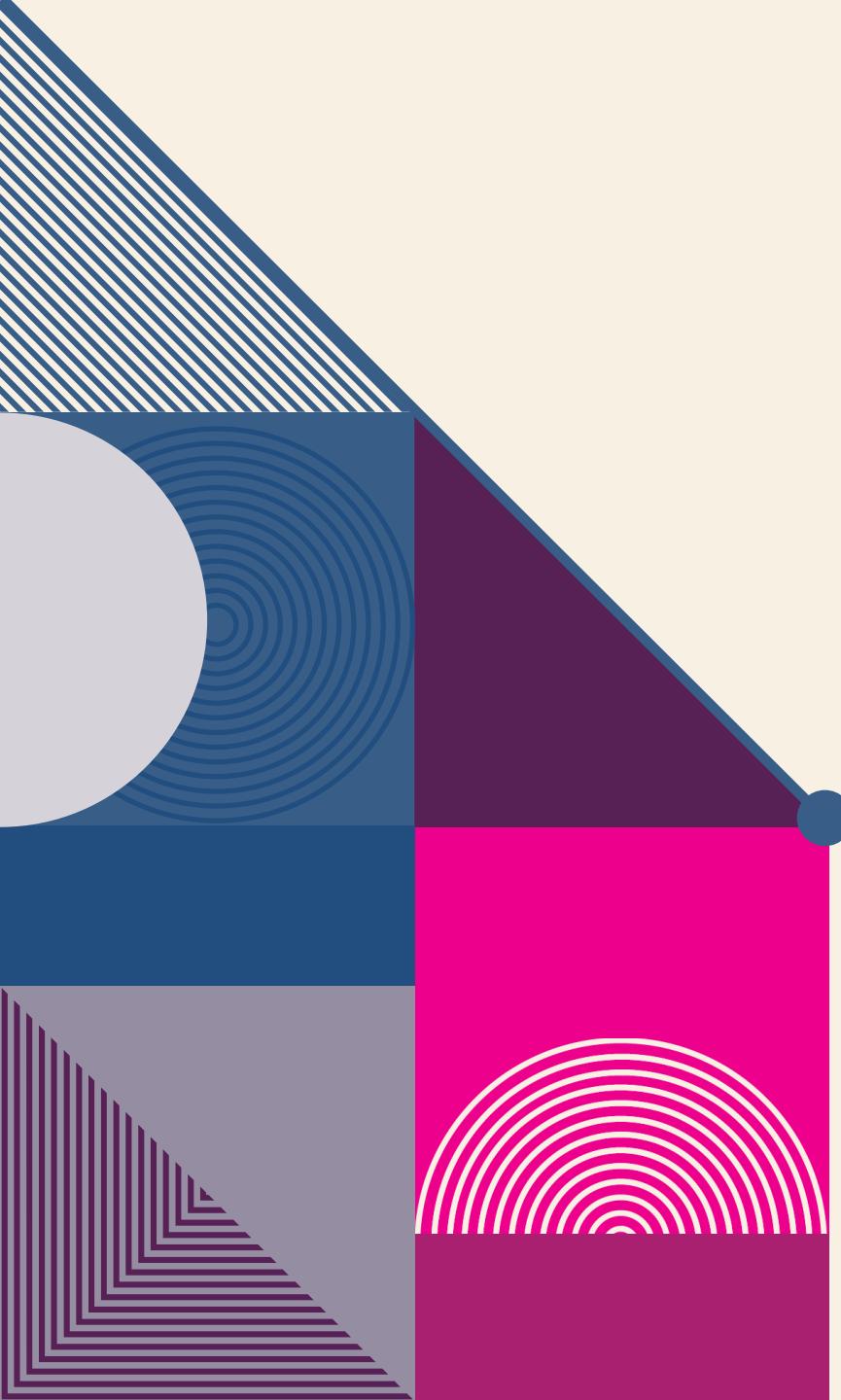




FEED THROUGH PESTICIDES

POM Working Committee Discussion
April 2024

Sarah Caffery - Indiana
Morgan Griffith - Vermont



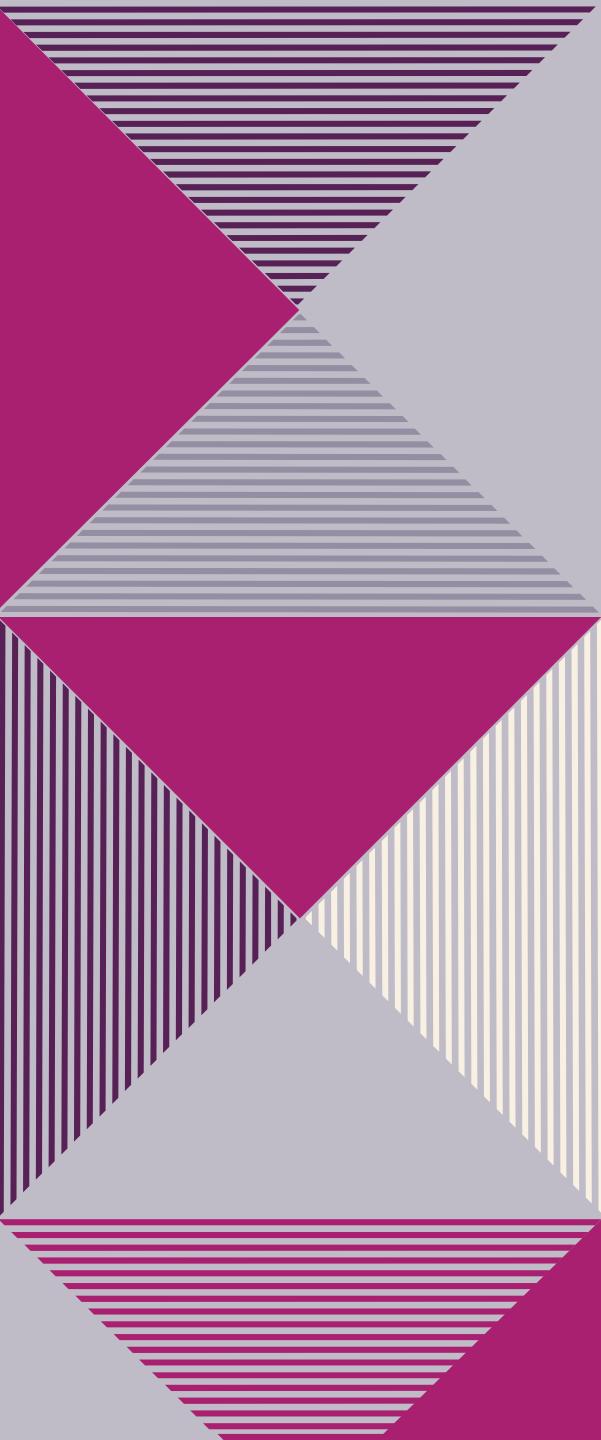
AGENDA

Regulations & Definitions

Previous Discussions/Actions

Case Findings

Next Steps



REGULATIONS & DEFINITIONS

General definition:

