

**TO:** Denise Webster, Program Specialist  
Pesticide Registration Branch

**FROM:** Medical Toxicology Branch

**Date:** 6/17/08  
**Revised Date:** 8/7/08

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**PRODUCT REGISTRATION RECOMMENDATION SHEET**

**Formulated Product Name:** NoMate LBAM MEC  
**Chemical Code #:** 5022, 5966 **ID #:** 228576 E  
**EPA Reg. #:** 42579- **SB 950 #:** NA  
**Document #:** 52127-0021  
**Company Name:** USDA APHIS Plant Protection and Quarantine

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**RECOMMENDATION:**

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

The NoMate LBAM MEC acute oral, dermal and inhalation toxicity, primary eye and dermal irritation studies are acceptable and all of the study data indicate Toxicity Category IV hazards. The localized lymph node (LLNA) dermal sensitization study is acceptable and indicates that the test article is a potential skin sensitizer. The Buehler guinea pig dermal sensitization study is acceptable and indicates that the test material is not a dermal sensitizer.

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

**Program Specialist: Denise Webster**

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**DATA PACKAGE SUMMARY AND RECOMMENDATION SHEET**

**Active Ingredient:** 1. (E)-11-Tetradecen-1-yl acetate, 2. (E, E)-9, 11-tetradecadien-1-yl acetate  
**Formulated Product Name:** NoMate LBAM MEC  
**Formulation:** 1. 19.20%, 2. 0.80%; other ingredients: 80.00%  
**Chemical Code #:** 1. 5022, 2. 5966 **ID #:** 228576 E  
**EPA Reg. #:** 42579- **SB 950 #:** NA  
**Document #:** 52127-0021  
**Company Name:** USDA APHIS Plant Protection and Quarantine

**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):**

**NoMate LBAM MEC Acute Toxicity Categories**

<b>Acute Oral LD50</b>	IV
<b>Acute Dermal LD50</b>	IV
<b>Acute Inhalation LC50</b>	IV
<b>Eye Irritation</b>	IV
<b>Dermal Irritation</b>	IV
<b>Dermal Sensitization</b>	Dermal sensitizer (LLNA) Not a dermal sensitizer (Buehler)

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**NoMate LBAM MEC Acute Toxicity Studies**

**Acute Oral LD50**

0021; 239675; "Acute Oral Toxicity Study (UDP) in Rats" (Kuhn, J.O., Stillmeadow, Inc., Sugar Land, TX, Laboratory Study Number: 11766-08, 05/05/08). 870.11. NoMate LBAM MEC (Lot Number 8063, 19.20% (E)-11-Tetradecen-1-yl acetate, 0.80% (E, E)-9, 11-tetradecadien-1-yl acetate) was administered by gavage in a single dose to 3 female Sprague-Dawley albino rats at 5000 mg/kg. No animals died. No clinical signs were observed. No effect on body weight was observed. Necropsy revealed no observable abnormalities. LD<sub>50</sub> (F) > 5000 mg/kg. Toxicity Category IV. **Acceptable.** (Corlett, 06/10/08)

**Acute Dermal LD50**

0021; 239676; "Acute Dermal Toxicity Study in Rats" (Kuhn, J.O., Stillmeadow, Inc., Sugar Land, TX, Laboratory Study Number: 11767-08, 05/12/08). 870.12. NoMate LBAM MEC (Lot Number 8063, 19.20% (E)-11-Tetradecen-1-yl acetate, 0.80% (E, E)-9, 11-tetradecadien-1-yl acetate) was applied to the clipped dorsal skin of 5 Sprague-Dawley albino rats per sex per dose at a dose level of 5050 mg/kg for 24 hours. No animals died. No clinical signs or signs of dermal irritation were observed. No effects on body weight gain were observed. Necropsy revealed no observable abnormalities. LD<sub>50</sub> (M/F) > 5050 mg/kg. Toxicity Category IV. **Acceptable.** (Corlett, 06/11/08)

**Acute Inhalation LC50**

0021; 239677; "Acute Inhalation Toxicity Study in Rats" (Crutchfield, V., Stillmeadow, Inc., Sugar Land, TX, Laboratory Study Number: 11768-08, 05/28/08). 870.13. NoMate LBAM MEC (Lot Number 8063, 19.20% (E)-11-Tetradecen-1-yl acetate, 0.80% (E, E)-9, 11-tetradecadien-1-yl acetate) was diluted 1:1 v/v in deionized water, aerosolized, and administered in a nose-only manner to 5 Sprague-Dawley albino rats per sex per dose at dose level (mean exposure

concentration, gravimetrically determined) of 2.12 mg/l (mean MMAD (GSD) = 2.1 (6.0)  $\mu$ m) for 4 hours. No animals died. Piloerection and activity decrease were observed in all animals after exposure with all clinical signs clearing in all animals by day 6. Body weight loss was observed in 1 male and in 1 female during the first week. Necropsy revealed no observable abnormalities.  $LC_{50}$  (M/F) > 2.12 mg/l. Toxicity Category IV. **Acceptable.** (Corlett, 06/11/08)

