

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (15-767)
WASHINGTON, DC 20460

EPA REGISTRATION NO. 618-95	DATE OF ISSUANCE FEB 20 1987
TERM OF ISSUANCE	
NAME OF PESTICIDE PRODUCT AFFIRM Technical	

NOTICE OF PESTICIDE: REGISTRATION
 REREГИSTRATION
(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Merck and Company, Inc.
Merck Sharp and Dohme
Research Laboratories
Agricultural Research Development
Three Bridges, NJ 08887

124/190131
18/1

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is additionally registered in accordance with section 6(e)(5) provided that you:

1. Make the labeling changes listed below before you release the product for shipment:

- a. Add the phrase "EPA Registration No. 618-95."
- b. Add the phrase "chemical resistant" before the words "goggles and gloves" in the precautionary statements.
- c. In the use treatment instructions, delete the phrase "for at least 15 minutes" unless you can justify the need for this length of time. This also applies to the Technical Bulletin for AFFIRM TECHNICAL.

2. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

ATTACHMENT IS APPLICABLE

BEST AVAILABLE COPY

SIGNATURE OF APPROVING OFFICIAL
[Handwritten Signature]

DATE
2/22/87

Note: The Agency has reviewed your request for a waiver from the requirement of the acute neurotoxicity study (EPA Guideline 81-7) for avermectin and has concluded that this data requirement is not applicable for this type of product based on the following conclusions:

- Avermectin is not an organophosphate and has no cholinesterase-inhibiting activity.
- The neurotoxicity of abamectin is not delayed. Toxic signs include mydriasis (dilated pupils), ataxia (unsteadiness), and muscle tremors. In single oral dosing studies, toxic signs are seen within 24 to 48 hours and disappear within 4 days of dosing. In a classical delayed neurotoxicity study, signs are not seen for 8 to 10 days.
- No study performed that has been submitted with histopathology evaluation performed has shown any compound-related axonal degeneration.

A stamped copy of the label is enclosed for your records.

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

Enclosures

Product 06403

ENVIRONMENTAL HAZARDS

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 sewer 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 only for the formulation of fire ant bait products. 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 instructions 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 BAIT INSECTICIDES ONLY AND IS NOT FOR RESALE UNDER THIS LABEL.

STORAGE AND DISPOSAL

STORAGE: Store AFFIRM TECHNICAL in a cool, dry place away from food, drink and animal feeding stuffs. If spilled, do not flush to waterways (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 STATEMENTS). Residual surface material may be removed with towels moistened with methanol.

DISPOSAL: Pesticide Disposal—Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal (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 Hazardous 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 clinging 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 contaminated and cannot be reused, dispose of in the same manner.

Metal Container: Triple rinse (or equivalent). Then offer for recycling or conditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

**AFFIRM TECHNICAL
(AN INSECTICIDE FOR FORMULATION USE ONLY)**

Active Ingredient

Avermectin P - A mixture of Avermectin A_{1a}, 5-O-demethyl-Avermectin A_{1a}, 5-O-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl)-

Inert Ingredients
Related Compounds

CAS-86753-29-9

DANGER - POISON



STATEMENT OF PRACTICAL TREATMENT

If Ingested—Immediately give one or two glasses of water and vomit 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 for at least 15 minutes. Get medical attention in all cases. (Show this label where possible.)

