121-92

12/22/2006

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

> OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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

DEC 2 2 2005

Dear Mr. Metzger,

Subject: Non-Fast Track Label Amendment Product Name: Cutter Insect Repellent 15KA EPA Reg. No. 121-92 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 121-92
  - a. Remove "Cutter Insect Repellent 15KA is water [sweat] resistant.
  - b. Remove claim 1 "New"
  - d. Remove claims 30, 31, and 33 from the label.

e. Remove claim number 35: "8 hours protection against Culex mosquitoes." from the label. Retain the approved 4.5 hour claim for mosquitoes. The eight 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.

Product Manager 10 Insecticides Branch Registration Division (7505P)

Enclosure

Front Panel

the product.

#### **OPTIONAL MARKETING TFXT** STC Pesti [Now . . . protection in an odorless formula that feels light and CUTTER Cont [Cutter Insect Repellent 15KA provides up to 4.5 hours [of] protection again for re mosquitoes. It also provides effective protection against ticks, biting flies, o CLE/ flies, gnats, no-see-ums, chiggers and fleas.] outdo Insect Repellent 15KA [Cutter Insect Repellent 15KA provides up to 8 hours [of] protection against PRE Culex mosquito. It also provides effective protection against ticks, biting flip Haza flies, gnats, no-see-ums, chiggers and fleas.] CAU Wast [Cutter Insect Repellent 15KA with Picaridin is specially formulated for [fish chew hunters and other Outdoorsmen] [active lifestyles]. [Cutter Insect Repellen react is water [sweat] resistant and will not damage plastics or other synthetic ma [Because Cutter Insect Repellent 15KA provides protection without the odo Firs See back panel for Marketing Claims perfect for hunters. And now formulated with Picaridin so it will not damage If in I lines or other synthetic materials.) Rem a Poi [Works on clothing too! Spray socks, cuffs, hats and other clothing opening not damage cotton, wool, nylon, acetate or spandex.1 Have ACCEPTED doctc with COMMENTS In EPA Letter Dated DEC 2 2 2006 Under the Federal Insecticide, Fungicide, and Rodenticide Act. 767-{ Back Panel STOP. Read and follow all directions and precautions on this Phys as amended, for the pesticide registered under EPA Reg. No. label. FLAM flame 130°F DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsister NOT labeling. Do Not Apply more than once per day. with Hold 4 to 6 inches from skin while spraying, keeping nozzle pointed away fr Active Ingredient: Que: Slightly moisten skin. Excessive amounts or more frequent reapplication s [Visit unnecessary. Do not apply over cuts, wounds, or irritated skin. Do not apply r and mouth. Apply sparingly around ears. When using on children, apply to Made hands and then put it on the child. Use just enough repellent to cover expo **KEEP OUT OF REACH OF CHILDREN** Divis Do not use under clothing. Avoid overapplication of this product. Do not POL enclosed areas. If used on face, spray on hands first and then apply spar St. L CAUTION Read cautions on back avoid eyes. Do not spray directly onto face. After returning indoors, wash tre EPA with soap and water. Wash treated clothing before wearing it again. WHE PRODUCT ON CHILDREN: Do not apply to their hands. To apply to child's neck, spray the product into your hands and apply to the child. Take care Net Weight 6 oz (170 g) mouth and eyes and apply sparingly around their ears. Do not allow children

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## STORAGE AND DISPOSAL

**Pesticide Storage:** Store the product in a cool, dry place, out of reach of children. **Container Disposal:** Do not puncture or incinerate! **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. Never place unused product down any indoor or outdoor drain.

# 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 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

**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.

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 <u>www.skeeterbites.com]</u>

Made in the USA for Spectrum, Division of United Industries Corporation P O Box 142642 St. Louis, MO 63114-0642 EPA Reg. No. 121- 92 EPA Est. No. 9688-MO-1

## **OPTIONAL MARKETING CLAIMS**

- 1. New! (to be used for 6 months from first date of shipment)
- 2. [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 one will know you're wearing repellent except the bugs
- 11. No detectable [skin feel] or odor
- 12. You won't smell it, and neither will the deer
- 13. You'll forget you're wearing it
- 14. Protection for the entire family
- 15. Repels mosquitoes for up to 4.5 Hours
- 16. Up to 4.5 hour protection from mosquitoes
- 17. Not sticky or greasy
- 18. No oily residue
- 19. Non-staining
- 20. [Heavy duty] [Sport] Formula
- 21. Can be applied to clothing
- 22. Won't damage cotton, wool, nylon, [acetate, rayon, spandex] or other synthetic materials
- 23. Won't damage [plastics] [watch crystals] or other synthetic materials
- 24. won't damage [fishing line, gun barrel, plastic lenses][sporting equipment]
- 25. For active sports
- 26. Sprays upside down
- 27. New locking cap
- 28. Repels mosquitoes, ticks, [biting lies, deer flies, no-see-ums, chiggers, gnats and fleas] [and other biting insects].
- 29. Repels deer ticks that may carry Lyme disease
- 30. Water resistant [sport] [formula]
- 31. Sweat resistant [sport] [formula]
- 32. A better smelling way to keep bugs [away] [at bay]!
- 33. From [the makers of] Cutter Advanced, the #1 brand of picaridin insect repellents.
- 34. Clean, dry feel
- 35. with 8 hours of protection against the Culex mosquito
- 36. Light, clean feel
- 37. Light, Clean, [Odorless]
- 38. Long Lasting Protection

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