



004691-00130-101597

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Systems Integration Group, Inc.

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OCT 15 1997

Ms. Karen Vasquez
Boehringer Ingelheim Animal Health Inc.
2621 North Belt Highway
St. Joesph, MO 64506

Dear Ms. Vasquez:

Subject: Label Amendments in Response to Basic Suppliers Deletion of Certain DDVP Uses
Vapona Concentrate Insecticide
EPA Registration No. 4691-130
RAVAP E. C. Livestock, Poultry & Premise Insecticide Spray
EPA Registration No. 4691-136
Kennel and Yard Spray Concentrate
EPA Registration No. 4691-137
Your Submission Dated May 17, 1995

The amendment 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 indicated below prior to release for shipment of product bearing the amended labeling:

For EPA Registration No. 4691-130:

1. Under Environmental Hazards delete "For terrestrial uses." Your product is labeled only for terrestrial uses.
2. The statement of practical treatment must appear on the front panel for a product in toxicity category one based upon oral, dermal or inhalation exposure.
3. Revise the paragraph, Required Protective Clothing to read as follows:

Personal Protective Equipment (PPE)

Some materials that are chemical resistant to this product are listed below. If you want more options follow the instructions of category "C" on an EPA chemical resistance category selection chart in the Worker Protection Standard.

Applicators and other Handlers Must Wear:

- Coveralls over long-sleeved shirt and long pants.

- Chemical-resistant gloves such as Barrier Laminate, Butyl Rubber, Nitrile Rubber, Neoprene Rubber, Polyvinyl Chloride or Viton
 - Chemical-resistant footwear plus socks
 - Protective eyewear
 - Chemical resistant headgear for overhead exposure
 - Chemical resistant apron required for mixing/loading and cleaning equipment
 - Respirator with either an organic vapor removing ON cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TX-23C) or a canister approved for pesticides (MSHA/NIOSH approval number TC-14G)
- Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this products concentrate. Do not reuse them. Follow manufacture'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.

4. Under Livestock Use Directions add: Do not make direct application to livestock more frequently than once per day."

For EPA Registration No. 4691-136:

1. Qualify personal protective clothing as follows: "... or face shield and chemical resistant gloves and shoes, long sleeved shirt, pants and socks when handling."
2. Under Pesticide Disposal revise the statement to: "Pesticide wastes are acutely toxic....."
3. Under Environmental Hazards delete "For terrestrial uses." Your product is labeled only for terrestrial uses.
4. The site Kennels should not be under the category heading "Poultry and Livestock Facilities." Remove it and place it under a separate heading.
5. Under Livestock Use Directions add: Do not make direct application to livestock more frequently than once per day."

We are not reviewing the labeling submitted with your April 24, 1997 submission since it is different from that submitted with your May 17, 1995 submission. The May 17, 1995 label bears the correct signal word and precautionary statements.

For EPA Registration No. 4691-137

1. Add the following: "For Agricultural/Commercial Use Only not for Sale for any Other Uses" to the front panel.
2. Add the following to the Environmental Hazards statements: "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 by cleaning of equipment or disposal of equipment washwaters.”

3. Qualify personal protective clothing as follows: “...or face shield and chemical resistant gloves and shoes, long sleeved shirt, pants and socks when handling.”
4. Under Storage and Disposal add the following (based on your Toxicity Category): “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.”
5. Under use directions revise “to the point of runoff” to read “but do not allow runoff to occur.”

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

Sincerely,

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

NET CONTENTS: 2.5 GALLONS (9.5 LITERS)

Vapona® Concentrate Insecticide

Controls Flies, Gnats, and Mosquitoes on Cattle and around livestock and poultry premises.

For Agricultural/Commercial Use Only
Not For Sale For Any Other Uses

DILUTE
PRIOR TO USE

Active Ingredients	% By Weight
Dichlorvos:	
2,2-Dichlorovinyl dimethyl phosphate	40.2%*
Related Compounds	3.0%*
Inert Ingredients	56.8%**
Total	100.0%

This product contains 3.88 lbs. of Dichlorvos per gallon.

*Equivalent to 43.2% w/w VAPONA Insecticide.

**Contains petroleum hydrocarbons.

Keep Out of Reach of Children



RED → DANGER POISON

PELIGRO

ACCEPTED
with COMMENTS
EPA Letter Dated

See side panels for additional precautionary statements.

OCT 15 1997

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 56493-26



OBSERVE LABEL DIRECTIONS

Manufactured for:
Fermenta Animal Health Company
Kansas City, MO 64153-2314

EPA Reg. No. 56493-26
EPA Est. 5481-CA-1
9704

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center immediately. Induce vomiting by giving victim 1 or 2 glasses of water and touching back of throat with finger. Never induce vomiting or give anything by mouth to an unconscious or convulsing person.

IF INHALED: Remove victim to fresh air immediately. Apply artificial respiration if indicated. Get medical attention.

IF IN EYES: Hold eyelids open and flush with a steady gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Remove contaminated clothing immediately and wash affected area with soap and water. Call a physician immediately. Wash clothing before reuse.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: POISONOUS IF SWALLOWED, INHALED OR ABSORBED THROUGH THE SKIN AND EYES. RAPIDLY ABSORBED THROUGH SKIN. REPEATED INHALATION OR SKIN CONTACT MAY WITHOUT SYMPTOMS, PROGRESSIVELY INCREASE SUSCEPTIBILITY TO DICHLORVOS (DDVP) POISONING. Do not swallow or get in eyes, or skin or on clothing. Do not breathe vapor. Do not contaminate food or feed products.