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENT

Lot _____ Assay Weight _____
Drum _____ Net Weight _____

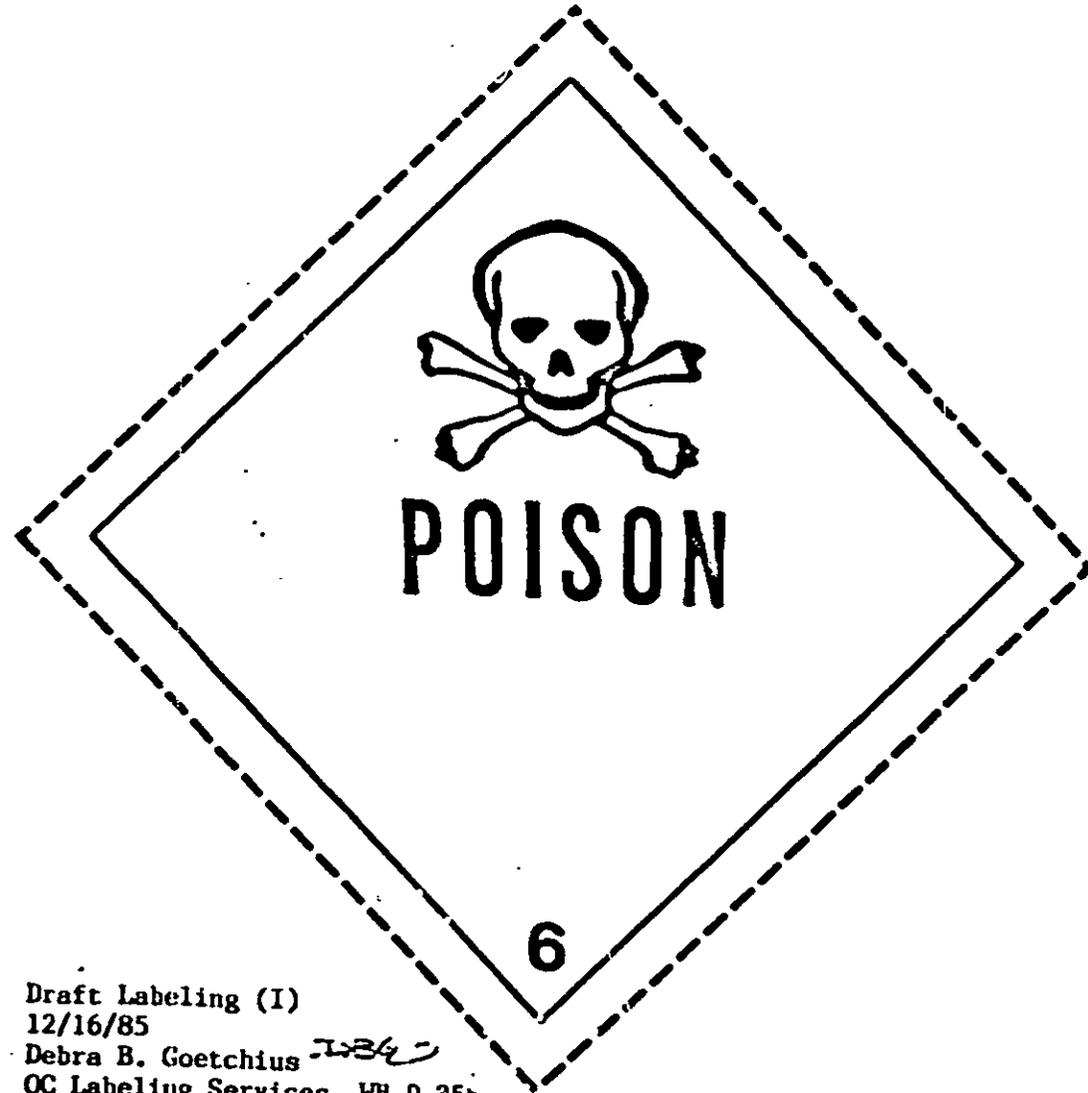
EPA Establishment No. 618-PA-1

EPA Registration No. _____

MERCK & CO., INC., Rahway, New Jersey 07065

POISONOUS SOLIDS, NOS UH 2811

(Avermectin B₁ - A mixture of Avermectin A_{1a},
5-o-demethyl- and Avermectin A_{1a},
5-o-demethyl-25-de(1-methylpropyl)-
25-(1-methylethyl)-)



Draft Labeling (I)
12/16/85
Debra B. Goetchius *1234*
QC Labeling Services, WB D-355

Procedures for use of AFFIRM^R Technical in the
Manufacture of AFFIRM^R (0.011% avermectin B₁) end use products

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 20 1987

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

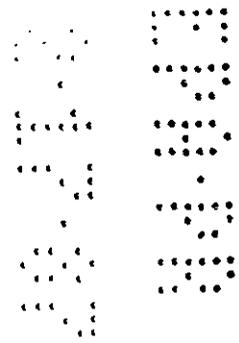
618-95

MERCK & CO., INC.