#### **Eye Irritation**

0021; 239674; "Acute Eye Irritation Study in Rabbits" (Kuhn, J.O., Stillmeadow, Inc., Sugar Land, TX, Laboratory Study Number: 11769-08, 05/05/08). 870.24. 0.1 ml of NoMate LBAM MEC (Lot Number 8063, 19.20% (E)-11-Tetradecen-1-yl acetate, 0.80% (E, E)-9, 11-tetradecadien-1-yl acetate) was placed into the conjunctival sac of 1 eye of each of 3 New Zealand White rabbits. No corneal opacity or iritis was observed. Grade 1 conjunctival irritation was observed 1 hour after treatment with all signs of conjunctival irritation clearing in all treated eyes 24 hours after treatment. Toxicity Category IV. **Acceptable.** (Corlett, 06/11/08)

#### **Dermal Irritation**

0021; 239678; "Acute Dermal Irritation Study in Rabbits" (Kuhn, J.O., Stillmeadow, Inc., Sugar Land, TX, Laboratory Study Number: 11770-08, 05/12/08). 870.25. 0.5 ml of NoMate LBAM MEC (Lot Number 8063, 19.20% (E)-11-Tetradecen-1-yl acetate, 0.80% (E, E)-9, 11-tetradecadien-1-yl acetate) was applied to the clipped dorsal skin of each of 3 New Zealand White rabbits for 4 hours using a semi-permeable dressing. No erythema or edema was observed in any test animal at any time during 72-hour observation period following patch removal. Toxicity Category IV. **Acceptable.** (Corlett, 06/12/08)

#### **Dermal Sensitization**

\*\* 52127-0021; 239869; "Skin Sensitization: Local Lymph Node Assay in Mice"; (J.O. Kuhn; Stillmeadow, Inc., Sugar Land, TX; Study No. 11765-08; 5/9/08); The dorsal skin on the ears of 5 female CBA/J mice/group was treated by topical application with 25  $\mu$ l/ear/day of 0 (vehicle: propylene glycol), 25 and 50% preparations of NoMate<sup>®</sup> LBAM MEC in propylene glycol and undiluted test material (lot no. 8063, E-11-Tetradecenyl acetate: 19.2%, E,E-9, 11-Tetradecadienyl, acetate: 0.80%) for 3 days. Additionally, 5 female mice/group were dosed in the same manner with 0 (vehicle: 4:1 acetone:olive oil) or 90% hexylcinnamaldehyde (vehicle: 80% acetone/20% olive oil) for 3 days. Three days later, 20  $\mu$ Ci of <sup>3</sup>H-thymidine was injected iv into the tail vein of each animal and 5 hours later each animal was euthanized. The draining auricular lymph nodes were removed and single cell suspensions were prepared from the lymph node tissue. These suspensions were washed and treated with 5% trichloroacetic acid. The precipitated DNA was incubated for 18 hours at 4<sup>o</sup> C. Liquid scintillation was used to measure the radioactivity being emitted from the preparations and the disintegrations/minute (dpm) was measured. A stimulus index (SI) was determined by dividing the mean dpm of each experimental group by the mean value for the vehicle control. The SI index was 2.6, 4.2 and 3.0 for the 25, 50 and 100% preparations, respectively. The positive control was functional. **Study acceptable.** (Moore, 6/11/08)

52127-0021; 240791; "Skin Sensitization Study in Guinea Pigs"; (J.O. Kuhn; Stillmeadow, Inc., Sugar Land, TX; Study No. 11922-08; 7/28/08); The skin of 10 Hartley-Albino guinea pigs/sex was treated with 0.4 ml of NoMate<sup>®</sup> LBAM MEC (lot no. 8063, E-11-Tetradecenyl acetate: 20.16%, E,E-9, 11-Tetradecadienyl, acetate: 0.84%), undiluted, for 6 hours under an occlusive wrap, once per week, for 3 weeks in the induction phase. For the challenge, after a 2 week interlude after the last induction treatment, the skin of these treated animals along with that of 10 naïve controls was treated for 6 hours with 0.4 ml of the undiluted test material under an occlusive wrap at a location previously untreated. No dermal irritation was evident for the treated animals during the induction phase or for either the treated or naïve control animals during the 48 hour observation period of the challenge phase. The test material is not a dermal sensitizer as determined in the Buehler assay. The positive control (DNCB) in the first assay was not functional; a second study in which  $\alpha$ -hexylcinnamaldehyde was applied resulted in a positive response. **Study acceptable.** (Moore, 8/1/08)

**CONCLUSIONS: Are data adequate to support registration?**

The NoMate LBAM MEC acute oral, dermal and inhalation toxicity, primary eye and 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 NoMate LBAM MEC acute oral, dermal and inhalation toxicity, primary eye and dermal irritation studies are acceptable and all of the study data indicate Toxicity Category IV hazards. The localized lymph node (LLNA) dermal sensitization study is acceptable and indicates that the test article is a potential skin sensitizer. The Buehler guinea pig dermal sensitization study is acceptable and indicates that the test material is not a dermal sensitizer.