

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 14 1991

300 / 5386596
17

Mr. Robert Shoup
 Fermenta Animal Health Company
 10150 North Executive Hills Boulevard
 P.O. Box 901350
 Kansas City, MO 64190-1350

Dear Mr. Shoup,

Subject: Amendment - Labeling and Name Change
 Vapona[®] Feedlot Insecticide Emulsifiable
 EPA Registration Number 56493-26
 Your Submission Dated November 6, 1990

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, provided that you make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

1. For products in Toxicity Category I (DANGER), the Statement of Practical Treatment must appear on the front panel of the label.
2. Revise the Statement of Practical Treatment as follows:
 - a. Add an "If Inhaled" statement.
 - b. For If Swallowed, change "Call a physician or Poison Control Center." to "Call a physician or Poison Control Center immediately." This sentence should be added to each of the statements.
3. Revise the Environmental Hazards as follows:

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to fish, birds and other wildlife. Do not apply to water or wetlands (swamps, bogs, marshes and potholes). Do not apply where runoff is likely to occur or when weather conditions favor drift from areas treated. Drift and runoff from treated

(cont.)

CONCURRENCES

| | | | | | | | |
|---------|---------|--|--|--|--|--|--|
| SYMBOL | | | | | | | |
| SURNAME | TML | | | | | | |
| DATE | 3/15/91 | | | | | | |

areas may be hazardous to aquatic organisms in treated areas. Do not contaminate water when disposing of equipment washwaters.

4. Change "Inert Ingredients include petroleum hydrocarbons." to "Contains petroleum hydrocarbons."

5. The address on the label must be qualified with a statement similar to "Manufactured By," or "Manufactured For," etc.

6. Since the product is intended for agricultural use and the dosages are expressed in volumetric terms, on the front panel beneath the ingredients statement include the weight of the active ingredient per unit volume of product. Also, in the chart for dilution, indicate the percent spray solution for the corresponding dilution rates.

7. The statement referring to atropine as the emergency antidote (i.e., "Atropine is the emergency antidote for Vapona Insecticide poisoning.") should appear under the Note to Physician.

8. The misuse statement (i.e., "It is a violation of Federal law to use...") should appear as a separate paragraph.

9. Add the hypersensitivity statement about Brahman cattle under the remarks section under "Livestock Use Directions", i.e., "Brahman and Brahman cross cattle should not be treated as they may show hypersensitivity to organophosphates."

The one-day withdrawal period should also appear under the remarks section.

Also under remarks add "Do not apply to calves under 6 months of age. Do not wet the hide."

10. Change "Inert Ingredients include petroleum hydrocarbons." to "Contains petroleum hydrocarbons."

11. The address on the label must be qualified with a statement similar to "Manufactured By," or "Manufactured For," etc.

Submit five copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

Sincerely,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure


VAPONA• Concentrate Insecticide

Controls Flies, Gnats, Mosquitoes.
Use in and around feedlots, livestock and poultry premises.

| ACTIVE INGREDIENTS | % BY WT. |
|--|----------|
| Dichlorvos: 2,2-Dichlorovinyl dimethyl phosphate | 40.2%* |
| Related Compounds | 3.0%* |
| INERT INGREDIENTS | 56.8%** |
| TOTAL | 100.0% |

*Equivalent to 43.2% w/w VAPONA Insecticide.
**Inert ingredients include petroleum hydrocarbons.

Keep Out of Reach of Children *← 12 pint type*

DANGER  POISON *] red 18 pint type*

See Side Panels for Precautionary Statements

Fermenta Animal Health Co.
P. O. Box 901350
Kansas City, MO 64190

Net Contents: 5 Gallons
EPA Reg. No. 56493-26
EPA Est.

ACCOUNTED FOR
with COMMENTS
in EPA Letter Dated:

MAR 14 1991

STATEMENT OF PRACTICAL TREATMENT

Atropine is the emergency antidote for Vapona Insecticide poisoning.

If swallowed: Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or, if available, by administering syrup of ipecac. Do not induce vomiting or give anything by mouth to an unconscious person. Call a physician or Poison Control Center.

If on skin: Immediately remove the patient from the vicinity of the insecticide, remove all contaminated clothing, and wash skin with soap and running water.

If in eyes: Wash eyes immediately with running water.

If Warning Symptoms Appear: Keep patient prone and quiet. Start artificial respiration immediately if patient is not breathing. Transport the patient immediately to the nearest hospital. (See Warning Symptoms below).

Note to Physician

Warning Symptoms: Symptoms include weakness, headache, tightness in chest, blurred vision, non-reactive pin-point pupils, salivation, sweating, nausea, vomiting, diarrhea and abdominal cramps.

Treatment: Atropine is the specific therapeutic antagonist of choice against parasympathetic nervous stimulation. If there are signs of parasympathetic stimulation, atropine sulfate should be injected at ten-minute intervals, in doses of 1 to 2 milligrams until complete atropinization has occurred.

Morphine is contraindicated.

Pralidoxime chloride (2-PAM chloride) may also be used as an effective antidote in addition to and while maintaining full atropinization. In adults, an initial dose of 1 gram of 2-PAM should be injected, preferably as an infusion in 250 cc of saline over a 15-to-30-minute period. If this is not practical, 2-PAM may be administered slowly by intravenous injection as a 5 percent solution in water over not less than two minutes. After about an hour, a second dose of 1 gram of 2-PAM will be indicated if muscle weakness has not been relieved. For infants and children the dose of 2-PAM is 0.25 grams.