P. O. Box 2000

Rahway, NJ 07065

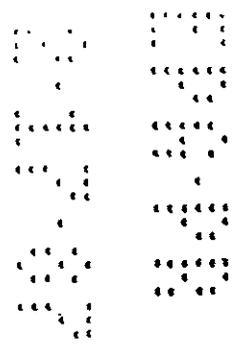
December 1985



Procedures for use in the
Manufacture of AFFIRM (0.011% avermectin B₁) end use products

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TECHNICAL BULLETIN

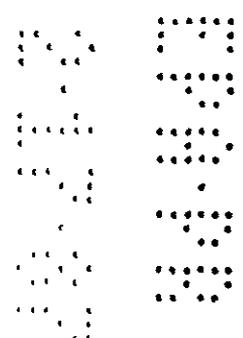
Procedures for use of AFFIRM Technical in the
Manufacture of AFFIRM end use products

A. Introduction

The manufacture of a granular pesticidal product involves the application of AFFIRM Technical by a spraying operation, to a solid carrier in a closed blender.

AFFIRM Technical, for use in the preparation of AFFIRM end use product is optimized under production conditions to maximize yield and give excellent product uniformity.

Compliance with the conditions for production described on the following pages will result in the efficient production of AFFIRM end use product.



B. Procedure for Preparation of AFFIRM 0.011% Avermectin B₁ End Use Product

I. Summary

The AFFIRM fire ant bait is prepared via spray impregnation of a solution of AFFIRM Technical and once-refined soya oil onto pregel defatted corn grits. The t-butylhydroquinone (TBHQ) and AFFIRM Technical are prepared as a concentrate, then diluted with the required amount of soya oil and sprayed onto the pregel defatted corn grits.

II. Equipment

1. The primary piece of equipment is a Munson blender or equivalent capable of spray impregnation of the soya oil, TBHQ and avermectin B₁ solution onto the pregel defatted corn grits.
2. A concentrate and dilution tanks capable of maintaining 120-135°F liquid temperature.
3. Material handling equipment are required as indicated in the attached diagram.

III. Detailed Method of Manufacture

Preparation of 0.5% avermectin B₁ tert-butylhydroquinone (TBHQ) Concentrate

Formulation

AFFIRM technical (active ingredient avermectin B ₁)0.55%	ai
TBHQ0.50%	
Soybean Oil98.95%	

1. Load steam heated mixing kettle with soybean oil.
2. Heat soybean oil to 130-135°F.
3. Add AFFIRM technical.
4. Add TBHQ.
5. Mix until all the TBHQ and avermectin B₁ are dissolved.
6. Allow the solution to cool to 120°F-130°F.
7. Pump 5 gallons of concentrate through the delivery lines to the spray vessel. Return the 5 gallons to the concentrate kettle.

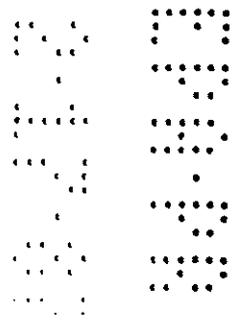
- 8. Take sample and assay for avermectin B₁ and TBHQ concentration.
- 9. Make appropriate adjustments.
- 10. Take sample and re-assay.

