

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

TECHNICAL REVIEW BRANCH
SIMILARITY CLINIC DETERMINATION

20/APR/2005

MEMORANDUM

Subject: Name of Pesticide Product: Cutter Insect Repellent 15KA
EPA Reg. No. /File Symbol: 121-OE
DP Barcode: D315505
Decision No: 354564
PC Code: 070705

From: Eugenia McAndrew, Biologist *EM*
Technical Review Branch *SC*
Registration Division (7505C)

To: Joseph Tavano, RM Team 10
Insecticide Branch
Registration Division (7505C)

Applicant: Spectrum
Division of United Industries Corp.
P.O. Box 142642
St. Louis, MO 63114-0642

FORMULATION FROM LABEL:

| <u>Active Ingredient(s):</u> | <u>% by wt.</u> |
|------------------------------|-----------------|
| 070705 Picaridin | 15.0 |
| <u>Other Ingredients:</u> | 85.0 |
| | Total: 100.00 |

ACTION REQUESTED/BACKGROUND: Spectrum has applied for registration of Cutter Insect Repellent 15KA, EPA File Symbol 121-OE, requesting to bridge acute toxicity data submitted for another one of its products, Cutter Insect Repellent 15KP, EPA File Symbol 121-OR. Both products have a label claim of 15% picaridin. The acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary dermal irritation and skin sensitization studies submitted for the cited product (MRID 464663-03, -04, -05, -07 and -08) were reviewed and classified as acceptable in a previous TRB memo (McAndrew; D313952; EPA File Symbol 121-OR; 15/MAR/2005). The Registrant is submitting a new primary eye irritation study (MRID 46483703) conducted at Product Safety Labs, Dayton, New Jersey for review.

RECOMMENDATIONS:

1. We have evaluated the formulations of the proposed product, 121-OE, and the cited product, 121-OR, and have determined that they are substantially similar. The acute toxicity data referenced above may be bridged to the new product.
2. The primary eye irritation study has been reviewed and is classified as acceptable.
3. The acute toxicity profile for Cutter Insect Repellent 15KP, EPA File Symbol 121-OR, is as follows:

| | | | |
|---------------------------|----------|------------|---------------|
| acute oral toxicity | IV | Cited | MRID 46466303 |
| acute dermal toxicity | IV | Cited | MRID 46466304 |
| acute inhalation toxicity | IV | Cited | MRID 46466305 |
| primary eye irritation | III | Acceptable | MRID 46483703 |
| primary skin irritation | IV | Cited | MRID 46466307 |
| dermal sensitization | Negative | Cited | MRID 46466308 |

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

PRODUCT ID #: 000121-00092

PRODUCT NAME: Cutter Insect Repellent 15KP

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: 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, or using tobacco.

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. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Reviewer: Eugenia McAndrew
Risk Manager: 10

April 20, 2005

STUDY TYPE: Primary Eye Irritation - NW Rabbit; OPPTS 870.2400; OECD 405

TEST MATERIAL: Cutter Insect Repellent 20K Concentrate (Lot # KSC-0804-0416; 20% picaridin; in a pressurized aerosol container)

CITATION: Merkel, D. Cutter Insect Repellent 20K. Primary Eye Irritation Study in Rabbits. Product Safety Labs, Dayton, New Jersey. Laboratory Report Number 15908. October 29, 2004. MRID 46483703. Unpublished.

SPONSOR: Spectrum, Division of United Industries Corp., P.O. Box 142642, St. Louis, MO 63114-0642

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 46483703), 0.1 mL of Cutter Insect Repellent 20K Concentrate (Lot # KSC-0804-0416; 20% picaridin; in a pressurized aerosol container) was instilled into the right eye of three male young adult New Zealand albino rabbits (Source: Robinson Services, Inc., Clemmons, NC). "The test substance was received in a pressurized aerosol can. The right eye of each rabbit was held open and the test substance was administered in a single burst for approximately one second at a distance of about 10 cm, directly into the eye. The actual dose was estimated by weighing the container before and after each instillation. Each animal received a dose of approximately 0.26-0.33 grams of the test substance." The left eye served as the control. Animals were then observed at 1, 24, 48 and 72 hours and on 4 and 7 days post-instillation. Irritation was scored by the method of Draize. A fluorescein dye evaluation procedure was used at 24 hours to evaluate the extent of corneal damage or to verify reversal of effects.

Iritis and conjunctivitis were noted in all three eyes at the one hour observation. Corneal opacity was noted in 2/3 eyes at 24 hours. The irritation decreased gradually with time. All eyes were free of irritation by day 7.

In this study, formulation is moderately irritating. EPA Toxicity Category III.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS AND DISCUSSION:

| Observations | Number "positive"/number tested | | | | | |
|-----------------|---------------------------------|-----|-----|-----|------|-----|
| | Hours | | | | Days | |
| | 1 | 24 | 48 | 72 | 4 | 7 |
| Corneal Opacity | 0/3 | 2/3 | 2/3 | 2/3 | 2/3 | 0/3 |
| Iritis | 3/3 | 3/3 | 3/3 | 3/3 | 0/3 | 0/3 |
| Conjunctivae: | | | | | | |
| Redness | 3/3 | 3/3 | 3/3 | 3/3 | 1/3 | 0/3 |
| Chemosis | 3/3 | 1/3 | 0/3 | 0/3 | 0/3 | 0/3 |
| Discharge | 3/3 | 0/3 | 0/3 | 0/3 | 0/3 | 0/3 |

*Score of 2 or more required to be considered "positive."

A. Observations: Iritis and conjunctivitis were noted in all three eyes at the one hour observation. Corneal opacity was noted in 2/3 eyes at 24 hours. The irritation decreased gradually with time. All eyes were free of irritation by day 7.

B. Reviewer's Conclusions: We agree with study author's conclusion that the test substance is moderately irritating to the eye.

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D315505
2. **PC CODE:** 070705
3. **CURRENT DATE:** 20/APR/2005
4. **TEST MATERIAL:** Cutter Insect Repellent 20K Concentrate (Lot # KSC-0804-0416; 20% picaridin; in a pressurized aerosol container)

| Study/Species/Lab Study # /Date | MRID | Results | Tox. Cat. | Core Grade |
|--|-------------|--|------------------|-------------------|
| Primary eye irritation/rabbit Product Safety Labs 15908/10-29-04 | 46483703 | Corneal opacity in 2/3 eyes, iritis and conjunctivitis in 3/3 eyes. Irritation resolved by day 7. | III | A |

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, W = Waived