Clear chest by postural drainage.

Repeated exposure to cholinesterase inhibitors may, without warning, cause prolonged susceptibility to very small doses of any cholinesterase inhibitor.

Allow no further exposure until cholinesterase regeneration has occurred as determined by blood test.

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

Danger

Vapona Insecticide is poisonous if swallowed, inhaled or absorbed through skin or eyes. Do not get on skin or eyes. Do not breathe fumes. Avoid exposure to fumes. Wear clean rubber gloves, protective clothing and goggles when handling the Vapona Insecticide to prepare emulsions. Wear a mask or pesticide respirator jointly approved by the Mining Enforcement and Safety Administration and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II. Keep all unprotected persons out of operational area.

In case of contact, wash immediately with soap and water. Wash thoroughly with soap and water before eating or smoking. Wash all contaminated clothing with soap and hot water before reuse.

Must be diluted prior to use. Observe all precautions when handling Vapona Insecticide and the diluted emulsion.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds and other wildlife. Keep out of lakes, streams and ponds. Do not apply where runoff is likely to occur. Do not apply when weather conditions favor drift from areas treated. Do not contaminate water when disposing of equipment washwater.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Not for use or storage in or around the home.

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in original container only. Store in a safe place where children or animals cannot reach the product or its diluted emulsion. Protect from freezing.

Container Disposal: Triple-rinse (or equivalent). Then puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

WARRANTY AND LIMITATION OF DAMAGES

Seller warrants that this material conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use and Buyer assumes the risk of any use contrary to such directions. Seller makes no other express or implied warranty, including any other express or implied warranty of Fitness or of Merchantability, and no agent or Seller is authorized to do so except in writing and with specific reference to this warranty. In no event shall Seller's liability for any breach of warranty exceed the purchase price of the material as to which a claim is made.

DIRECTIONS FOR USE

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

This product must be mixed with water or diesel oil, depending on use, prior to using. It is suitable for use in conventional power or low pressure knapsack sprayers, mist blowers or foggers. Select the specific site, method of use and insect problem, then dilute as directed. Follow the remarks for the safe use and best results in using this product. It is recommended that only the amount of diluted emulsions that will be used immediately be prepared from this product. Prior to use read the Precautionary Statements elsewhere on this product label.

This product can be used on lactating dairy cattle and requires only 1-day withdrawal period when used on beef cattle.

BEST AVAILABLE COPY

DIRECTIONS FOR USE (Cont'd)

Livestock Use Directions - Dilute In Water Only

For direct application to beef and dairy cattle.

| USE | INSECTS CONTROLLED | DILUTION VAPONA IN WATER | REMARKS |
|-----------------------------|---|--|---|
| Dairy Cattle Beef Cattle | Horn Flies Face Flies Stable Flies House Flies Mosquitoes | 1 gal. in 50 gal. or 5 oz. in 2 gal. | Apply 1 to 2 fl. oz. of diluted solution (do not exceed 2 oz.) per animal daily as a fine mist spray. Be sure to cover all parts of animal for best results. Do not apply dermally in combination with Trichlorfon. |

Indoor Premise/Area Use Directions - Dilute in Water Only

For indoor application to livestock facilities.

| USE | INSECTS CONTROLLED | DILUTION VAPONA IN WATER | REMARKS |
|---|--|---|---|
| Dairy Barns Poultry Houses Horse Stables Swine Barns Other Animal Buildings | Flies Gnats Mosquitoes Roaches Sowbugs Ants | 1 gal. in 100 gal. or 2 oz. in 1.5 gal. | Apply as a space spray to open air space at the rate of 1 quart (32 oz) of diluted solution per 8,000 cubic feet or as a coarse wet spray to indoor surfaces at the rate of 1 quart of diluted solution per 1000 sq. ft. Before applying reduce air movement as much as possible by closing doors, windows, and other openings. Do not use this solution in areas where animals have received a direct application within eight hours. Do not contaminate water, feed, or foodstuffs, milk or milking utensils. |
| | | 1 gal. in 50 gal. or 5 oz. in 2 gal. | Apply as above at the rate of 1 pint (16 oz) per 8,000 cubic feet or 1 pint (16 oz) per 1000 sq. ft. when a reduced quantity of water is desired and equipment can adequately provide coverage of area to be treated. |
| Manure Piles | Fly Maggots | 1 gal. in 100 gal. or 2 oz. in 1.5 gal. | Apply as above at the rate of 1 to 2 qts. of solution per 100 sq. ft. of manure once a week. |

Outdoor Area Use Directions - Dilute in Water (Misting) or Diesel Oil (Fogging)

For outdoor area treatment of livestock holding facilities.

| USE | INSECTS CONTROLLED | DILUTION VAPONA IN DILUENT | REMARKS |
|--|------------------------------|--|---|
| Cattle Feedlots Stockyards Holding Pens Corrals Other Outdoor Animal Areas | Flies Gnats Mosquitoes | 1 gal. in 100 gal. or 1 qt. in 25 gal. | Apply at an overall application rate of approximately 5 gallons of diluted solution per acre. Fog or mist during the time insects are most active, usually late afternoon and when there is little wind. Particular attention should be given to areas where flies congregate such as around feed bunks, fences, and walls of buildings. Avoid direct application to exposed feed and water. Animals may be present during treatment. |

BEST AVAILABLE COPY