Preparation of AFFIRM 0.011% Fire Ant Bait

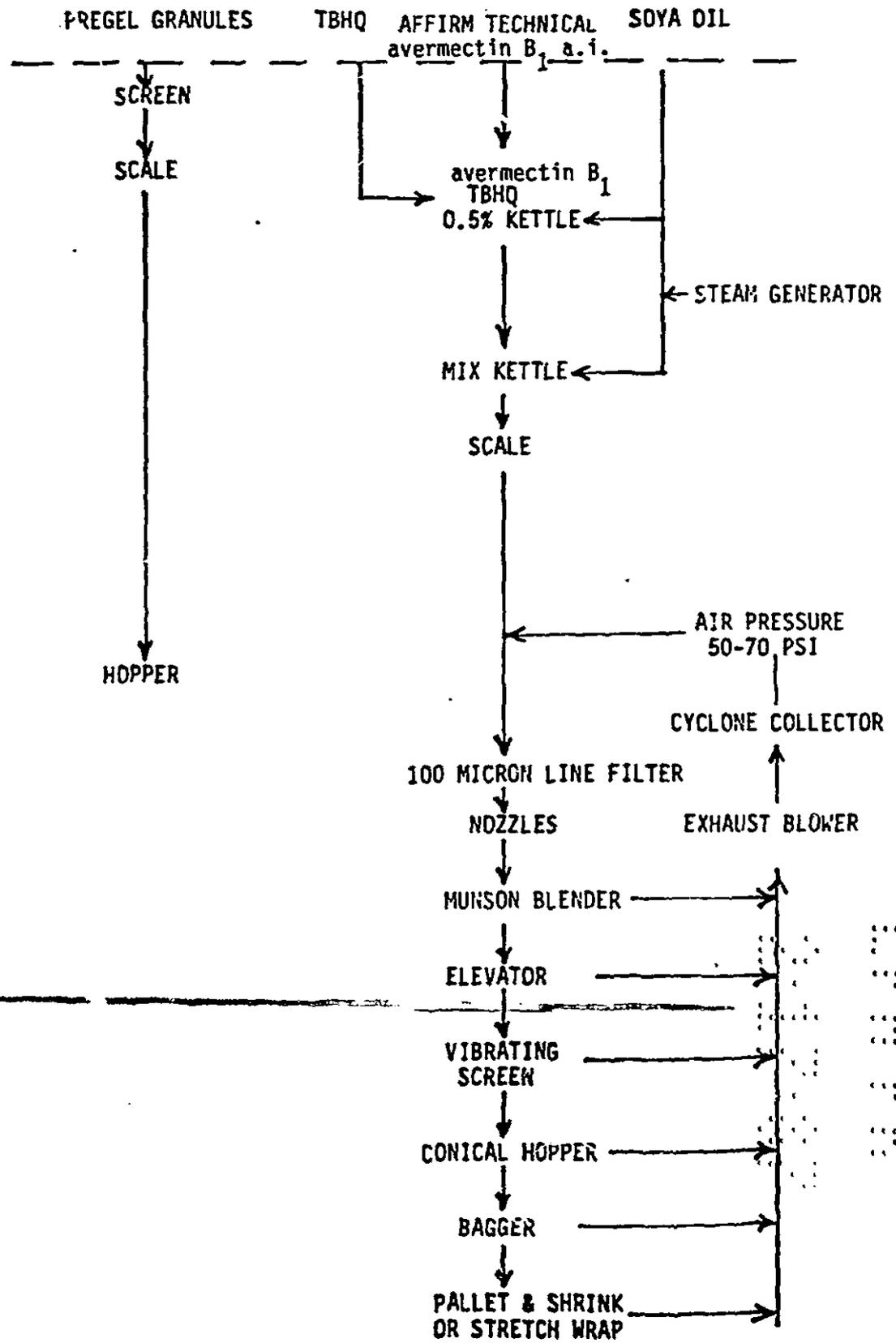
Formulation

Pregel Defatted Corn Cob.....	70.0%
0.5% avermectin B ₁ /TBHQ Conc.....	2.2%
Soybean Oil.....	27.8%

- 1. Load Munson with pregel defatted corn cob screened to 6x20 mesh.
- 2. Load pressure kettle with soybean oil which has been heated to 120°F.
- 3. Add the 0.5% avermectin B₁/TBHQ Concentrate to the pressure kettle and mix for 5 minutes.
- 4. The Concentrate/soybean oil mixture is sprayed onto the pregel defatted corn cob at a pressure of 50-70 psi.
- 5. Post-mix batch for 5 minutes.
- 6. Discharge the material into the bagging hopper.
- 7. Package into the appropriate containers.
- 8. Pull 1 lb samples at three (3) points during discharge. Assay for avermectin B₁ content.
- 9. Quarantine the material pending Quality Control release.



