TO: Denise Webster, Program Specialist  
Pesticide Registration Branch  

FROM: Medical Toxicology Branch  

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

PRODUCT REGISTRATION RECOMMENDATION SHEET  

Formulated Product Name: SPLAT LBAM  
Chemical Code #: 5022, 5966  
EPA Reg. #: 42579-  
Document #: 52127-0020  
Company Name: USDA APHIS Plant Protection and Quarantine  

ID #: 228575 E  
SB 950 #: NA  

RECOMMENDATION:  

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

The SPLAT LBAM 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.
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: SPLAT LBAM
Formulation: 1. 9.167%, 2. 0.534%; other ingredients: 90.299%
Chemical Code #: 1. 5022, 2. 5966
EPA Reg. #: 42579- SB 950 #: NA
ID #: 228575 E
Document #: 52127-0020
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):

**SPLAT LBAM Acute Toxicity Categories**

<table>
<thead>
<tr>
<th>Toxicity Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Oral LD50</td>
<td>IV</td>
</tr>
<tr>
<td>Acute Dermal LD50</td>
<td>IV</td>
</tr>
<tr>
<td>Acute Inhalation LC50</td>
<td>IV</td>
</tr>
<tr>
<td>Eye Irritation</td>
<td>IV</td>
</tr>
<tr>
<td>Dermal Irritation</td>
<td>IV</td>
</tr>
<tr>
<td>Dermal Sensitization</td>
<td>Dermal sensitizer (LLNA), Not a dermal sensitizer (Buehler)</td>
</tr>
</tbody>
</table>

**SPLAT LBAM Acute Toxicity Studies**

**Acute Oral LD50**

0020; 239687; “Acute Oral Toxicity Study (UDP) in Rats” (Kuhn, J.O., Stillmeadow, Inc., Sugar Land, TX, Laboratory Study Number: 11760-08, 05/05/08). 870.11. SPLAT LBAM™ (Batch No. 2454501, 9.167% (E)-11-Tetradecen-1-yl acetate, 0.534% (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. LD50 (F) > 5000 mg/kg. Toxicity Category IV. Acceptable. (Corlett, 06/04/08)

**Acute Dermal LD50**

0020; 239671; “Acute Dermal Toxicity Study in Rats” (Kuhn, J.O., Stillmeadow, Inc., Sugar Land, TX, Laboratory Study Number: 11761-08, 05/05/08). 870.12. SPLAT LBAM™ (Batch No. 2454501, 9.167% (E)-11-Tetradecen-1-yl acetate, 0.534% (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 dose level of 5050 mg/kg for 24 hours. No animals died. No clinical signs or signs of dermal irritation were observed. One male animal and one female animal lost weight between days 0 and 7 of the study. Necropsy revealed no observable abnormalities. LD50 (M/F) > 5050 mg/kg. Toxicity Category IV. Acceptable. (Corlett, 06/04/08)

**Acute Inhalation LC50**

0020; 239672; “Acute Inhalation Toxicity Study in Rats” (Crutchfield, V., Stillmeadow, Inc., Sugar Land, TX, Laboratory Study Number: 11762-08, 05/28/08). 870.13. SPLAT LBAM™ (Batch No. 2454501, 9.167% (E)-11-Tetradecen-1-yl acetate, 0.534% (E, E)-9, 11-tetradecadien-1-yl acetate) was diluted 1:4 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 2.07 mg/l (mean MMAD (GSD) = 2.1 (6.5) μm) for 4
hours. No animals died. No clinical signs were observed. One male animal lost weight between
days 7 and 14 of the study. Necropsy revealed dark red liver in 2 males and 1 female and pale
lungs in 1 male and 2 females. LC$_{50}$ (M/F) > 2.07 mg/l. Toxicity Category IV. (Corlett, 06/11/08)

**Eye Irritation**

0020; 239670; “Acute Eye Irritation Study in Rabbits” (Kuhn, J.O., Stillmeadow, Inc., Sugar
Land, TX, Laboratory Study Number: 11763-08, 05/28/08). 870.24. 0.1 ml of SPLAT LBAM™
(Batch No. 2454501, 9.167% (E)-11-Tetradecen-1-yl acetate, 0.534% (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 redness was observed in
2 treated eyes 24 hours after treatment with all signs of conjunctival irritation clearing in all treated
eyes 4 days after treatment. Toxicity Category IV. **Acceptable.** (Corlett, 06/05/08)

**Dermal Irritation**

0020; 239673; “Acute Dermal Irritation Study in Rabbits” (Kuhn, J.O., Stillmeadow, Inc., Sugar
Land, TX, Laboratory Study Number: 11763-08, 05/28/08). 870.25. 0.5 ml of SPLAT LBAM™
(Batch No. 2454501, 9.167% (E)-11-Tetradecen-1-yl acetate, 0.534% (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. No edema was observed. Grade 1 erythema was observed in all 3 animals 1 hour, 24
hours, 48 hours, 72 hours, 7 days, and 10 days after patch removal; 14 days after patch removal,
grade 1 erythema was observed in 1 animal. Toxicity Category IV. **Acceptable.** (Corlett,
06/05/08)

**Dermal Sensitization**

** 52127-0020; 239870; “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 ul/ear/day of 0 (vehicle:
propylene glycol), 25 and 50% preparations of Splat LBAM™ in propylene glycol and undiluted test
material (no. lot no. provided, E-11-Tetradecenyl acetate: 9.167%, E,E-9, 11-Tetradecadienyl,
acetate: 0.534%) 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 uCi of $^3$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
suspending were washed and treated with 5% trichloroacetic acid. The precipitated DNA was
incubated for 18 hours at 4$^\circ$ 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 5.86, 3.99 and 5.95 for the 25, 50 and 100%
preparations, respectively. The positive control was functional. **Study acceptable.** (Moore,
6/11/08)

52127-0020; 240456; “Skin Sensitization Study in Guinea Pigs”; (J.O. Kuhn; Stillmeadow, Inc.,
Sugar Land, TX; Study No. 11920-08; 7/8/08; The skin of 10 Hartley-Albino guinea pigs/sex was
washed and treated with 5% trichloroacetic acid. The precipitated DNA was incubated for 18 hours at 4$^\circ$ 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 5.86, 3.99 and 5.95 for the 25, 50 and 100%
preparations, respectively. The positive control was functional. **Study acceptable.** (Moore,
7/15/08)

**CONCLUSIONS:** Are data adequate to support registration?
The SPLAT LBAM acute oral, dermal and inhalation toxicity, primary eye and dermal irritation and the two 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 SPLAT LBAM 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.