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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION PESTICIDES AND TOXIC SUBSEANCES

Mr. William Metzger Vice President, Regulatory and Government Affairs Spectrum, a Division of United Industries Corp. Box 142642 St. Louis, MO 63114-0642

DEC 22 2006

Dear Mr. Metzger,

Subject: Non-Fast Track Label Amendment

Product Name: Cutter Insect Repellent 12KT

EPA Reg. No. 121-93

Submission dated August 11, 2006

The amendments referred to above, submitted in connection with registration under Section (3)(c)(7) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is acceptable subject to the comments and terms for conditional registration outlined below.

- 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 registration of your product under FIFRA section 4.
- 2. Make the following label changes to EPA Reg. No 121-93
  - a. Remove "Cutter Insect Repellent 12KT is water [sweat] resistant.
  - b. Remove claim 1 "New"
  - d. Remove claims 29, 30, and 32 from the label.
  - e. Remove claim number 34: "6 hours protection against Culex mosquitoes." from the label. Retain the approved 3.5 hour claim for mosquitoes. The six hour claim would increase the reapplication interval despite the fact that a user will not be aware of the types of mosquitoes biting them. Other species may attempt to bite besides *Culex* spp.
- 3. The cited acute toxicity and product chemistry data are acceptable for both products. Updated DERs are attached.

4. The request to add biting flies, ticks, deer ticks, chiggers, no-see-ums and fleas is conditionally acceptable provided you agree to submit product specific efficacy data as described in draft EPA Product Performance Guideline 810.3700 for each pest by May 5, 2009. Testing protocols should be submitted by July 1, 2007.

Please refer to Kevin Sweeney's efficacy study review dated December 2, 2004 that describes data to be generated for each pest together with a mosquito field study.

5. With regard to product performance studies cited in your data matrix, I attached copies of the ethics reviews of two of the efficacy studies conducted with humans. Note that one study review requires you to submit additional information. For the other study, you must submit additional information so that it may be cited for registration purposes. Please respond to the findings of these ethics reviews by March 7, 2007. Additional product performance data will be required to support mosquito repellency claims for these products if these two studies cannot be used for registration purposes. If this is the case, these data should be submitted by May 5, 2009. If these data are necessary, test protocols should be submitted by July 1, 2007.

You should note that if you fail to satisfy any of the conditions imposed on this registration, e.g., you fail to submit the required data by the specified deadlines or the data submitted were not generated in accordance with the applicable test guidelines, or agreed upon protocols, EPA may issue notice to cancel this use under FIFRA 6(e).

A stamped copy of the label is enclosed for your records. If you have questions or concerns, please contact Kevin Sweeney at (703) 305-5063.

Ano<del>c</del>rely,

Richard Gebker

Product Manager 10 Insecticides Branch

Registration Division (7505P)

FN: 121-93-A1.doc

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Front Panel

# CUTTER Insect Repellent 12KT

See back panel for Marketing Claims

ACCEPTED
with COMMENTS
In EPA Letter Dated
DEC 2 2 2006
Under the Federal Insecticide.
Pungicide, and Rodenticide Act,
as amended, for the posticide
registered under EPA Reg. No.

Active Ingredient:	
Picaridin	12.09
Other Ingradients	ያል በዓ

# KEEP OUT OF REACH OF CHILDREN

WARNING Read cautions on back

Contains 18 [Towelettes] [Wipes] Total Net Wt 3 oz (85 g)

## **OPTIONAL MARKETING TEXT**

[Now . . . protection in an odorless formula that feels light and clean!]

[Cutter Insect Repellent 12KT provides up to 3.5 hours [of] protection against mosquitoes. It also provides effective protection against ticks, biting flies, deer flies, gnats, no-see-ums, chiggers and fleas.]

[Cutter Insect Repellent 12KT provides up to 6 hours [of] protection against the Culex mosquito. It also provides effective protection against ticks, biting flies, deer flies, gnats, no-see-ums, chiggers and fleas.]

[Cutter Insect Repellent 12KT with Picaridin is specially formulated for [fishermen, hunters and other Outdoorsmen] [active lifestyles]. [Cutter Insect Repellent 12KT is water [sweat] resistant and will not damage plastics or other synthetic materials.]

