



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 22 2006

Dear Mr. Metzger,

Subject: Non-Fast Track Label Amendments
Product Name: Cutter Insect Repellent 7K
EPA Reg. No. 121-89
Product Name: Cutter Insect Repellent 5KT
EPA Reg. No. 121-90
Submissions 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 121-89
 - a. Remove "Cutter Insect Repellent 7K is water [sweat] resistant.
 - b. Remove: "Finally, an insect repellent you won't mind using."
 - c. Remove claim 1 - "New"
 - d. Remove claims 36, 37, and 39 from pages 2 and 3 of the label.
 - e. Remove claim number 41: "6 hours protection against Culex mosquitoes."
Retain the approved four 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. Make the following label changes to EPA Reg. No. 121-90:
 - a. Remove "Cutter Insect Repellent 5KT is water [sweat] resistant.
 - b. Remove: "Finally, an insect repellent you won't mind using."
 - c. Remove claim 1 – "New"
 - d. Remove claims 38, 39, and 41.
 - e. Remove claim number 43: "6 hours protection against Culex mosquitoes." Retain the approved four 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.

4. The cited acute toxicity and product chemistry data are acceptable for both products. Updated DERs are attached.

5. The request to add biting flies, ticks, deer ticks, chiggers, no-see-ums and fleas is conditionally acceptable for EPA Reg. No. 121-89 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.

6. For EPA Reg. No. 121-90 the request to add ticks, deer flies and gnats 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.

For bullets 5 & 6, 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.

7. 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 to make the study acceptable for registration purposes. The other study was determined to be "unacceptable" and can longer 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 each label is enclosed for your records. If you have questions or concerns, please contact Kevin Sweeney at (703) 305-5063.

Sincerely,

Richard Gebken

Richard Gebken

Product Manager 10

Insecticides Branch

Registration Division (7505P)

Enclosure

Front Panel

CUTTER

Insect Repellent 5KT

See back panel for Marketing Claims

ACCEPTED
with COMMENTS
In EPA Letter Dated
DEC 22 2006
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
121-90

Active Ingredient:5.75%
Picaridin5.75%
Other Ingredients94.25%

KEEP OUT OF REACH OF CHILDREN

CAUTION 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!]

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

[Cutter Insect Repellent 5KT contains Picaridin, which provides up to 4 hours [of] protection against mosquitoes [with a light, clean scent!]. This specially formulated repellent also contains Aloe Vera & Vitamin E, leaving your skin feeling soft and smooth. It also provides effective protection against ticks, biting flies, deer flies, gnats, no-see-ums, chiggers and fleas.] Convenient [towelette] [wipe] for easy application.

[Cutter Insect Repellent 5KT with Picaridin is specially formulated for active lifestyles]. [Cutter Insect Repellent 5KT is water [sweat] resistant and will not damage plastics or other synthetic materials.]

[Because Cutter Insect Repellent 5KT provides protection without the odor [or sticky feeling], you'll forget you're wearing it.

[Clean, Odorless, Effective. Finally an insect repellent you won't mind using. Great for everyone in the family]

Cutter Insect Repellent 5KT contains Picaridin, the active ingredient found in the best selling European insect repellent. This repellent provides insect protection without an unpleasant [chemical] odor or greasy skin feel.

[Now, you can apply insect repellent without the smell and oily skin feel reminding you that you're wearing repellent. Cutter Insect Repellent 5KT provides effective insect protection while leaving your skin feeling smooth and smelling clean and fresh.]

[Cutter Insect Repellent 5KT provides up to 4 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 5KT 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 5KT with Picaridin is specially formulated for [fishermen, hunters and other Outdoorsmen] [active lifestyles]. [Cutter Insect Repellent 5KT is water [sweat] resistant and will not damage plastics or other synthetic materials.]

[Because Cutter Insect Repellent 5KT 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.]

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9
6

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.

[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. Reapply every 3 to 4 hours. Do not apply more than 3 times a day. 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**

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

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- 90

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. Soft on skin, tough on bugs
4. Light feel, strong protection
5. Feels great on you, tough on bugs [too]
6. Pleasant, effective protection [from mosquitoes, chiggers, biting flies, no-see-ums, gnats and fleas]
7. Effective, dependable protection
8. Repels mosquitoes, chiggers, biting flies, no-see-ums, gnats and fleas
9. Repels mosquitoes for hours
10. Repels mosquitoes that may [transmit] [carry] West Nile virus
11. Clean, fresh scent
12. No unpleasant odor [formula]
13. No one will know you're wearing repellent except the bugs
14. Next generation [insect repellent] [formula] (to be used for 6 months from the first date of shipment)
15. Protection for the entire family

16. Repels mosquitoes for up to 4 Hours
17. Not greasy or oily
18. Non-sticky
19. No oily residue
20. Non-staining
21. Innovative formula (to be used for 6 months from the first date of shipment)
22. Bayer technology
23. Won't harm plastics
24. Won't damage synthetic materials
25. Won't damage plastic or synthetic sporting equipment [(fishing line, fishing rods, tackle, gun stocks, tents, rafts, sunglasses)] plastic lenses[(sporting equipment)]
26. [Insect] protection without the [repellent] odor
27. For active lifestyles
28. Long Lasting Protection from mosquitoes
29. Convenient [towelette] [Wipe] for easy application
30. Easy to apply
31. Wipe on Protection
32. Now available in the U.S. (to be used for 6 months from the first date of shipment)
33. Fragrance free
34. Unscented
35. Contains Picaridin
36. Repels mosquitoes, ticks, [biting flies, deer flies, no-see-ums, chiggers, gnats and fleas] [and other biting insects].
37. Repels deer ticks that may carry Lyme disease
38. Water resistant [sport] [formula]
39. Sweat resistant [sport] [formula]
40. A better smelling way to keep bugs [away] [at bay]!
41. From [the makers of] Cutter Advanced, the #1 brand of picaridin insect repellents.
42. Clean, dry feel
43. with 6 hours of protection against the Culex mosquito
44. Light, clean feel
45. Light, Clean, [Odorless]
46. Long Lasting Protection
47. Feels light and clean