REQUIRED PROTECTIVE CLOTHING

Persons who handle this product must wear the following protective clothing: protective suit of one or two pieces covering all parts of the body except head, hands, and feet, chemical resistant gloves; chemical resistant shoes (or chemical resistant shoe coverings or chemical resistant boots); respirator with either an organic vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-140); and a chemical resistant apron.

NOTE TO PHYSICIAN-POISONING 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 10 minute intervals in doses of 1 to 2 milligrams until complete atropinization has occurred. Pralidoxime chloride (2-PAM) 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 gram. Morphine is an improper treatment. Clear chest by postural drainage. Oxygen administration may be necessary. Observe patient continuously for 48 hours. 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 been attained as determined by blood test.

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to fish, birds and other wildlife. For terrestrial uses, do not apply to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply where runoff is likely to occur or when weather conditions favor drift from areas treated. Drift and runoff from treated areas may be hazardous to aquatic organisms in treated areas. Do not contaminate water when disposing of equipment washwaters.

Physical or Chemical Hazards

Do not use or store near heat or open flame. Do not use with thermal foggers or heat-generating devices.

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 rinse 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.

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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 non-thermal 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. Do not store diluted 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.

Livestock Use Directions - Dilute in Water Only

For direct application to beef and dairy cattle (including lactating).

MUST BE DILUTED PRIOR TO APPLICATION

Use	Insects Controlled	Dilution Vapors In Water	Remarks
Dairy Cattle (including lactating), Beef Cattle	Horn Flies Face Flies Stable Flies House Flies Mosquitoes	1 gal. in 50 gal. or 5 oz. in 2 gal. (1% Dilution)	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 in combination with other dermal organophosphate pesticides (e.g. trichlorfon). Brahman and Brahman cross cattle should not be treated as they may show hypersensitivity to organophosphates. Do not wet the hide. Do not apply to calves under 6 months of age. One day withdrawal is required on beef cattle.

Indoor Premises/Areas Use Directions - Dilute in Water Only

For indoor application to livestock facilities.

Use	Insects Controlled	Dilution Vapors In Water	Remarks
Dairy Barns, Poultry Houses, Swine Barns, Other Animal Buildings	Flies Gnats Mosquitoes Roaches Sowbugs Ants	1 gal in 100 gal or 2 oz in 1.5 gal (0.5% Dilution)	Apply as a space spray mist 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 organophosphate pesticide application within eight hours. If animals are present, ventilate treated area immediately following spray application. Do not contaminate water, feed, or foodstuffs, milk or milking utensils.
Manure Piles	Fly Maggots	1 gal in 50 gal or 5 oz in 2 gal (1.0% Dilution)	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.
		1 gal in 100 gal or 2 oz in 1.5 gal (0.5% Dilution)	Apply as above at the rate of 1 to 2 qts of solution per 100 sq. ft. of manure once a week.

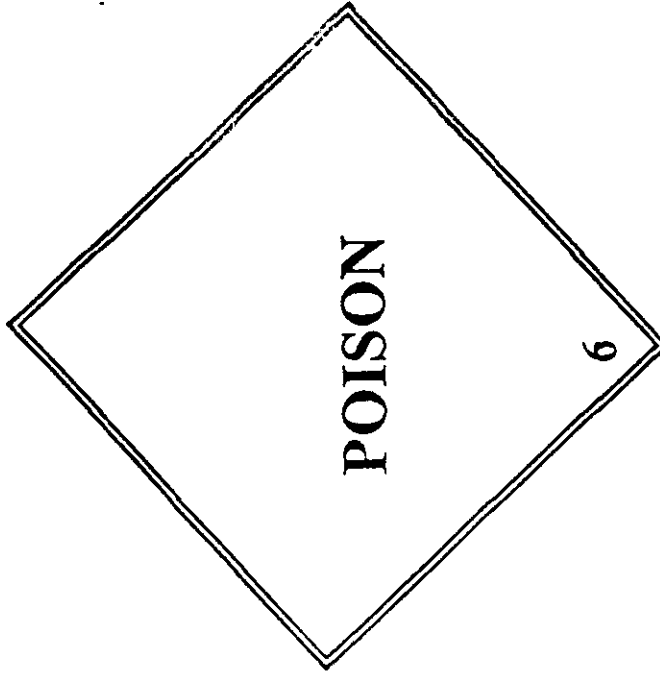
Outdoor Area Use Directions - Dilute in Water (Misting) or Diesel Oil (Fogger)

For outdoor area treatment of livestock holding facilities.

Use	Insects Controlled	Dilution Vapors in Diluent	Remarks
Cattle Feedlots Stockyards Holding Pens Corrals	Flies Gnats Mosquitoes	1 gal in 100 gal or 1 qt in 25 gal (0.5% Dilution)	Apply at an overall application rate of approximately 5 gallons of diluted solution per acre. Fog or mist during the time herds 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 food banks, fences, and walls of buildings. Avoid direct application to exposed food and water. Animals may be present during treatment.

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 accepts 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 merchantability, and no agent of 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.



ORGANOPHOSPHORUS PESTICIDE, LIQUID, TOXIC,
N.O.S. (DICHLORVOS), UN 3018, RQ