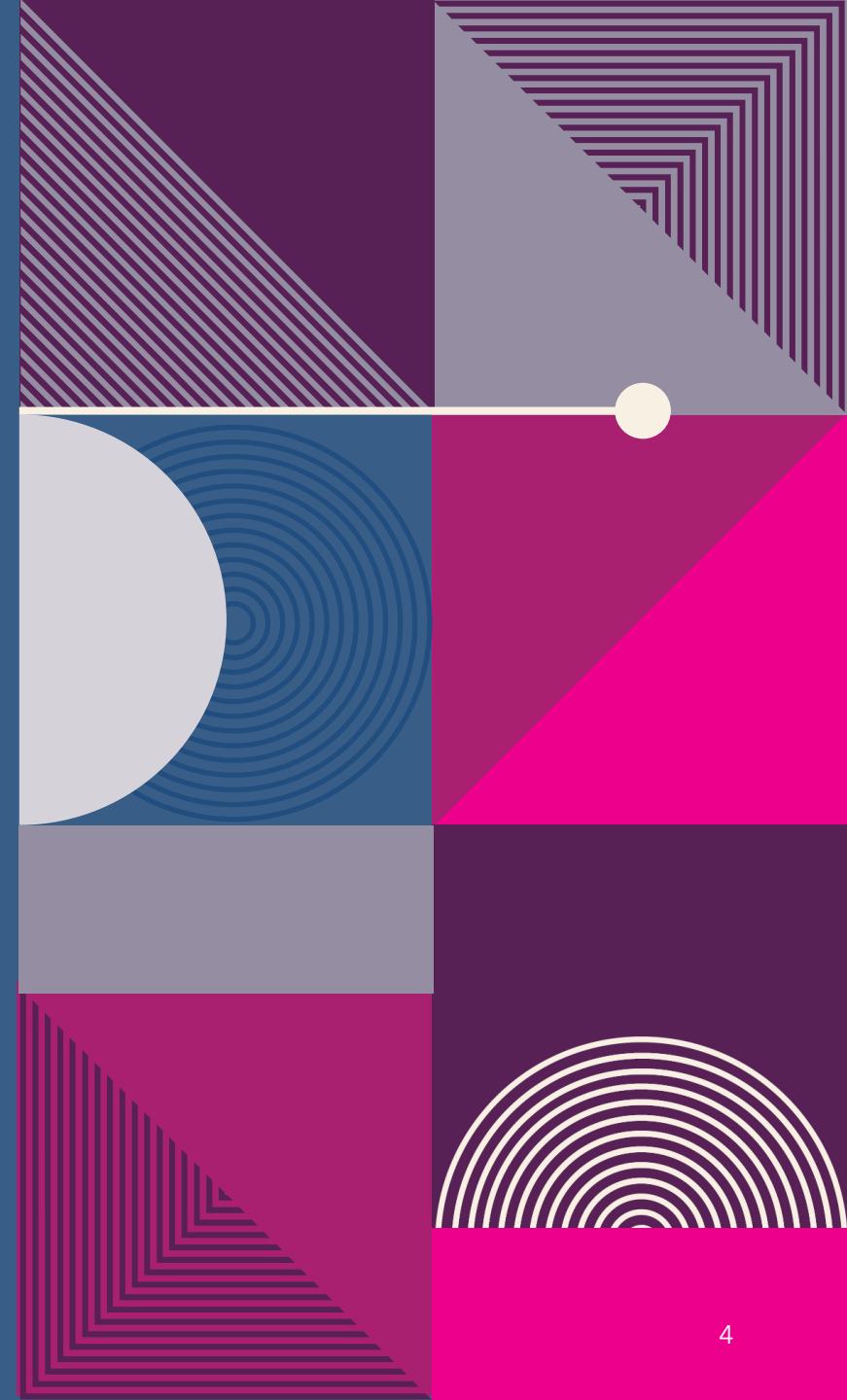
Feed-through pesticides are typically incorporated into animal food; however, they have no direct effect on the animal. They move through its digestive tract relatively unchanged and are deposited in the animal's manure. These products contain pesticides that do not harm the animals themselves, but the pesticides instead act on their targets in the manure.

REGULATIONS

40 CFR § 152.3 Definitions

Pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, **other than any article that:**

- (1) Is a new animal drug under FFDCA sec. 201(w), or
- (2) Is an animal drug that has been determined by regulation of the Secretary of Health and Human Services not to be a new animal drug, or
- (3) Is an animal feed under FFDCA sec. 201(x) that bears or contains any substances described by paragraph (s)(1) or (2) of this section.

