

TO: Denise Webster, Program Specialist
Pesticide Registration Branch

FROM: Medical Toxicology Branch

Date: 6/17/08
Revised Date: 7/14/08

PRODUCT REGISTRATION RECOMMENDATION SHEET

Formulated Product Name: LBAM Pheromone Technical
Chemical Code #: 5022, 5023, 5966 **ID #:** 228573 E
EPA Reg. #: 52991- **SB 950 #:** NA
Document #: 52127-0018
Company Name: Bedoukian Research Inc.

RECOMMENDATION:

Submitted as additional data. No recommendation requested at this time.

The LBAM Pheromone Technical acute oral toxicity, primary dermal irritation and dermal sensitization studies are acceptable. The acute oral toxicity and primary dermal irritation study data indicate Toxicity Category IV and III, respectively. The dermal sensitivity study results do not indicate that the active ingredient is a dermal sensitizer.

TO--File: Registration
Branch: Registration
FROM--Medical Toxicology

Program Specialist: Denise Webster

DATA PACKAGE SUMMARY AND RECOMMENDATION SHEET

Active Ingredient: 1. E-11-Tetradecenyl acetate, 2. Z-11-Tetradecenyl acetate, 3. E,E-9, 11-Tetradecadienyl, acetate

Formulated Product Name: LBAM Pheromone Technical

Formulation: 1. 80.8%, 2. 12.3%, 3. 4.1%; other ingredients:2.8%

Chemical Code #: 1. 5022, 2. 5023, 3. 5966

ID #: 228573 E

EPA Reg. #: 52991-

SB 950 #: NA

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Company Name: Bedoukian Research Inc.

SUMMARY ("One-liners" from each study worksheet, significant information not mentioned in worksheets, other pertinent information for ongoing review or registration. Attach additional sheets if needed):

Acute Toxicity Categories

Acute Oral LD50	IV
Acute Dermal LD50	Study not submitted
Acute Inhalation LC50	Study not submitted
Eye Irritation	Study not submitted
Dermal Irritation	III
Dermal Sensitization	Not a dermal sensitizer

Acute Toxicity Studies

Acute Oral LD50

52127-0018; 239666; "Acute Oral Toxicity - Up and Down Procedure (UDP)"; (D.R. Cerven; MB Research Laboratories, Spinnerstown, PA; Project No. MB 08-16818.01; 5/29/08); Three female Wistar rats received 5000 mg/kg of Cas#'s (33189-72-9) (54664-98-1) 11-Tetradecen-1-ol, Acetate 11E and 9, 11-Tetradecadien-1-ol, acetate (9E, 11E), Lot/Batch# 2008052-0014 orally, by gavage. No deaths resulted from the treatment. One of the animals demonstrated a slight weight loss during the 2nd week of observations. Wetness around the anogenital area was noted for one animal up to one day post-dose. No lesions were evident in the necropsy examination. LD50 (F) > 5000 mg/kg; Toxicity Category IV; **Study acceptable.** (Moore, 6/9/08)

Acute Dermal LD50

Study not submitted.

Acute Inhalation LC50

Study not submitted.

Eye Irritation

Study not submitted.

Dermal Irritation

52127-0018; 239667; "Acute Dermal Irritation in Rabbits"; (L.J. DiDonato; MB Research Laboratories, Spinnerstown, PA; Project No. MB 08-16818.03; 5/30/08); The skin of 3 New Zealand white rabbits was exposed to 0.5 ml/site, one site/animal, of Cas#'s (33189-72-9) (54664-98-1) 11-Tetradecen-1-ol, Acetate 11E and 9, 11-Tetradecadien-1-ol, acetate (9E, 11E),

Lot/Batch# 2008052-0014 for 4 hours under a semi-occlusive wrap. Erythema, grades 2 (1/3) and 1 (2/3), was noted at 1 and 24 hours post-exposure, diminishing to grade 1 (2/3) at 48 and 72 hours, grade 1 (1/3) at 7 days and clearing by 14 days. Edema, grade 1 (2/3) was evident at 1 hour post-exposure, persisting with grade 1 (3/3) at 24 and 48 hours, increasing to grades 2 (1/3) and 1 (2/3) at 72 hours, diminishing to grade 1 (2/3) at 7 days and clearing by 14 days. Toxicity Category III; **Study acceptable.** (Moore, 6/9/08)

Dermal Sensitization

52127-0018; 239668; "Delayed Contact Dermal Sensitization Test - Buehler Method"; (D.A. Hall; MB Research Laboratories, Spinnerstown, PA; Project No. MB 08-16818.06; 5/30/08); The skin of 10 Hartley albino guinea pigs/sex was treated with 0.4 ml of Cas#'s (33189-72-9) (54664-98-1) 11-Tetradecen-1-ol, Acetate 11E and 9, 11-Tetradecadien-1-ol, acetate (9E, 11E), Lot/Batch# 2008052-0014 for 6 hours, once per week for 3 weeks in the induction phase, using a Hilltop Chamber. Two weeks later these animals were treated with 0.4 ml of a 25% preparation of the test material in acetone for 6 hours at a previously untreated site. An additional 10 control animals were treated in the same manner. By the third induction treatment, nine of the treated animals demonstrated an erythema grade 1 or 2 at 24 and/or 48 hours post-exposure. In the challenge treatment, none of the 20 induced animals exhibited positive dermal irritation score (≥ 1) at 24 or 48 hours post-exposure. None of the 10 control animals demonstrated a positive response over the 48 hour post-exposure observation period as well. The test material is not a dermal sensitizer in the Buehler assay. The positive control was functional. **Study acceptable.** (Moore, 6/9/08)

CONCLUSIONS: Are data adequate to support registration?

The LBAM Pheromone Technical acute oral toxicity, primary dermal irritation and dermal sensitization studies are acceptable.

RECOMMENDATIONS: What type of registration action is being requested? In case of ongoing registration, register or do not register? What other specific studies or data are requested?

Submitted as additional data. No recommendation requested at this time.

The LBAM Pheromone Technical acute oral toxicity, primary dermal irritation and dermal sensitization studies are acceptable. The acute oral toxicity and primary dermal irritation study data indicate Toxicity Categories IV and III, respectively. The dermal sensitivity study results do not indicate that the active ingredient is a dermal sensitizer.

