

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

**FROM:** Medical Toxicology Branch

**Original Date:** 6/17/08  
**Revised:** 6/19/08  
**Revised:** 8/7/08

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**PRODUCT REGISTRATION RECOMMENDATION SHEET**

**Formulated Product Name:** Disrupt Bio-Flake LBAM  
**Chemical Code #:** 5022, 5966                      **ID #:** 228574 E  
**EPA Reg. #:** 42579-                                      **SB 950 #:** NA  
**Document #:** 52127-0019  
**Company Name:** USDA APHIS Plant Protection and Quarantine

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**RECOMMENDATION:**

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

The Disrupt Bio-Flake LBAM acute dermal toxicity, primary eye and dermal irritation and dermal sensitization studies are acceptable. The acute oral and inhalation toxicity studies are supplemental. The acute dermal toxicity and primary eye and dermal irritation study data indicate Toxicity Category IV hazards. The Buehler guinea pig dermal sensitization study indicates that the test material is not a dermal sensitizer. A localized lymph node (LLNA) dermal sensitization study was undertaken to assess the test article's potential to be a skin sensitizer in that assay. However, the physico-chemical properties of the material did not permit the performance of the test.

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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:** Disrupt Bio-Flake LBAM  
**Formulation:** 1. 13.87%, 2. 0.85%; other ingredients: 85.28%  
**Chemical Code #:** 1. 5022, 2. 5966 **ID #:** 228574 E  
**EPA Reg. #:** 42579- **SB 950 #:** NA  
**Document #:** 52127-0019  
**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):**

**Disrupt Bio-Flake LBAM Acute Toxicity Categories**

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

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**Disrupt Bio-Flake LBAM Acute Toxicity Studies**

**Acute Oral LD50**

0019; 239684; "Acute Oral Toxicity Study (UDP) in Rats" (Kuhn, J.O., Stillmeadow, Inc., Sugar Land, TX, Laboratory Study Number: 11754-08, 05/09/08). Attempts were made to grind DISRUPT Bio-Flake® LBAM Product 100811 (Lot Number 8AM004B, 13.87% (E)-11-Tetradecen-1-yl acetate, 0.85% (E, E)-9, 11-tetradecadien-1-yl acetate), oblong pellets, to an acceptable size for oral dosing. One procedure consisted of grinding the test article for 24 hours in a grinder. Another procedure consisted of placing the test article in a freezer (-80° C) for 18 hours and then placing it in a blender for 30 seconds. Also, an attempt to solubilize the test article was made by heating it to 50° C in potential solvents. None of these attempts were reported as being successful. **Supplemental study** (not a guideline study). (Corlett, 06/12/08)

**Acute Dermal LD50**

0019; 239688; "Acute Dermal Toxicity Study in Rats" (Kuhn, J.O., Stillmeadow, Inc., Sugar Land, TX, Laboratory Study Number: 11755-08, 05/09/08). 870.12. DISRUPT Bio-Flake® LBAM Product 100811 (Lot Number 8AM004B, 13.87% (E)-11-Tetradecen-1-yl acetate, 0.85% (E, E)-9, 11-tetradecadien-1-yl acetate), moistened with deionized water, 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, 06/12/08)

**Acute Inhalation LC50**

0019; 239669; "Acute Inhalation Toxicity Study in Rats" (Crutchfield, V., Stillmeadow, Inc., Sugar Land, TX, Laboratory Study Number: 11756-08, 05/09/08). Attempts were made to grind DISRUPT Bio-Flake® LBAM Product 100811 (Lot Number 8AM004B, 13.87% (E)-11-Tetradecen-1-yl acetate, 0.85% (E, E)-9, 11-tetradecadien-1-yl acetate), oblong pellets, to an

acceptable size for inhalation dosing. One procedure consisted of grinding the test article for 24 hours in a grinder. Another procedure consisted of placing the test article in a freezer (-80° C) for 18 hours and then placing it in a blender for 30 seconds. Also, an attempt to solubilize the test article was made by heating it to 50° C in potential solvents. None of these attempts were reported as being successful. **Supplemental study** (not a guideline study). (Corlett, 06/12/08)

#### **Eye Irritation**

0019; 239685; "Acute Eye Irritation Study in Rabbits" (Kuhn, J.O., Stillmeadow, Inc., Sugar Land, TX, Laboratory Study Number: 11757-08, 05/09/08). 870.24. A 56 mg pellet of DISRUPT Bio-Flake® LBAM Product 100811 (Lot Number 8AM004B, 13.87% (E)-11-Tetradecen-1-yl acetate, 0.85% (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 in one treated eye 24 hours after treatment with all signs of conjunctival irritation clearing in all treated eyes 48 hours after treatment. Toxicity Category IV. Previously study was deemed unacceptable but possibly upgradeable with a description of how the dosing quantity of 56 mg/eye was determined; email of 6/19/08 from Janice Kuhn was sufficient to upgrade the study; **Study acceptable**. (Corlett, 06/12/08, revised Moore, 6/19/08)

#### **Dermal Irritation**

0019; 239686; "Acute Dermal Irritation Study in Rabbits" (Kuhn, J.O., Stillmeadow, Inc., Sugar Land, TX, Laboratory Study Number: 11758-08, 05/09/08). 870.25. 500 mg of DISRUPT Bio-Flake® LBAM Product 100811 (Lot Number 8AM004B, 13.87% (E)-11-Tetradecen-1-yl acetate, 0.85% (E, E)-9, 11-tetradecadien-1-yl acetate), moistened with deionized water, 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**

52127-0019; 240189; "Skin Sensitization Study in Guinea Pigs"; (J.O. Kuhn; Stillmeadow, Inc., Sugar Land, TX; Study No. 11897-08; 6/27/08); The skin of 10 Hartley-Albino guinea pigs/sex was treated with 400 mg of DISRUPT Bio-Flake® LBAM (lot Number 8AM010B, 15.84% (E)-11-Tetradecen-1-yl acetate, 0.95% (E, E)-9, 11-tetradecadien-1-yl acetate), moistened with 0.4 ml of deionized water, 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 400 mg of the test material moistened with 0.4 ml of deionized water 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, 7/15/08)

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

The Disrupt Bio-Flake LBAM acute dermal toxicity, primary eye and dermal irritation and dermal sensitization studies are acceptable. The acute oral and inhalation toxicity studies are supplemental.

#### **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 Disrupt Bio-Flake LBAM acute dermal toxicity, primary eye and dermal irritation and dermal sensitization studies are acceptable. The acute oral and inhalation toxicity studies are supplemental. The acute dermal toxicity and primary eye and dermal irritation study data indicate Toxicity Category IV hazards. The Buehler guinea pig dermal sensitization study indicates that the test material is not a dermal sensitizer. A localized lymph node (LLNA) dermal sensitization study was undertaken to assess the test article's potential to be a skin sensitizer in that assay. However, the physico-chemical properties of the material did not permit the performance of the test.