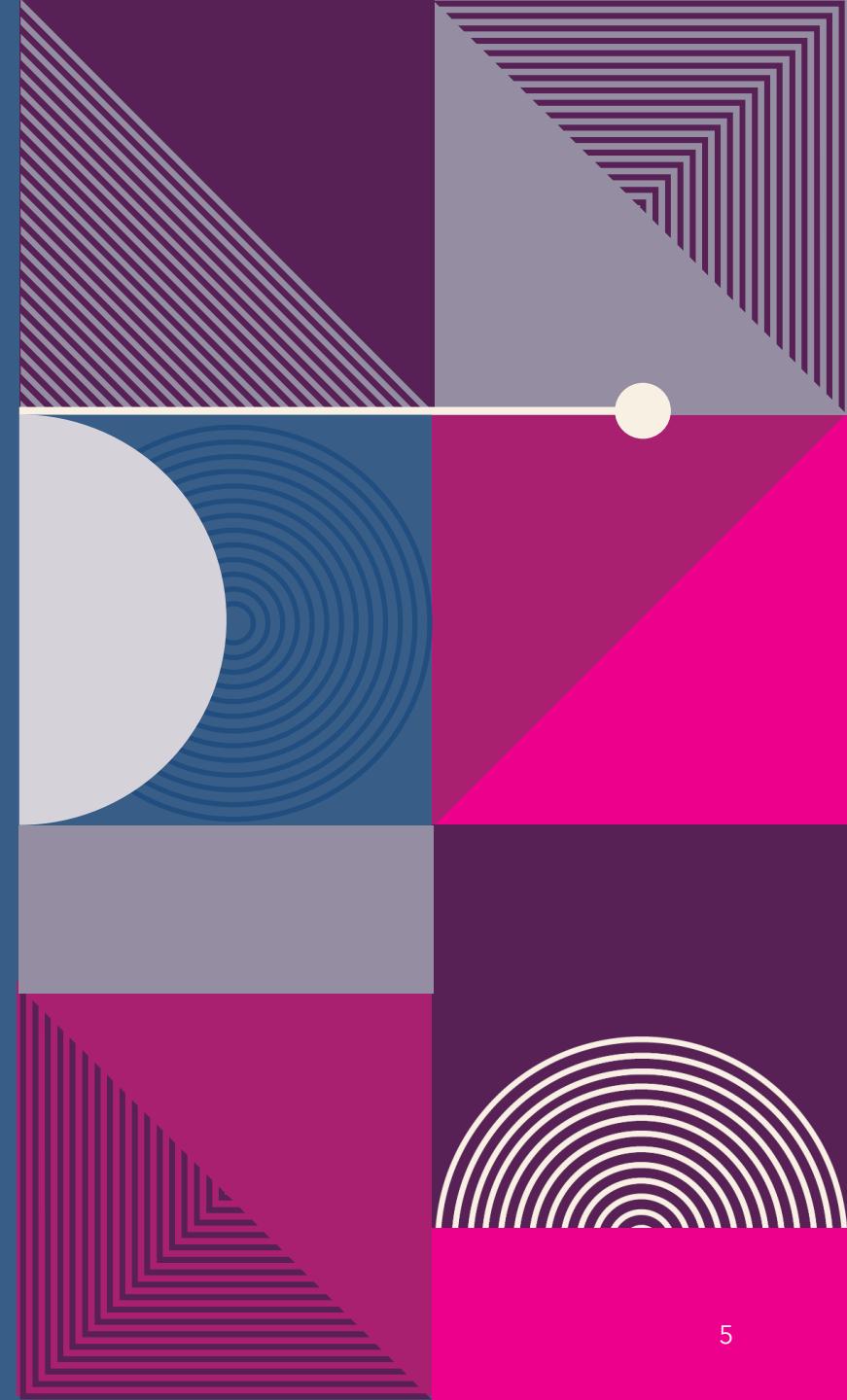


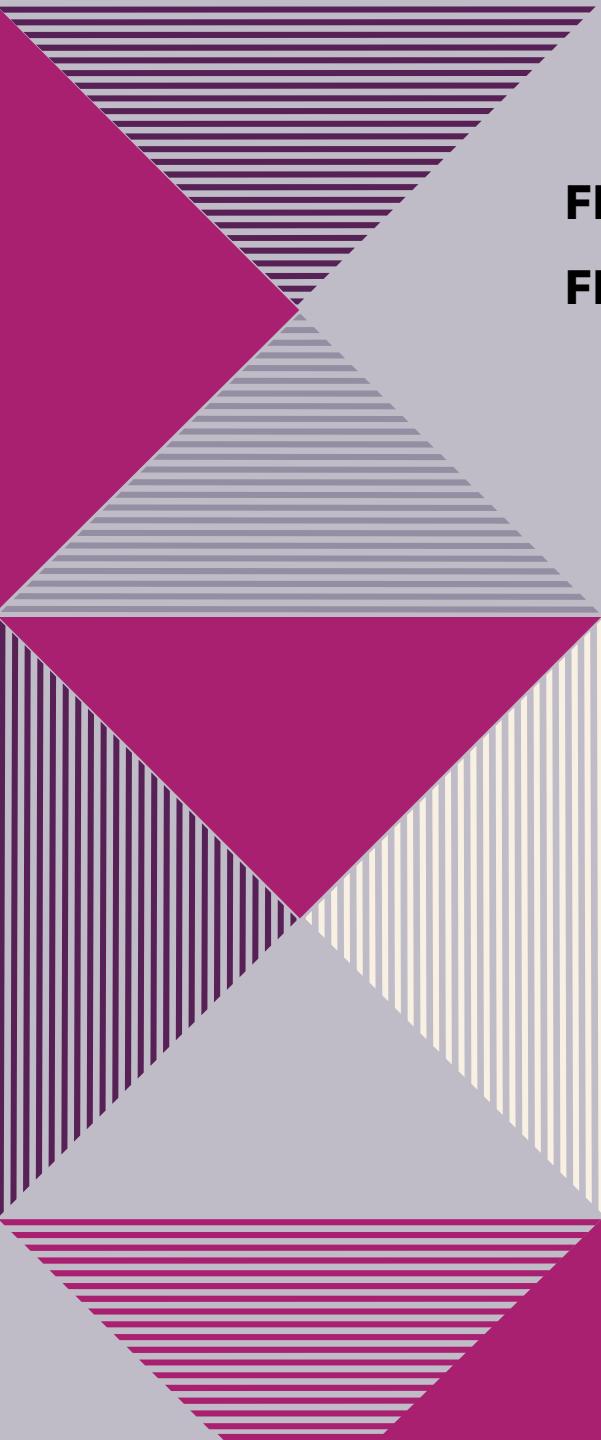
REGULATIONS

Pesticides: 40 CFR § 152.3 Definitions

Custom blending means the service of mixing pesticides to a customer's specifications, usually a pesticide(s)-fertilizer(s), pesticide-pesticide, or a pesticide-animal feed mixture, when:

- (1) The blend is prepared to the order of the customer and is not held in inventory by the blender;
- (2) The blend is to be used on the customer's property (including leased or rented property);
- (3) The pesticide(s) used in the blend bears end-use labeling directions which do not prohibit use of the product in such a blend;
- (4) The blend is prepared from registered pesticides; and
- (5) The blend is delivered to the end-user along with a copy of the end-use labeling of each pesticide used in the blend and a statement specifying the composition of the mixture.





EPA POLICY

FIFRA Compliance Enforcement Guidance Manual Policy

FIFRA Compliance Program Policy No. 3.4 - Custom Blenders

In order for a custom blender to avoid liability for failure to meet the requirements of Section 3, the following conditions must be met:

- 1) The blend is prepared to the order of the user and is not held in inventory by the blender; and
- 2) The pesticide(s) used in the blend bears end-use labeling* directions which do not prohibit use of the product in such a blend; and
- 3) The blend is prepared in a registered establishment; and
- 4) The blend is delivered to the user together with:
 - o A copy of the end-use labeling of the pesticide used in the blend, and
 - o A statement specifying the composition of the mixture.

*The term "end-use labeling" means labeling containing directions for use in pest control and otherwise meeting the requirements of 40 CFR 162.10. Labeling indicating that a product is intended only for use in manufacturing or formulating pesticides shall not be considered "end-use labeling".



