A FIFRA Enforcement Case Study for SFIREG Review

Vermont Agency of Agriculture

June 26, 2017
And So, What Is The ClariFly Use Pattern?
Diflubenzuron  CAS # 35367-38-5

<table>
<thead>
<tr>
<th>Formulations</th>
<th>EPA Reg. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Livestock Premix 0.04%</td>
<td>89459-3</td>
</tr>
<tr>
<td>Milk Replacer Add Pack 0.16%</td>
<td>89459-1</td>
</tr>
<tr>
<td>Livestock Premix 0.67%</td>
<td>89459-2</td>
</tr>
<tr>
<td>Larvicide 2.67%</td>
<td>89459-82</td>
</tr>
<tr>
<td>Manuf. Use Concentrate 8.0%</td>
<td>270-379-89459</td>
</tr>
</tbody>
</table>
CHEMICAL CHARACTERISTICS

Diflubenzuron is a chitin inhibitor. Chemical Family = substituted urea

<table>
<thead>
<tr>
<th>CHEMICAL NAME:</th>
<th>N-[[4-chlorophenyl] amino] carbonyl] -2, 6-difluoro-benzamide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Name:</td>
<td>Diflubenzuron</td>
</tr>
<tr>
<td>CAS Number:</td>
<td>65367-38-5</td>
</tr>
<tr>
<td>Empirical Formula:</td>
<td>C_{14}H_{12}Cl F_{2}N_{2}O_{2}</td>
</tr>
<tr>
<td>Properties:</td>
<td>White crystalline solid</td>
</tr>
<tr>
<td></td>
<td>Soluble in Organic Solvents</td>
</tr>
<tr>
<td></td>
<td>No Odor</td>
</tr>
</tbody>
</table>

REGULATORY STATUS OF DIFLUBENZURON

Diflubenzuron is a larvicide with activity against flies (house, stable, face, and horn) and many leaf eating larvae of insects feeding on agricultural, forest and ornamental plants (gypsy moths and rust mites). The active ingredient, diflubenzuron, was first registered by the EPA in 1976. Diflubenzuron has completed an extensive reregistration process, resulting in the publication by the EPA of the Reregistration Eligibility Document (RED) in 1997.
In The Beginning . . .
There Was A Feed Plant Inspection.
And the pesticide inspector said: “All is not well, here.”

So as pesticide regulators, you should share this story with your Plant Industry / Ag Commodity Divisions.

Shared Staff Positions
Or Not?
How Does ClariFly Work and How Is It Used?

ClariFly® Larvicide is ingested via feed which the animal disperses via its manure.

ClariFly® Larvicide inhibits the development of a functioning exoskeleton during molting to cause larval death before the pupal stage.

Eggs will hatch into larvae that will feed and attempt to undergo 3 larval instars. ClariFly® Larvicide breaks the life cycle of flies developing in treated manure by not allowing the larvae to successfully molt from one instar to the next.

Female flies lay eggs in fresh manure or other organic waste.
Scope of Vermont’s ClariFly Investigation And, the Regulatory Challenges.

1) Pesticide Use and Applicator Certification
2) Dealer Licensing and Sales (based on State RUP Status)
3) Producer Establishment (PEI) Status

Where Does The Pesticide Use/Application Happen?
  → At Feed Mill or On-Farm
Where Does Sale/Distribution Take Place?
  → At Feed Mill (or by Sales Staff)
Where Does Repackaging Occur?
  → At Feed Mill
### 2016 Clarify Usage in Vermont (estimated)

<table>
<thead>
<tr>
<th>FEED MANUFACTURER</th>
<th>AMOUNT (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kent Nutrition (Blue Seal Richford)</td>
<td>2,000</td>
</tr>
<tr>
<td>Poulin Grain (all)</td>
<td>17,000</td>
</tr>
<tr>
<td>Morrison’s</td>
<td>0</td>
</tr>
<tr>
<td>Feed Commodities (all)</td>
<td>9,000</td>
</tr>
<tr>
<td>Bourdeau (Middlebury)</td>
<td>2,000</td>
</tr>
<tr>
<td>Bourdeau (Sheldon)</td>
<td>0</td>
</tr>
<tr>
<td>Phoenix Feeds</td>
<td>43,224</td>
</tr>
<tr>
<td>Cargill (Swanton)</td>
<td>8,000</td>
</tr>
<tr>
<td>Whitman’s Feed</td>
<td>0</td>
</tr>
</tbody>
</table>