[Because Cutter Insect Repellent 12KT provides protection without the odor, it is perfect for hunters. And now formulated with Picaridin so it will not damage fishing lines or other synthetic materials.]

Back Panel

**STOP**. Read and follow all directions and precautions on this product label.

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **Do Not Apply more than once per day**.

(Directions for canister:)

Remove the lid from the container by pulling upward. Remove the protective foil. Lift flap on lid. Pull up the center [towelette][wipe] and thread the corner of [towelette][wipe] through the open flap in lid; **DO NOT** push finger through lid opening. Replace lid on container. [Towelettes][Wipes] should be pulled at an angle to dispense one at a time. The lid should be tightly closed on container between uses to keep [towelettes][wipes] from drying out. [Alternate directions for a single packet towelette: Tear open foil pack.] Unfold towelette and wipe evenly over exposed skin. Excessive amounts or more frequent reapplication should be unnecessary. Do not apply over cuts, wounds, or irritated skin. Do not apply near eyes and mouth. Apply sparingly around ears. When using on children, apply to your own hands and then put it on the child. Use just enough repellent to cover exposed skin. Do not use under clothing. Avoid overapplication of this product. After returning indoors, wash treated skin with soap and water. Wash treated clothing before wearing it again.



WHEN USING PRODUCT ON CHILDREN: Do not apply to their hands. To apply to child's face and neck, spray the product into your hands and apply to the child. Take care to avoid mouth and eyes and apply sparingly around their ears. Do not allow children to handle the product.

### STORAGE AND DISPOSAL

Pesticide 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.

### PRECAUTIONARY STATEMENTS

### Hazards to Humans and Domestic Animals

WARNING. Causes substantial but temporary eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating. drinking, chewing gum, using tobacco or using the toilet. Use of this product may cause skin reactions in rare cases.

### 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. Hotline Number: In case of an emergency call 1-800-767-9927.

## **Physical or Chemical Hazards**

COMBUSTIBLE. Do not use or store near heat or open flame.

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]

Made in the USA for Spectrum. Division of United Industries Corporation P O Box 142642 St. Louis, MO 63114-0642 EPA Reg. No. 121-93

EPA Est. No. 9688-MO-1

@ 2006

### **OPTIONAL MARKETING CLAIMS**

- New! (to be used for 6 months from first date of shipment)
- [Formulated] [Contains] [With] Picaridin
- 3. Fragrance Free
- 4. Unscented
- 5. [Light feel], strong protection
- 6. Feels light and clean
- 7. Light, clean feel
- 8. Repels mosquitoes
- 9. Repels mosquitoes that may [transmit] [carry] West Nile virus
- 10. No detectable skin feel or odor
- 11. You'll forget you're wearing it
- 12. Protection for the entire family
- 13. Repels mosquitoes for up to 3.5 Hours
- 14. Up to 3.5 hour protection from mosquitoes
- 15. Not sticky or [greasy] [oily]
- 16. No oily residue
- 17 Non-staining
- 18. [Heavy duty] [Sport] Formula
- 19. Can be applied to clothing
- Will not damage cotton, wool, nylon, facetate, rayon, spandexl or other synthetic materials
- 21. Will not damage [plastics] [watch crystals] or other synthetic materials
- 22. Will not damage [fishing line] [or plastic sporting equipment]
- 23. For active lifestyles
- 24. Convenient [towelette] [wipe] for easy application
- 25. Easy to apply
- 26. Wipe on Protection
- 27. Repels mosquitoes, ticks, [biting lies, deer flies, no-see-ums, chiqqers, anats and fleas] [and other biting insects].
- 28. Repels deer ticks that may carry Lyme disease
- 29. Water resistant [sport] [formula]
- 30. Sweat resistant [sport] [formula]
- 31. A better smelling way to keep bugs [away] [at bay]!
- 32. From [the makers of] Cutter Advanced, the #1 brand of picaridin insect repellents.
- 33. Clean, dry feel
- 34, with 6 hours of protection against the Culex mosquito
- 35. Light, clean feel
- 36. Light, Clean, [Odorless]
- 37. Mosquito Wipes