PREVIOUS DISCUSSIONS & ACTIONS



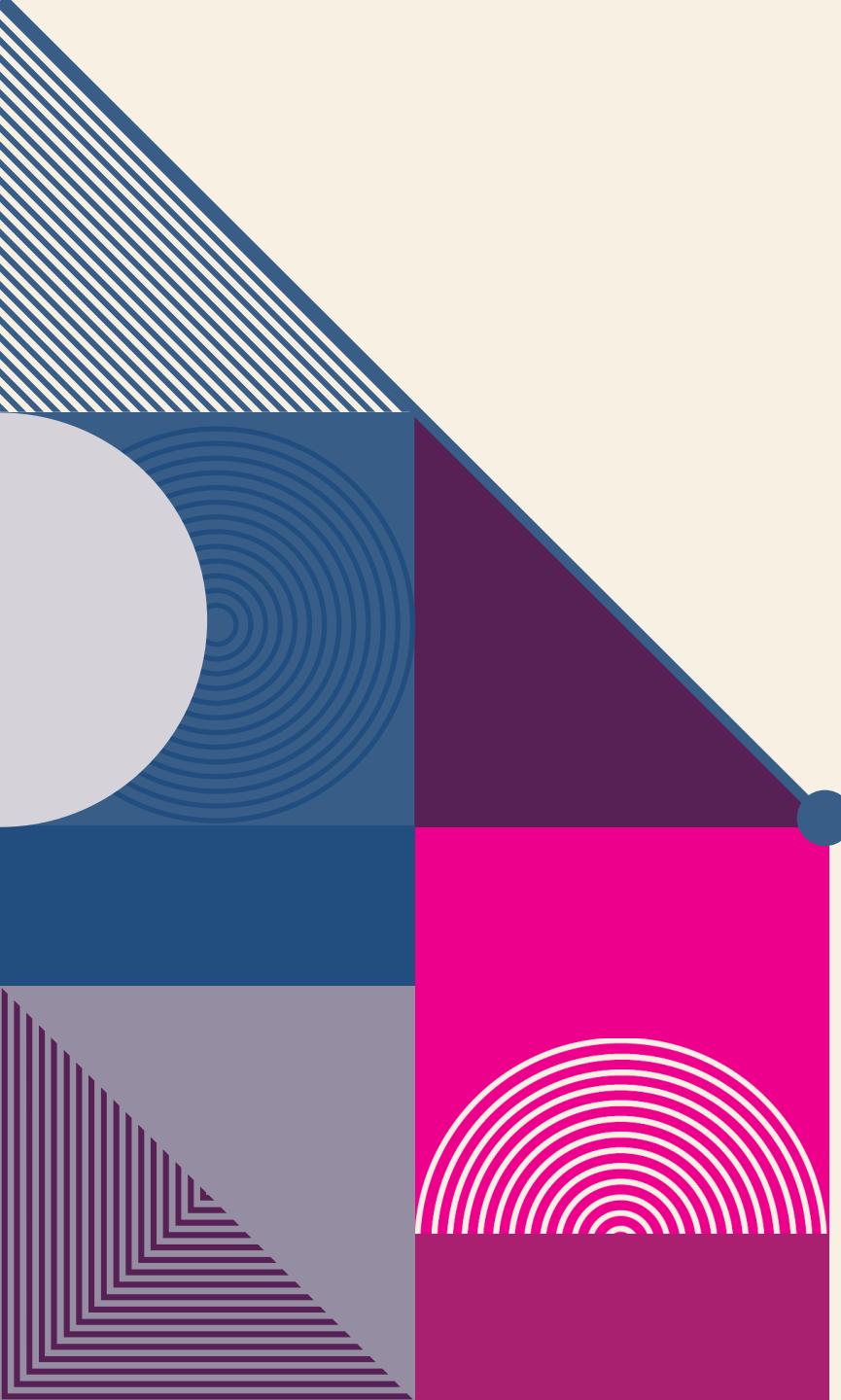
VERMONT GUIDANCE TO FEED MANUFACTURER - 2017

...the pesticides that are added to animal feed, that are not active in or on the animal are regulated as *pesticides* and have certain requirements to be sold and labeled properly.

Ongoing discussions have been held with the pesticide registrant. They will be working with their sales staff to ensure that the product in Vermont is being applied in compliance with pesticide regulations. If a feed manufacturer wishes to sell or distribute in another manner, the pesticide registrant and the state will assist the manufacturer to come into compliance.

That *may* include:

- Acquire/renew an EPA Establishment number and report pesticide production to EPA annually.
- Employment of at least 1 certified noncommercial pesticide applicator and report annual usage to VAAFM.
- An EPA-approved end user label to be affixed to feed packages or bulk feed paperwork.
- Obtaining a Class B dealer license for sales of product directly to the farmer.



AAPCO/SFIREG

2017

- Discussions started at Full SFIREG
- POM tasked with next steps
- Conversations with FDA at JWC meeting

2019

- Memo drafted to share with SLAs
- Final Memo dated 7/30/2019

[Microsoft Word - Minutes for June 17 Full SFIREG .docx \(aapco.org\)](#)
[sfireg-clarifly.pdf \(aapco.org\)](#)

[Microsoft Word - jwc minutes 9-2017.docx \(aapco.org\)](#)

[Microsoft Word - JWC April 2019 Minutes.docx \(aapco.org\)](#)

[Microsoft Word - final SFIREG minutes June 2019.docx \(aapco.org\)](#)

MEMORANDUM

DATE: July 30, 2019
TO: Pesticide Regulatory Agencies in the United States, Territories, and Tribes
FROM: Liza Fleeson Trossbach, Chair 
State FIFRA Issues Research and Evaluation Group
SUBJECT: Clarification Regarding Pass-Through Pesticides in Animal Feed

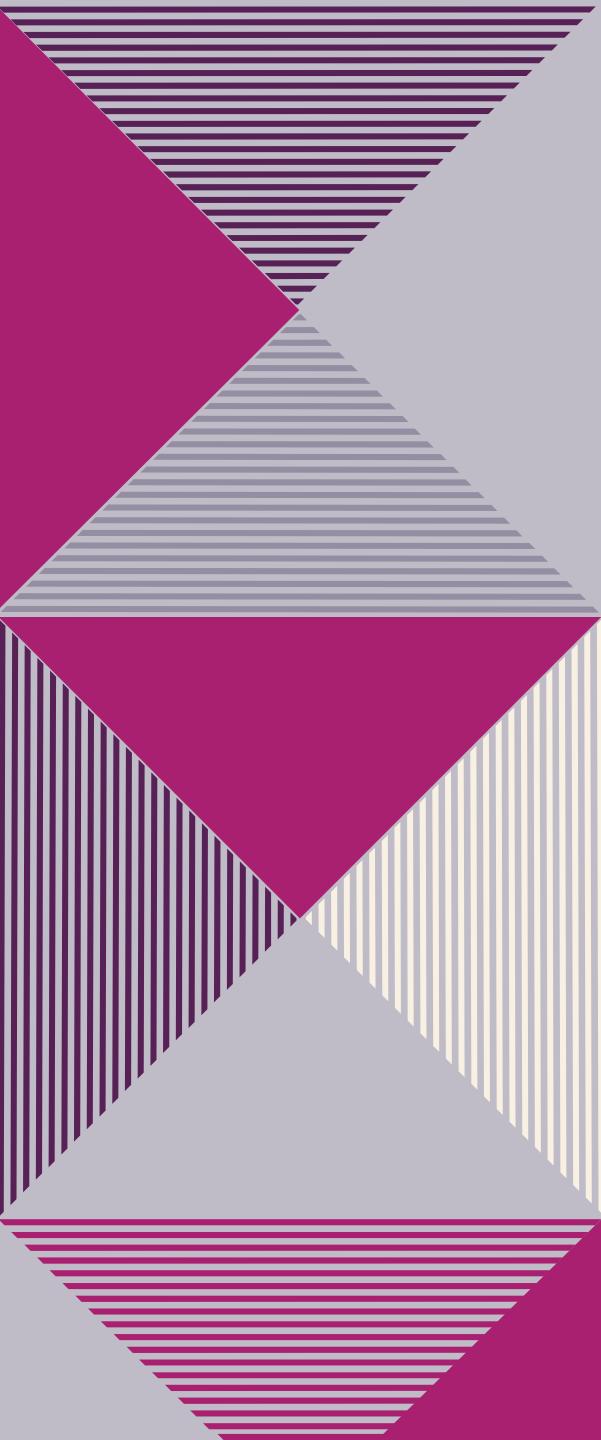
2019 SFIREG Memo

https://aapco.org/wp-content/uploads/2024/03/sfireg-memo_pass-through-insecticides_07_30_2019.pdf

In June 2017, the Vermont Agency of Agriculture brought the issue of a pass-through larvicide (diflubenzuron) that was being blended in animal feed in Vermont to the attention of the State FIFRA Issues Research and Evaluation Group (SFIREG). The purpose of placing diflubenzuron in animal feed is to prevent the development of fly larvae in manure, thus controlling fly populations in livestock and dairy operations. It was requested by Vermont that this issue, and the inappropriateness of this insecticidal use being classified as a feed additive or medicated feed, be sent to the US Environmental Protection Agency (EPA) for clarification.

Since Congress in 1975 amended the FIFRA definition of pesticide to exclude any article that is a new animal drug within the meaning of the Federal Food, Drug and Cosmetic Act (FFDCA), EPA and the Food and Drug Administration (FDA) have discussed how to best provide oversight for insect growth regulators mixed with animal feed for the purpose of preventing the development of fly larvae in manure. Currently, EPA considers insect growth regulators such as diflubenzuron mixed with animal feed for the purpose of controlling the development of fly larvae in manure to be pesticides; i.e., when insect growth regulators are mixed into animal feed with the intention that the insect growth regulator is to pass through the animal for the ultimate purpose of controlling insect or other pest populations in the animal's manure. Insect growth regulators intended to be used in this way must be registered and regulated as pesticides.

The sole purpose of this correspondence is to offer clarification related to this specific use of pesticides in animal feed for the control of immature and/or adult insects or other pests in manure. SFIREG encourages you to share this information with your Feed Control Officials.



SUMMARY OF FEED-THROUGH PESTICIDE RESIDUES IN DOMESTIC SURVEILLANCE AND IMPORT SAMPLES OF ANIMAL FOOD AND ANIMAL FOOD INGREDIENTS DURING FISCAL YEAR 2000 THROUGH 2018.