**Note:** Pounds of A.I. **NOT** Tons of Feed 81,224
ClariFly Feeding Rates

Beef / Dairy  =  0.1 mg/Kg body weight

Equine  =  0.15 mg/Kg body weight

Swine  = 0.2-0.3 mg/Kg body weight

Average Feeding Rate = 0.015 lb A.I. / Ton of Feed
                      (varies by body weight)

Therefore, 81,224 lbs A.I. used in approx. 5 millions Tons of Feed
The Problem Starts Here:
Registrant Literature/Guidance confusing for Feed Mill Operators

REGULATORY STATUS OF CLARIFLY® LARVICIDE

ClariFly® Larvicide was registered by the EPA in 2006 as the first diflubenzuron cattle product for use in feed. The following excerpt from the 2014 Feed Additive Compendium summarizes the regulatory status of the use of diflubenzuron in cattle feed. “FDA Status: No feed mill license required, product is a food additive. When used in medicated feeds, medicated feed application requirement is determined by regulatory status of the drug. EPA Status: Product is a pesticide when used in non-medicated feeds. EPA registration is required for feeds offered for sale except when custom-blended per the provisions of 40 CFR 167.3. In medicated feeds, the product is a feed additive and no EPA registration is required when the source of diflubenzuron is an EPA-registered product.”

“To medicate a feed ... or not to medicate a feed ... ? that is the determination.”

For Reference:
FDA Center for Veterinary Medicine
Program and Policy Procedures Manual
Section 1240.3500   New Animal Drug Determinations
Status / Resolution of Investigation

- Vermont Feed Manufacturers Now Operating Under EPA Est. Nos. - (New and/or Renewed PEIs)
  Repackaging Operations for Sale to Producers/Farms

- Vermont Feed Plants Now Have Certified Applicator(s) On Staff
  On-Site Blending and Bagging Operations
  Category 1B - Agricultural Animal Pests

- Vermont Feed Plants Now Licensed As Pesticide Dealers
  Labeled Product/Formulation Sales for On-Farm Mixing

- Registrant (Wellmark) Provided Compliance Coordination w/ VT Feed Dealers Assoc.

In Conclusion;
SFIREG Request Is For Consultation w/ EPA and
For Determination By OECA Regarding Use/Status of Pass-Through Insecticides
(Regardless of Medicated Feed Criteria)
Library of Label Examples

ClariFly® Livestock Premix 0.04% LARVICIDE

- A premix containing diflubenzuron insect growth regulator for inclusion in rations to prevent the emergence of house flies, stable flies, face flies, horn flies from the manure of treated cattle, horses and swine

SPECIMEN LABEL

ACTIVE INGREDIENT
Diflubenzuron* [CAS # 35367-38-5] ...................................... 0.04%
OTHER INGREDIENTS ......................................................... 99.96%
TOTAL ............................................................................. 100.00%

*Contains 181.6 milligrams of diflubenzuron/lb
EPA Reg. No. 89459-3
EPA Est. Nos. See container for reference

KEEP OUT OF REACH OF CHILDREN
CAUTION

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.

If on skin • Take off contaminated clothing.
• Rinse skin immediately with plenty of water for 15 – 20 minutes.
• Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a
ClariFly®
Add-Pack
FLY CONTROL
FOR USE WITH WHOLE MILK OR MILK REPLACER

Prevents the development of house flies, stable flies, face flies and horn flies in manure from treated calves, including veal calves.

ACTIVE INGREDIENT:
Dithiocarbamate (Cas# 35367-38-5) ........................................... 0.16%
OTHER INGREDIENTS .......................................................... 99.84%
TOTAL ............................................................ 100.00%
* Contains 70.64% alio x dithiocarbamate for label.

KEEP OUT OF REACH OF CHILDREN
CAUTION
See back panel for additional Precautionary Statements

Store in original container in a cool, dry place.
NET WT: 10 lbs (4.54 kg)
Use as part of an integrated Pest Management Program for control of flies developing in the manure of treated cattle, horses, and swine.

**LIVESTOCK PREMIX 0.67%**

**ACTIVE INGREDIENT (% by weight):**
- Diflubenzuron (CAS No 35652-38-5) - 0.67%
- OTHER INGREDIENTS - 99.33%
- TOTAL - 100.00%

*Contains 3.04 grams of diflubenzuron per pound.

**KEEP OUT OF REACH OF CHILDREN CAUTION**

**PRECAUTIONARY STATEMENTS — HAZARDS TO HUMANS**

**CAUTION**

Caution indicates eye irritation. Avoid contact with eyes or clothing. Wash protective equipment. Wash hands thoroughly with soap and water after handling and before eating, cooking, chopping food, using bathroom, or caring for livestock.

**FIRST AID**

- **Eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Seek medical attention.
- **Ingestion:** Do not induce vomiting. Seek medical attention.
- **Skin irritation:** Wash with soap and water.
- **Inhalation:** Seek medical attention.

