, & 12 month intervals. The results must be submitted in a hard copy and an electronic format is also requested.
4. As agreed on in your email dated August 27, 2008, you will remove the label claims on application to clothing.
5. As agreed in your letter of March 12, 2007 the request to add mosquitoes, biting flies, chiggers, gnats, no-see-ums and fleas to the product label is conditionally acceptable provided you submit product specific efficacy data as described in draft EPA Product Performance Guideline 810.3700 for each pest by May 5, 2009. EPA acknowledges receipt of the requested data for mosquitoes and ticks for your picaridin products that are currently under science review. These studies will be considered by the Human Studies Review Board during their January 2009 meeting.
6. The 'Precautionary Statements' should be changed to read as follows:  
"Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco."
7. Add the following statements to the 'Directions for Use':  
"Do not apply to excessively sunburned skin."  
"Do not use under clothing."  
"When using on children, apply to your hands and then put it on the child."  
"Do not spray in enclosed areas."  
"If used on face, spray on hands first and then apply and avoid eyes."  
"Do not spray directly on face."  
"After returning indoors, wash treated skin with soap and water. If product gets on clothing, wash before wearing again."  
"Apply sparingly around ears."
8. The basic Confidential Statement of Formula (CSF) dated September 6, 2005 is acceptable and is the CSF of record for this product.
9. Submit three (3) copies of your final printed labeling before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. Please find attached the data evaluation reviews (DERs) for: product chemistry; acute toxicology; and dermal penetration together with an updated risk assessment. Transmittal of the dermal penetration DER and the updated risk assessment is made following the concurrence of Dr. Ghona Sangha in a telephone conversation held on October 30, 2008. If you have any questions regarding this registration, please contact Kevin Sweeney at (703) 305-5063.

Sincerely,



Richard Gebken  
Product Manager 10  
Insecticide Branch  
Registration Division (7505P)

Enclosure

Front Panel

# CUTTER

## Insect Repellent SS

SPF 30  
Very [Water] [Water/Sweat] [Water/Perspiration] Resistant  
Sunscreen

See back panel for other Marketing Claims

ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
OCT 29 2008  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
121-97

Active Ingredient:  
Picaridin .....15.0%  
Other Ingredients ..... 85.0%

KEEP OUT OF REACH OF CHILDREN

**CAUTION** Read cautions on back

Net [Contents] 6 fl oz (177 mL)

### OPTIONAL MARKETING TEXT

*[Now . . . Pleasant protection against mosquitoes that's effective for hours!]*

Cutter Insect Repellent SS provides [total] outdoor skin protection conveniently in one bottle. The 15% Picaridin [provides protection from] [repels] mosquitoes for up to 5 hours and also [repels] [provides protection from] ticks, biting flies, no-see-ums, chiggers and fleas. The water resistant SPF 30 sunscreen protects from harmful UVA and UVB rays. This fragrance free formula is hypoallergenic, PABA-free and non-greasy. Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun..

Back Panel

SPF 30 Very water resistant.  
Helps prevent sunburn.  
Higher SPF gives more sunburn protection.  
Retains SPF after 80 minutes of [activity in the water] [or] [sweating] [perspiring]  
[PABA-free] [Hypoallergenic]  
[Provides] High Protection against [sunburn] [sunburn and tanning] or  
[For skin highly sensitive to sunburn]

### STOP. READ ENTIRE LABEL BEFORE EACH USE. DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Hold 4 to 6 inches from skin while spraying, keeping nozzle pointed away from face. Apply evenly before sun exposure and as needed. Reapply every 3 to 4 hours for continued insect repellency. Excessive amounts or more frequent reapplication is unnecessary. Do not apply over cuts, wounds, irritated or sunburned skin. For Sunscreen protection reapply as needed or after towel drying, swimming or [sweating] [perspiring]. Do not apply more than 3 times a day.

Do not apply to children's hands. To apply to face and neck, spray the product into your hands and apply. Take care to avoid mouth and eyes and apply sparingly around ears. Do not allow children to handle the product. Do not apply to children under 6 months of age: ask a doctor.

**Precautionary Statements****Hazards to Humans and Domestic Animals****CAUTION:**

Causes moderate eye irritation.

Avoid contact with eyes or clothing.

Wash thoroughly with soap and water after handling.

If you or your child react to this product, discontinue use, wash treated skin and call your local poison control center.

**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 5 minutes, then continue rinsing.

Call a Poison Control Center or doctor for treatment advice.

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

**STORAGE AND DISPOSAL**

**Storage:** Store the product in a cool, dry place, out of reach of children.

**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-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**Physical or Chemical Hazards**

**FLAMMABLE.** Keep away from heat and open flame.

**ACTIVE SUNSCREEN INGREDIENTS:** Octocrylene (10%), Octinoxate (7.5%), Oxybenzone (6%), Octisalate (5%)

**NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.**

**Questions or Comments?** Call 1-800-332-5553

[Visit our web site at [www.skeeterbites.com](http://www.skeeterbites.com)]

Made in the USA for Spectrum,  
Division of United Industries Corporation  
PO Box 142642  
St. Louis, MO 63114-0642

EPA Reg. No. 121-

EPA Est. No. 9688-MO-1

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**OPTIONAL MARKETING CLAIMS**

1. New! (to be used for 6 months from first date of shipment)
2. With Aloe Vera [and] [Vitamin E]
3. Light feel, strong protection
4. Effective, dependable protection
5. Repels mosquitoes, chiggers, biting flies, no-see-ums, gnats and fleas
6. Repels mosquitoes for hours
7. Repels mosquitoes that may [transmit] [carry] West Nile virus
8. No unpleasant odor [formula]
9. No one will know you're wearing repellent except the bugs
10. Next generation [insect repellent][formula](to be used for 6 months from the first date of shipment)
11. Repels mosquitoes for up to 5 Hours
12. Not greasy or oily
13. Non-sticky
14. Non-staining
15. Innovative formula (to be used for 6 months from the first date of shipment)
16. Won't harm plastics
17. Won't damage synthetic materials
18. Won't damage plastic or synthetic sporting equipment [(fishing line, fishing rods, tackle, gun stocks, tents, rafts, sunglasses)]
19. [Insect] protection without the [repellent] odor
20. Specially formulated to feel light on your skin
21. Feels light and clean
22. Sprayable Sunscreen
23. New Locking Cap
24. [Light] [Gentle] [Clean] Formula
25. Works great on biting flies
26. Gentle on your skin
27. Great for the yardwork
28. Protection for your active lifestyle