“The FDA, Center for Veterinary Medicine (CVM) has an active pesticide residue monitoring program that monitors a broad range of imported and domestic animal food commodities including ingredients and finished foods.”

Conclusion:

A review of the data available under CVM’s pesticide residue monitoring program for the last 18 years, showed that feed-through pesticides were occasionally detected, but at levels that fell within EPA’s established tolerances. During this time period, there were ninety-nine positive samples that were reported with only seven reported as being violative. This yielded a 14% ratio of violative samples to positive samples including four that were LC2 and three that were LC3. Although overall there was a low violation rate, several pesticides were found in non-approved animal food commodities, including methoprene in poultry, swine, elk, and sheep feed although only approved for use in cattle feed; cattle products containing cyromazine which is only approved for use in poultry feed; and poultry products containing diflubenzuron which is only allowed in cattle or equine products.

COMPLIANCE ADVISORY EPA R7

March 2023

Definition:

A custom blender is any establishment which provides the service of mixing registered pesticides to a customer's specifications, specifically, a pesticide-pesticide, pesticide-fertilizer, or pesticide-animal feed mixture. *Custom blending* means the service of mixing pesticides to a customer's specifications. The regulatory requirements stated in the 40 Code of Federal Regulations Part 167.3 include:

- the blend is prepared for a specific customer must **not be held in inventory**,
- the pesticides used in the blend must **bear end-use labeling** which does not prohibit the use of the pesticide in the blend,
- the blend is customized using registered pesticides,
- the blend is delivered to the end-user with a copy of the end-use labeling of each pesticide used in the blend and a statement specifying the composition of the mixture.
- The blend is to be used on the customer's property (included leased or rented property).

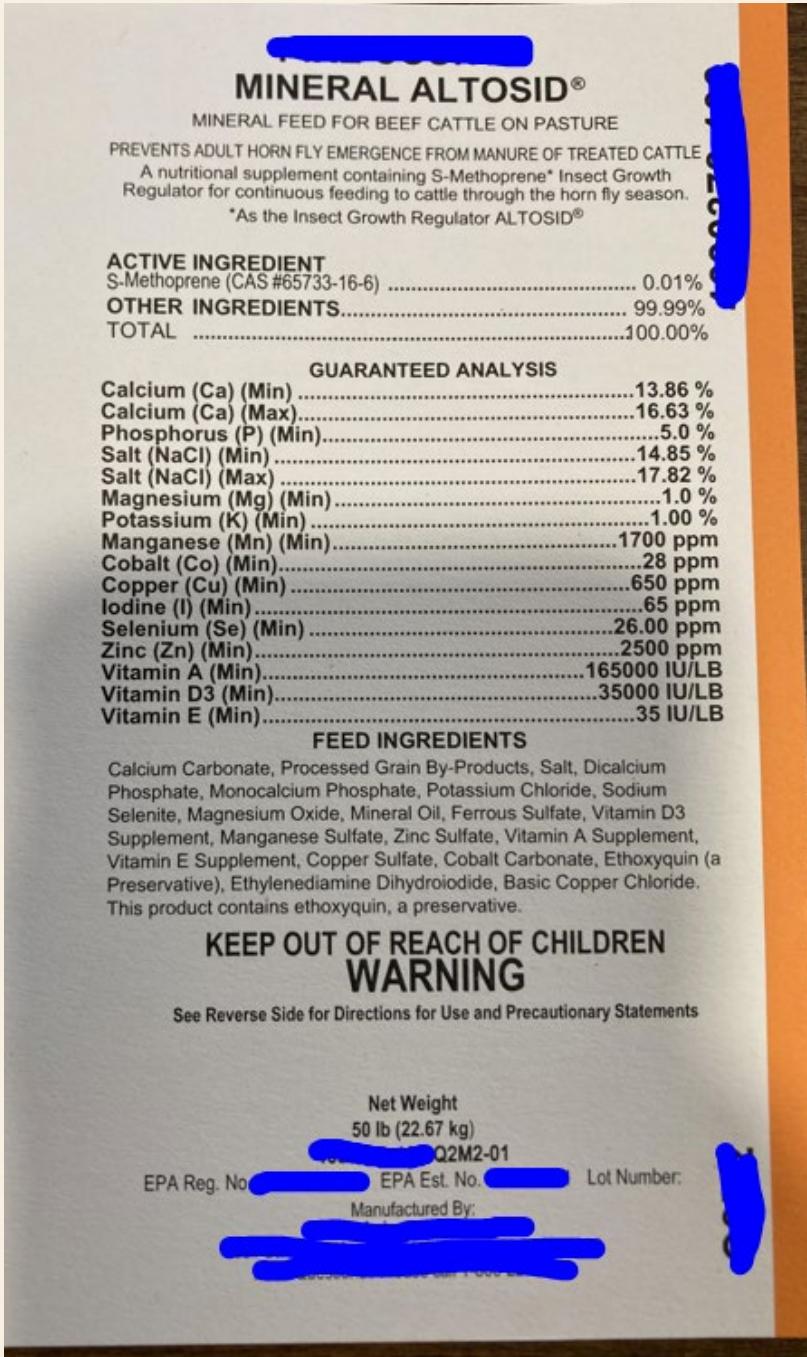
Facilities that custom blend *and do not meet the above requirements* must register as a pesticide producer under FIFRA Section 7. Further, if custom blend products are produced, sold or distributed, or held for sale or distribution *without meeting the above requirements*, the products would be considered unregistered and/or misbranded under FIFRA Section 3 and may be in violation of FIFRA. Facilities selling or distributing products claiming to be custom blended that

do not meet the above requirements may be in violation of FIFRA and be subject to enforcement, including Stop Sale Orders and/or federal penalties.



CASE FINDINGS

PESTICIDE



DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **GENERAL INFORMATION:** This product is to be used as a cattle feed-through pesticide for the control of horn flies. All feed ingredients listed on this product label must adhere to the specifications and limits (if applicable) ascribed by the Food and Drug Administration (FDA) for the use of pesticides in cattle feed. This product contains ethoxyquin, a preservative. The amount of ethoxyquin may vary according to the individual manufacturer's formulation and will not exceed the 150 ppm maximum limit established for ethoxyquin by FDA, per 21 CFR 573.380.

FEEDING AND MANAGEMENT INSTRUCTIONS: Feed this product to cattle only. When used as directed, [REDACTED] MINERAL ALTOSID® will provide sufficient (S)-methoprene insect growth regulator to prevent the emergence of adult horn flies from manure of treated cattle. Existing adult horn flies will not be affected. Start feeding before horn flies appear and continue use until cold weather marks the end of horn fly season. Allow free choice to cattle. Cattle should consume an average of 0.4 ounces of this product per 100 lbs. of cattle body weight per day, which is equivalent to 4 ounces per day for a 1,000 pound cow.

- 1) Assure cattle are not starved for nutrients in this product by providing them prior to feeding this product.
- 2) This product contains added copper. Do not feed to cattle in close proximity to sheep or other species that have a low tolerance to supplemental copper.
- 3) Offer cattle 50 pounds of this product for every 15 head of cattle.
- 4) Remove all other self limiting nutritional supplements while the cattle are consuming this product.
- 5) Locate this product where cattle congregate (watering, loafing, shade areas).
- 6) Replenish this product on a regular basis as needed.
- 7) If intake of this product is below 0.4 ounces per 100 lbs. cattle body weight per day, increase the number of feeding locations and/or change location(s) to areas more frequented by cattle.
- 8) If intake of this product is above 0.4 ounces per 100 lbs. cattle body weight per day, reduce the number of feeding locations and/or change location(s) to areas less frequented by cattle.
- 9) Introduction of this product after adult horn fly infestation is established will require treatment of cattle with adulticides if elimination of the adult fly population is desired.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal. **STORAGE:** Store in a cool place.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Completely empty bag, then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities by burning. If burned, stay out of smoke.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID:

- 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.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222, 24 hrs/day, 7 days/wk for emergency medical treatment information.