**PERSONAL PROTECTIVE EQUIPMENT:**
- Mask and other respirators when handling product. Use disposable dust mask, type N95, at least 400 PFE and appropriate protective clothing when handling the product. Also use gloves. Avoid skin contact.

**ENVIRONMENTAL HAZARDS:**
- This product is toxic to aquatic invertebrates. Do not contaminate water when disposing of equipment waste.

**USE INFORMATION:** Clarify Premix (LARVicide Livestock Premix) is intended for feeding into feeds or supplements for beef and dairy cattle, horses, and swine. For additional information, see label and instructions. It is not a product for cattle, horses, and swine. Use Clarify Premix as part of an integrated pest management program aimed at controlling populations in the treated environment. Consult your veterinarian or another person knowledgeable in pest management practices to determine the appropriate use, rate, and placement of this product. Always follow label instructions.

**DIRECTIONS FOR USE:**
- It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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**CATTLE MIXING DIRECTIONS**

**RATIONS WITH PRE-EVENT PREMIXES**

Mix with feed-grade mineral to produce a Clarify® Premix mineral mixture as shown in the table below.

<table>
<thead>
<tr>
<th>Rate (lbs)</th>
<th>Feed %</th>
<th>Feed %</th>
<th>Clarify® Premix</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 lbs</td>
<td>2.00%</td>
<td>2.00%</td>
<td>2.00%</td>
</tr>
<tr>
<td>4 lbs</td>
<td>1.50%</td>
<td>1.50%</td>
<td>1.50%</td>
</tr>
<tr>
<td>6 lbs</td>
<td>1.25%</td>
<td>1.25%</td>
<td>1.25%</td>
</tr>
<tr>
<td>8 lbs</td>
<td>1.00%</td>
<td>1.00%</td>
<td>1.00%</td>
</tr>
</tbody>
</table>

**MIXING-RATION FEEDING:** Use the table below as a guide for mixing Clarify® Premix with cattle or swine feed supplement.
FOR USE IN SWINE FEEDS AND SUPPLEMENTS AS PART OF AN INTEGRATED PEST MANAGEMENT PROGRAM TO CONTROL FLIES DEVELOPING IN MANURE

CONTAINS DIFLUBENZURON FOR CONTINUOUS FEEDING DURING THE FLY SEASON

STOPS THE DEVELOPMENT OF HOUSE FLIES IN THE MANURE OF TREATED SWINE INCLUDING NURSERY, GROW-FINISH AND BREEDING STOCK

SPECIMEN LABEL

ACTIVE INGREDIENTS:
Diflubenzuron [CAS# 35367-38-5] .................................................. 2.67%
OTHER INGREDIENTS* ................................................................. 97.33%
TOTAL: .......................................................................................... 100.0%

Contains 0.42 ounces (12.12 grams) of diflubenzuron per pound.
EPA Reg.No. 89459-82
EPA Est. No. 75806-AZ-1

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product, including health concerns, medical emergencies, or pesticide incidents, you may call 1-800-347-8272, 24 hours per day, 7 days per week.

ENVIRONMENTAL HAZARDS
This pesticide is toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

KEEP OUT OF REACH OF CHILDREN
CAUTION
See additional Precautionary Statements

PRECAUTIONARY STATEMENTS – HAZARDS TO
ClariFly
Larvicide
Manufacturing Use Product 8%

AN INSECT GROWTH REGULATING MANUFACTURING-USE PRODUCT FOR USE ONLY IN FORMULATING CATTLE FEED-THROUGH PRODUCTS FOR CONTROL OF FLIES DEVELOPING IN MANURE

SPECIMEN LABEL

ACTIVE INGREDIENT:
Dilfubenzuron (CAS# 35367-38-5) ........... .8%
OTHER INGREDIENTS: ...................... 92%
Total ..................................... 100%

Contains 1.28 ounces (35 grams) of dilfubenzuron per pound.

EPA Reg No. 270-378-89459
EPA Est. Nos. 75806-AZ-11, 2724-TX-11

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 eye.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-347-8272 for emergency medical treatment information.

PERSONAL PROTECTIVE EQUIPMENT: Wear long-sleeved shirt and pants, shoes plus socks and chemical resistant gloves. Follow manufacturer’s instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER RECOMMENDATIONS: Users should:
• Wash hands before eating, drinking, chewing gum, or smoking.

KEEP OUT OF REACH OF CHILDREN
CAUTION
SEE ADDITIONAL PRECAUTIONARY STATEMENTS

PRECAUTIONARY STATEMENTS – HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION