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

> OFFICE OF PREVENTION, PLS LICIDES 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 2006

Dear Mr. Metzger,

Subject: Non-Fast Track Label Amendment Product Name: Cutter Insect Repellent 10KP EPA Reg. No. 121-94 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 121-94

- a. Remove "Cutter Insect Repellent 10KP is water [sweat] resistant.
- b. Remove claim 1 "New"
- d. Remove claims 30, 31, and 33 from the label.

e. Remove claim number 35: "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.

Product Manager 10 Insecticides Branch Registration Division (7505P)

Enclosure

Cutter Insect Repellent 10KP	EPA Reg. No. 121-94	FN: 121-94-A1.doc	8/11//06
Front Panel		OPTIONAL MARKETING TEXT	
		[Now protection in an odorless formula that feels light and cleanl ]	
CUTTER		[Cutter Insect Repellent 10KP provides up to 3.5 mosquitoes. It also provides effective protection flies, gnats, no-see-ums, chiggers and tlees.]	
Insect Repellent 10	KP	[Cutter Insect Repellent 10KP provides up to 6 h Culex mosquito. It also provides effective protec flies, gnats, no-see-ums, chiggers and fleas.]	
		[Cutter Insect Repellent 10KP with Picaridin is s lifestyles]. [Cutter Insect Repellent 10KP is wate damage plastics or other synthetic materials.]	
See back panel for Marketing Claims		[Because Cutter Insect Repellent 10KP provides sticky feeling], you'll forget you're wearing it.	s protection without the odor [or
		[Clean, Odorless, Effective. Finally an insect re for everyone in the family]	pellent you won't mind using. great
ACCEPTED with COMMENTS In EPA Letter Date	eđ	Back Panel	<u>, , , , , , , , , , , , , , , , , , , </u>
UEL 2 2 2006 Under the Federal Insection Fungloide, and Rodenticide as exampled, for the peat	kde. Act.	<b>STOP</b> . Read and follow all directions a label.	and precautions on this product
registered under EPA Reg.	No.	DIRECTIONS FOR USE	
······································		It is a violation of Federal law to use this produce the labeling.	uct in a manner inconsistent with its
Active Ingredient: Picaridin Other Ingredients		Hold 4 to 6 inches from skin while spraying, kee Slightly moisten skin. Excessive amounts or mo unnecessary. Do not apply over cuts, wounds, or and mouth. Apply sparingly around ears. When	ore frequent reapplication should be r irritated skin. Do not apply near eyes using on children, apply to your own
KEEP OUT OF REACH OF CHILDREN		hands and then put it on the child. Use just eno Do not use under clothing. Avoid overapplicat	ion of this product. Do not spray in
		enclosed areas. If used on face, spray on hand avoid eyes. Do not spray directly onto face. After	returning indoors, wash treated skin
WARNING Read cautions on back		with soap and water. Wash treated clothing before PRODUCT ON CHILDREN: Do not apply to their pack, approve the product into your hands, and an	ir hands. To apply to child's face and
Net [Contents] 6 fl oz (177 mL)		neck, spray the product into your hands and an mouth and eyes and apply sparingly around their	rears. Do not allow children to handle
		the product.	
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# 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 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**

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 <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- 94 EPA Est. No. 9688-MO-1

. 9688-MO-1 © 2006

### 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 3.5 Hours
- 16. Up to 3.5 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 6 hours of protection against the Culex mosquito
- 36. Light, clean feel
- 37. Light, Clean, [Odorless]
- 38. Long Lasting Protection