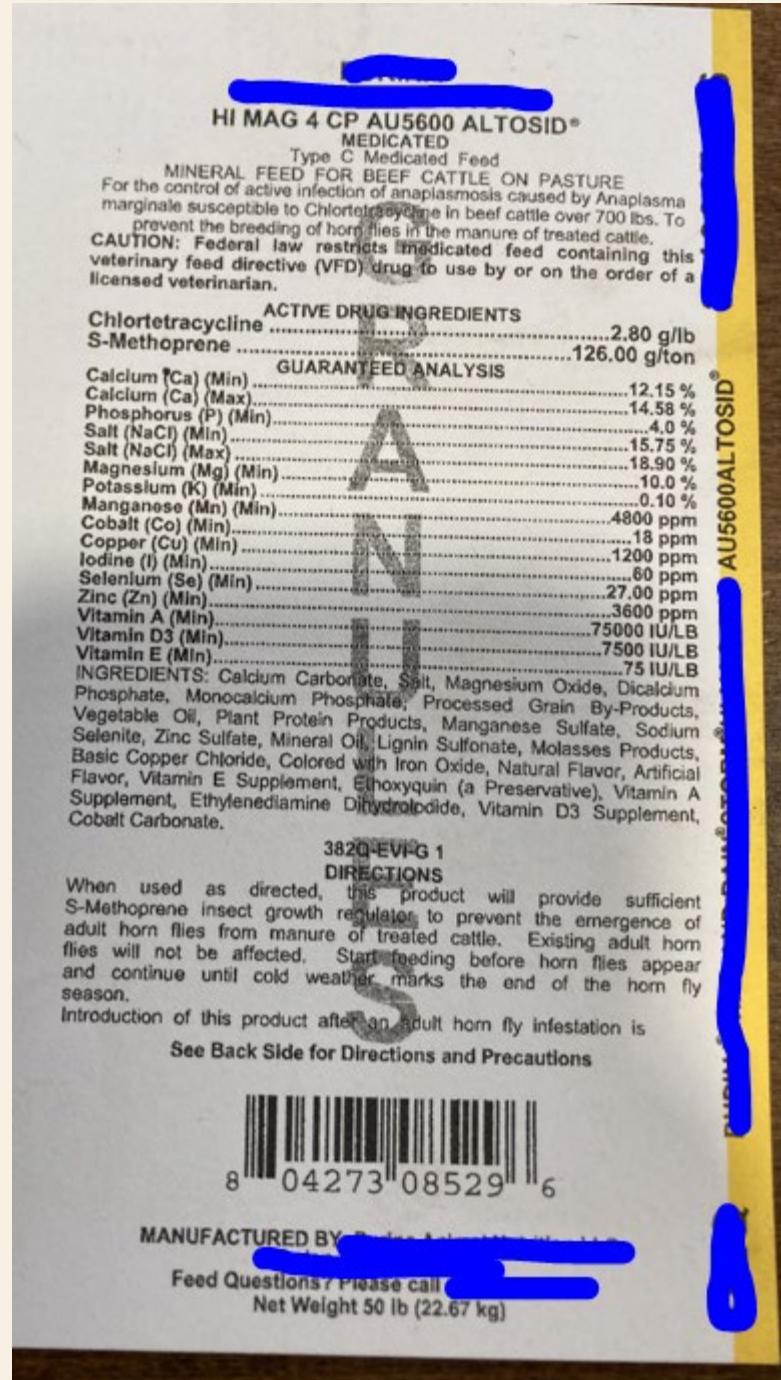
ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

This feed was made in a feed manufacturing facility that does not handle or store products containing animal proteins prohibited in ruminant feed.

Altosid® Insect Growth Regulator is a registered trademark of Wellmark International.

MEDICATED FEED



established will require treatment of cattle with adulticides if immediate elimination of the adult fly population is desired.
Hand feed daily to provide chlortetracycline at the rate of 0.5 mg/pound of body weight daily in beef cattle over 700 lbs and to provide 22.7 to 45.4 mg S-Methoprene per 100 lbs body weight/month. (0.756 to 1.51 mg S-Methoprene /100 lbs body weight/day).
0.01785 pounds of this cattle feed will medicate 100 lbs of body weight.
0.25 pounds (4 ounces) per day of this product will medicate one 1400 pound animal.
Altosid(R) is a registered trademark for Wellmark International.

IMPORTANT

Follow these management practices:

1. Cattle receiving phosphorus deficient diets should be monitored for the first few days to limit intake to the appropriate amount of Chlortetracycline as indicated in the feeding directions.
2. Place the mineral feeder near the water supply or in the animals' loafing area.
3. Feeding free choice salt is not required with this mineral.
4. Provide fresh, clean water near the feeding area.

CAUTION

Keep out of the reach of children.

Use only as directed.

Storage and Disposal: Do not contaminate water, food or feed by storage or disposal.

Product Disposal: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

DO NOT FEED TO SHEEP DUE TO HIGH LEVELS OF SUPPLEMENTAL COPPER.

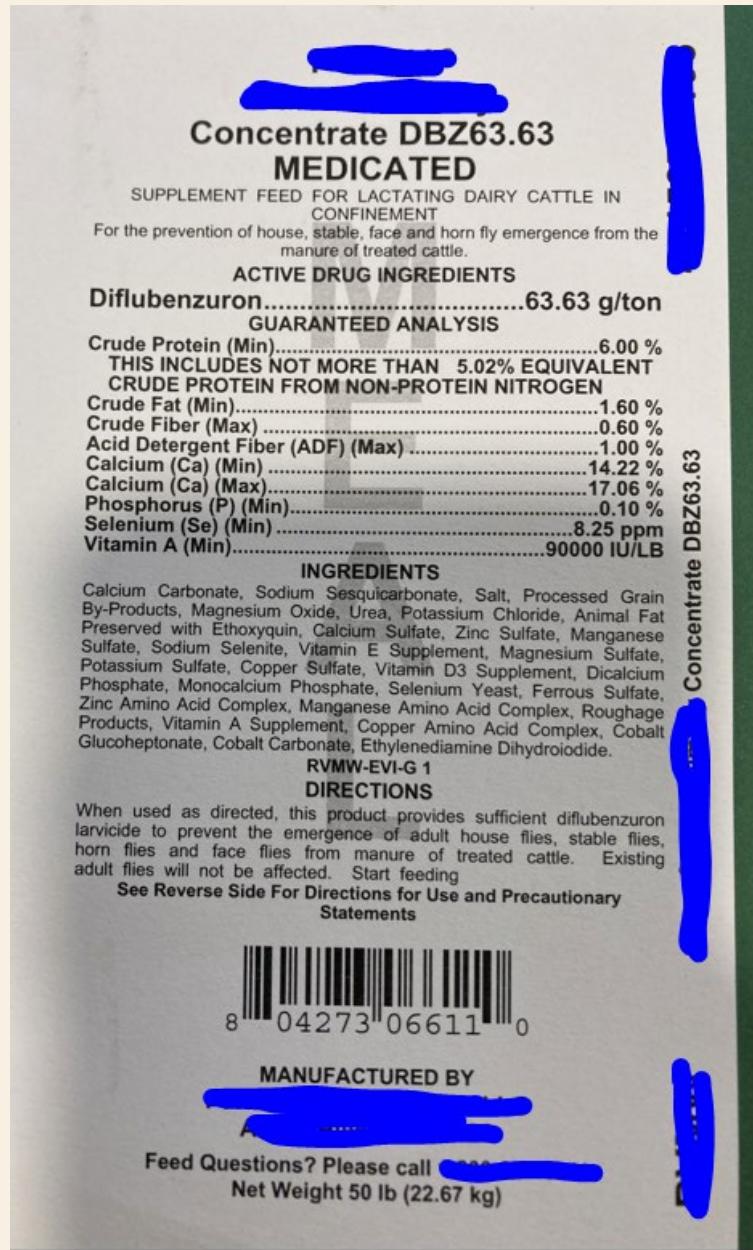
Store in a dry, well-ventilated area protected from rodents and insects. Do not feed moldy or insect-infested feed to animals as it may cause illness, performance loss or death.

