PM-15

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MAY 10

301 363785

Dr. Louis S. Grosso Herck Sharp & Dohme Research Laboratories Hillsborough Road Three Bridges, NJ 08887

Dear Dr. Grosso:

Subject: Amendment - Updated Labeling :Inclusion of Additional Registered End Use Sites/Crops and Alternate Brand Name

AFFIRM Technical

EPA Registration Number 618-95

Your Submissions Dated March 2 and May 1, 1990

The labeling referred to above, submitted on in connection with registration under the Federal Insecticide, Pungicide, 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:

- The child hazard warning ("Keep Out of Reach of Children") must appear on the front panel of the label, preferably above the signal word ("Danger").
- 2. Add the required heading, "Directions For Use", immediately before the misuse statement ("It is a violation...").
 - 3. Add a street name or P.O. Box number to the address on the label.

It is understood that the labeling submitted on May 1, 1990 supercedes the labeling submitted on March 2, 1990, which had included use in the manufacture of insecticide bait formulations in general. The latest labeling provides for use in the manufacture of insecticide baits for control of fire ants only, as well as the manufacture of registered end use formulations for use on ornamental plants, cotton and citrus.

The additional brand name, "Abanectin Technical", is acceptable and has been made a part of the record for this product.

Submit five (5) 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 (27505C)

LIMANU 5/10/50

CENTER PANEL

Product 00012

ARAMECTIN THEMSEAL

(AN INSECTICIDE FOR FORMULATION USE ONLY)

Active Ingredient Avermectin B_1 - A mixture of Avermectin A_{24} , 5-0-demethy1- and Avermectin A_{14} , 5-0-demethy1-25-de(1-methy1propy1)-25-	
(1-methylethyl)	. 70
Inert Ingredients	.25
Related Compounds	

CAS-65195-55-3

CAS-65195-56-4

DANGER - POISON



STATEMENT OF PRACTICAL TREATMENT

If Ingested - Immediately give one or two glasses of water and induce vomiting by gently touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person. If Inhaled - Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. If on Skin - Wash with plenty of soap and water. If in Eyes - Flush with plenty of water. Get medical attention in all cases. (Show the label where possible.)

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Lot

Assay Weight

Drus

Net Weight

EPA Establishment No. 618-PA-1 EPA Registration No. 618-95

(dompohent number)

MSD AGVET [logo] Division of MERCK & CO., Inc. RAHWAY, NEW JERSEY 07065, U.S.A.

ACCUPTED with COMMINING in UPA-Letter Dated:

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LEFT SIDE PANEL

For 24-hour emergency information regarding spills, leaks, exposure or accidents contact CHEMTREC 1-800-424-9300.

ENVIRONMENTAL HASARDS

This pesticide is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into saver systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

INSTRUCTIONS TO FORMULATORS

This technical product may be used for the manufacture of fire ant bait formulations and for insecticide/miticide formulations for use on the following crops: ornamental plants, citrus and cotton. Formulators using this product are responsible for obtaining Environmental Protection Agency Registration for their formulated products. Refer to MERCK & CO., Inc. Technical Bulletins for formulation instruction and other information.

IT IS A VIOLATION OF FEDERAL (U.S.A.) LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH THIS LABELING. THIS PRODUCT IS FOR THE FORMULATION OF FIRE ANT BAITS AND AGRICULTURAL INSECTICIDE/MITICIDE SPRAY FORMULATIONS AND IS NOT FOR RESALE UNDER THIS LABEL.

STORAGE AND DISPOSAL

STORAGE: Store ABAMECTIN TECHNICAL in a cool, dry place away from food, drink and animal feeding stuffs. If spilled, do not flush to vaterways (see ENVIRONMENTAL HAZARDS). Carefully collect and containerize spilled material in a manner that produces the least amount of airborne dust. Suitable protective equipment should be worn during any spill cleanup operation (see PRECAUTIONARY STATE-MENTS). Residual surface material may be removed with towels moistened with methanol.

PRSTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Inproper disposal of excess posticide, spray mixture, or rinsate is a violation of Pederal (U.S.A.) law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Rexerdous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Polyliner (plastic bag): Completely empty liner by shaking and tapping sides and bottom to loosen ulinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If drum is conteminated and cannot be reused, dispose of in the same manner. Metal Container: Triple rinse (or equivalent). Then offer for recycling or reconditioning. or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals DAMGER

FATAL IF SWALLOWED.

Harmful if absorbed through akin.

Avoid contact with eyes, skin and clothing.

Wash thoroughly with soap and water after handling and before eating or smoking.

Do not breathe dust.

Keep container tightly closed.

Keep away from food, drink, and animal feeding stuffs.

The following protective clothing must be worn during all handling and formulation operations: Airline mask or air supplied hood, chemical resistant goggles and gloves, full body garments with shoe protectors and head cover. Disposable clothing is recommended.

RECOMMENDATIONS FOR MEDICAL TREATMENT FOR AVERMECTIN B, ACUTE TOXICITY:

Early signs of intoxication include dilation of pupils, muscular incoordination and tramors. Toxicity following accidental ingestion of the technical product can be minimized by induced vomiting within one half hour of exposure.

If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive perenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels) as indicated by clinical signs, symptoms, and measurements.

In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since avermectin B_i is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic avermectin B_i exposure.

In cases of human exposure, for 24-hour emergency information call MERCK & CO., Inc. (215) 661-7300 during business hours (8:30 am to 4:30 pc tst) or (215) 661-5000 after hours or weekends.

BEST AVAILABLE COPY