USE ONLY AS DIRECTED

WARNING

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

COMPANY IDENTIFIED AS CUSTOM BLEND



before flies appear and continue use until cold weather marks the end of the fly season.

Introduction of this product after an adult fly infestation is established will require treatment of cattle and confinement areas with adulticides if immediate elimination of the adult fly population is desired.

Feed this product at a rate of 2 lbs to cattle weighing 1385 lbs bodyweight to provide 0.10 mg Diflubenzuron per kg of body weight.

IMPORTANT

Follow these management practices:

1. Provide a source of fresh clean water at all times.
2. Supplement [REDACTED] dairy minerals may be limit fed up to 2-3 ounces per head per day in sheltered feeders. For specific feeding program recommendations, see you [REDACTED]er.
3. Salt may be provided free-choice.
4. When changing roughages or milking rations, the change should be made gradually.
5. Consult your veterinarian for a recommended herd health program.

CAUTION

KEEP OUT OF REACH OF CHILDREN

Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Wear long-sleeved shirt and long pants, socks and shoes and gloves.

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.

Storage and Disposal: Do not contaminate water, food or feed by storage or disposal.

Storage: Store pesticide in original container in a dry place.

Product Disposal: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

Container Disposal: Completely empty bag. Then dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

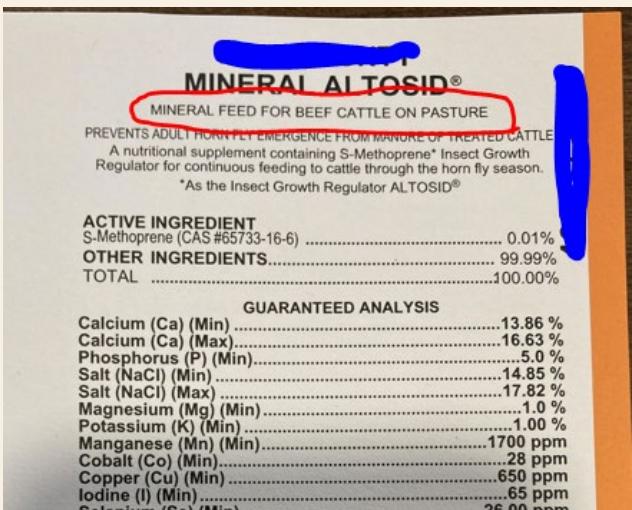
DO NOT FEED TO SHEEP DUE TO HIGH LEVELS OF SUPPLEMENTAL COPPER.

Store in a dry, well-ventilated area protected from rodents and insects. Do not feed moldy or insect-infested feed to animals as it may cause illness, performance loss or death.

USE ONLY AS DIRECTED

NOT FOR RESALE

FEED TAG FEED BAG



MEDICATED
Mineral for beef cattle on pasture
An insect growth regulator for control of horn fly, stable fly and face fly in the manure of cattle and calves.

ACTIVE INGREDIENT

Diflubenzuron (CAS# 35367-38-5).....363.2 G/Ton

GUARANTEED ANALYSIS

Calcium (Ca), Min.....	13.00%
Calcium (Ca), Max.....	15.00%
Phosphorus (P), Min.....	7.00%
Salt (NaCl), Min.....	20.00%
Salt (NaCl), Max.....	24.00%
Magnesium (Mg), Min.....	6.00%
Potassium (K), Min.....	1.40%
Copper (Cu), Min.....	1,650 ppm
Iodine (I), Min.....	175 ppm
Selenium (Se), Min.....	35 ppm
Zinc (Zn), Min.....	5,400 ppm
Vitamin A, Min.....	400,000 IU/lb
Vitamin D, Min.....	140,000 IU/lb
Vitamin E, Min.....	320 IU/lb

INGREDIENTS

Monocalcium Phosphate, Salt, Calcium Carbonate, Magnesium Oxide, Potassium Sulfate, Magnesium Sulfate, Dried Cane Molasses, Potassium Chloride, Mineral Oil, Zinc Oxide, Copper Sulfate, Processed Grain By-Products, Magnesium Limestone, Ferrous Sulfate, Manganese Oxide, Calcium Stearate, Sodium Sesquicarbonate, Vitamin E Supplement, Vitamin A Supplement, Ferrous Amino Acid Complex, Selenium Yeast, Zinc Amino Acid Complex, D-Activated Animal Sterol (Source of Vitamin D3), Manganese Amino Acid Complex, Soybean Oil, Ethylenediamine Dihydroiodide, Polysaccharide Complex of Zinc, Active Dry Yeast, Polysaccharide Complex of Iron, Copper Amino Acid Complex, Cobalt Carbonate, Polysaccharide Complex of Manganese, Calcium Aluminosilicates, Niacin Supplement, Brewers Dried Grains, Vitamin B12 Supplement, Polysaccharide Complex of Copper, Calcium Pantothenate, Riboflavin Supplement, Menadione Sodium Bisulfite Complex (source of Vitamin K activity), Sugar, Yeast Culture, Dried *Bacillus subtilis* Fermentation Extract, Dried *Aspergillus oryzae* Fermentation Extract, Dried Trichoderma reesii Fermentation Extract, Bifidobacterium thermophilum Fermentation Product Dehydrated, Enterococcus faecium Product Dehydrated, Cobalt Gluconate, Sodium Selenite and Natural Flavors.

FEEDING DIRECTIONS

_____ should be self-fed free choice in dry, wind free, rain protected feeders. Place feeders near a water source where animals gather. Provide fresh, clean water at all times. This mineral is designed to help fortify the ration with major and trace minerals, vitamins and yeast needed for optimum beef cattle performance.

Beef cattle should consume _____ at the rate of 4 oz/head/day to provide 45 mg of Diflubenzuron/head/day.

Manufactured By

NET WT 50 LB (22.7 kg)
EPA Reg No. _____

LOT#

W/G-MANNA-CEL
Mineral for beef cattle on pasture

ACTIVE INGREDIENT

Diflubenzuron (CAS# 35367-38-5).....363.2 G/Ton

GUARANTEED ANALYSIS

Calcium (Ca), Min.....	13.00%
Calcium (Ca), Max.....	15.00%
Phosphorus (P), Min.....	7.00%
Salt (NaCl), Min.....	15.00%
Salt (NaCl), Max.....	17.00%
Magnesium (Mg), Min.....	6.00%
Potassium (K), Min.....	1.50%
Copper (Cu), Min.....	1,650 ppm
Iodine (I), Min.....	175 ppm
Selenium (Se), Min.....	35 ppm
Zinc (Zn), Min.....	5,400 ppm
Vitamin A, Min.....	400,000 IU/lb
Vitamin D, Min.....	140,000 IU/lb
Vitamin E, Min.....	320 IU/lb

INGREDIENTS

Monocalcium Phosphate, Calcium Carbonate, Salt, Magnesium Oxide, Potassium Sulfate, Magnesium Sulfate, Processed Grain By-Products, Dried Cane Molasses, Potassium Chloride, Brewers Dried Yeast, Calcium Montmorillonite, Mineral Oil, Zinc Oxide, Copper Sulfate, Dried Whey, Magnesium Limestone, Ferrous Sulfate, Manganese Oxide, Calcium Stearate, Sodium Sesquicarbonate, Vitamin E Supplement, Vitamin A Supplement, Selenium Yeast, Zinc Amino Acid Complex, Extracted Citric Acid Presscake, Ferrous Amino Acid Complex, D-Activated Animal Sterol (Source of Vitamin D3), Manganese Amino Acid Complex, Soybean Oil, Silicon Dioxide, Ethylenediamine Dihydroiodide, Polysaccharide Complex of Zinc, Yucca Schiedegea Extract, Active Dry Yeast, Polysaccharide Complex of Iron, Copper Amino Acid Complex, Cobalt Carbonate, Polysaccharide Complex of Manganese, Calcium Aluminosilicates, Niacin Supplement, Brewers Dried Grains, Vitamin B12 Supplement, Polysaccharide Complex of Copper, Calcium Pantothenate, Riboflavin Supplement, Menadione Sodium Bisulfite Complex (source of Vitamin K activity), Sugar, Yeast Culture, Dried *Bacillus subtilis* Fermentation Extract, Dried *Aspergillus oryzae* Fermentation Extract, Dried Trichoderma reesii Fermentation Extract, Bifidobacterium thermophilum Fermentation Product Dehydrated, Enterococcus faecium Product Dehydrated, Sodium Selenite, Biotin, Thiamine Mononitrate, Cobalt Gluconate and Natural Flavors.

FEEDING DIRECTIONS

_____ should be self-fed in dry, wind free, rain protected feeders. Place feeders near a water source where animals gather. Provide fresh, clean water at all times. This mineral is designed to help fortify the ration with major and trace minerals, vitamins and yeast for optimum beef performance.

Beef Cattle should consume _____ at the rate of 4 oz/head/day to provide 45 mg of Diflubenzuron/head/day.

KEEP OUT OF REACH OF CHILDREN

Manufactured By

NET WT 50 LB (22.7 kg)
EPA Reg No. _____

LOT#
EPA EST NO. _____

W/G-MANNA-CEL
MEDICATED

Mineral for beef cattle on pasture

An insect growth regulator for control of horn fly, stable fly and face fly in the manure of cattle and calves.

ACTIVE INGREDIENT

Diflubenzuron (CAS# 35367-38-5).....477 G/Ton

GUARANTEED ANALYSIS

Calcium (Ca), Min.....	15.00%
Calcium (Ca), Max.....	17.00%
Phosphorus (P), Min.....	4.00%
Salt (NaCl), Min.....	19.00%
Salt (NaCl), Max.....	21.00%
Magnesium (Mg), Min.....	6.00%
Potassium (K), Min.....	1.50%
Copper (Cu), Min.....	1,650 ppm
Iodine (I), Min.....	175 ppm
Selenium (Se), Min.....	35 ppm
Zinc (Zn), Min.....	5,400 ppm
Vitamin A, Min.....	400,000 IU/lb
Vitamin D, Min.....	140,000 IU/lb
Vitamin E, Min.....	320 IU/lb

INGREDIENTS

Calcium Carbonate, Salt, Monocalcium Phosphate, Magnesium Oxide, Potassium Sulfate, Magnesium Sulfate, Processed Grain By-Products, Dried Cane Molasses, Potassium Chloride, Brewers Dried Yeast, Calcium Montmorillonite, Mineral Oil, Zinc Oxide, Copper Sulfate, Dried Whey, Magnesium Limestone, Ferrous Sulfate, Manganese Oxide, Sodium Sesquicarbonate, Vitamin E Supplement, Vitamin A Supplement, Selenium Yeast, Zinc Amino Acid Complex, Extracted Citric Acid Presscake, Ferrous Amino Acid Complex, D-Activated Animal Sterol (Source of Vitamin D3), Manganese Amino Acid Complex, Soybean Oil, Silicon Dioxide, Ethylenediamine Dihydroiodide, Polysaccharide Complex of Zinc, Yucca Schiedegea Extract, Active Dry Yeast, Polysaccharide Complex of Iron, Copper Amino Acid Complex, Cobalt Carbonate, Polysaccharide Complex of Manganese, Calcium Aluminosilicates, Niacin Supplement, Brewers Dried Grains, Vitamin B12 Supplement, Polysaccharide Complex of Copper, Calcium Pantothenate, Riboflavin Supplement, Menadione Sodium Bisulfite Complex (source of Vitamin K activity), Sugar, Yeast Culture, Dried *Bacillus subtilis* Fermentation Extract, Dried *Aspergillus oryzae* Fermentation Extract, Dried Trichoderma reesii Fermentation Extract, Bifidobacterium thermophilum Fermentation Product Dehydrated, Enterococcus faecium Product Dehydrated, Sodium Selenite, Biotin, Thiamine Mononitrate, Cobalt Gluconate and Natural Flavors.

FEEDING DIRECTIONS

_____ should be self-fed in dry, wind free, rain protected feeders. Place feeders near a water source where animals gather. Provide fresh, clean water at all times. This mineral is designed to help fortify the ration with major and trace minerals, vitamins and yeast needed for optimum beef cattle performance.

Consumption should be 4 oz/head/day to provide 45mg of Diflubenzuron/head/day.

CAUTION: Consumption of this product by sheep may result in copper toxicity.

Manufactured By

NET WT 50 LB (22.7 kg)
EPA Reg No. _____

LOT#

QUESTIONS:

WHAT CAN AN ESTABLISHMENT DO WITH A CUSTOM BLEND

- Advertise the blend?
- Create their own name for the blend?
- What happens with a PEI
 - How would an investigator clearly identify a custom blend?
 - What records requirements would an EPA Est. provide for outgoing pesticides/products?

QUESTIONS

Related to FIFRA Compliance/Enforcement Guidance Manual Policy Compendium.

- FIFRA Compliance Program Policy No. 3.4 - page 25 - Custom Blender
- FIFRA Compliance Program Policy No. 7.1 - page 42 - Custom Blenders
- Why are custom blenders required to be an EPA establishment, although not required to report custom blending information?

3) the blend is prepared in a registered establishment;
and

- Does this definition of "end-use labeling" mean that a manufacturing use product cannot be used for a custom blend?

—————
* The term "end-use labeling" means labeling containing directions for use in pest control and otherwise meeting the requirements of 40 CFR 162.10. Labeling indicating that a product is intended only for use in manufacturing or formulating pesticides shall not be considered end-use labeling.

- If you add a medication to a custom blend, does it need to be made at an EPA establishment?

REGULATIONS - FFDCA

40 CFR § 152.3 Definitions

Pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, **other than any article that:**

- (1) Is a new animal drug under FFDCA sec. 201(w), or
- (2) Is an animal drug that has been determined by regulation of the Secretary of Health and Human Services not to be a new animal drug, or
- (3) Is an animal feed under FFDCA sec. 201(x) that bears or contains any substances described by paragraph (s) (1) or (2) of this section.

Are the citations for FFDCA correct?

sec. 201

- (v) Connects to the term “new animal drug”**
- (w) Connects to the term “animal feed”**
- (x) connects to “informal hearings”**



NEXT STEPS

- Collaborate with FDA, EPA & SLAs for a joint Feed & Pesticide guidance