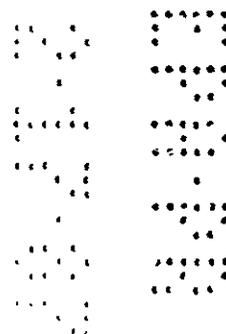
C. AFFIRM^R FIRE ANT BAIT FLOW SHEET



D. AFFIRM PRODUCT SPECIFICATIONS

PROPERTY	SPECIFICATIONS
Analysis (HPLC)	0.011-0.013% w/w ^{avermectins} (B ₁ a + B ₁ b)
Bulk Density	18-22 lbs/ft
Screen Analysis*	% Retained
+8 mesh	> 1.0
+16 mesh	
+20 mesh	> 90
+30 mesh	> 96
40 mesh	

* The specification for screen analysis requires the reporting of w/wt % retained on an 8, 16, 20, 30 and 40 mesh U.S. standard screen. Additionally, the amount passing a 40 mesh screen is also reported.

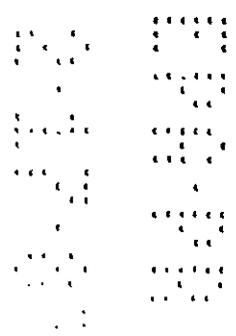


E. Production Areas - Safety Requirements

The production of AFFIRM 0.011% end use product may be divided into two areas for safety reasons.

The first area is the preparation of the avermectin B₁ concentrate and the associated delivery lines, which precede the dilution tank. In this area, the individual adding the AFFIRM Technical material will wear coveralls and gloves impervious to the carrier solvent. These gloves should extend at least half-way between the wrist and elbow to provide protection in the event of a spill or accidental splash. Additionally, an airline mask with eye protection is required. At the point of addition of AFFIRM Technical to the concentrate kettle an exhaust mechanism with an average face velocity of 100 ft³/min is required.

Once the AFFIRM Technical is charged into the kettle then individuals working in the areas of the dilution kettle and packaging, will be required to wear coveralls and gloves as described above. Additionally in this area, goggles and respirators will be required.



F. Industrial Hygiene

With proper work practices and personal hygiene, there is little likelihood that workers will be overexposed to avermectin B₁, the active ingredient of AFFIRM Technical. However, because of the possibility of splashes caused by broken hoses or those occurring during mixing or packaging, a worker's protective equipment is an important feature against such exposures. Protection should be provided for the eyes and skin. In addition, when needed, protection should also be provided for the respiratory system (for instance, when mists are being generated or when manufacturing takes place in an enclosed area). It should be noted, however, that protective equipment must never be considered a substitute for safe handling practices and personal cleanliness.

STATEMENT OF PRACTICAL TREATMENT

FIRST AID: 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 for at least 15 minutes. Get medical attention in all cases. (Show the label where possible).

Recommendations for Medical Treatment for avermectin B₁ Acute Toxicity:

Early signs of intoxication include mydriasis, ataxia, and muscle tremors. 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 parenteral 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 B₁ is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbituates, benzodiazepines, valproic acid) in patients with potentially toxic avermectin B₁ exposure.

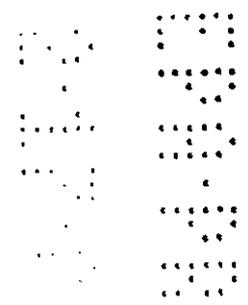
For 24-hour emergency information call MERCK & CO., Inc. (215) 661-5000.

G. Personal Hygiene and Care

At the end of each work day and when clothing is removed due to contamination, each individual should take a shower using plenty of soap and making sure that all exposed areas of the body are thoroughly cleaned. Only clean clothing should be worn home. The contaminated work clothes should be washed in a central laundry facility or properly destroyed to prevent further contamination.

After handling pesticides, workers should wash their hands, especially before smoking or eating.

If clothing becomes contaminated, they should be removed and personal hygiene and care, including a shower, should follow. Clean work clothes should then be put on.



H. Spills, Leaks, and Disposal Recommendations

The three forms in which avermectin B₁ may require cleanup are: AFFIRM Technical, the avermectin B₁ oil solutions and the AFFIRM 0.011% (active ingredient) end use product.

Spilled AFFIRM Technical material should be carefully collected and containerized in a manner that produces the least amount of airborne dust. Suitable protective equipment should be worn during any spill cleanup operation. Residual surface material may be removed with towels moistened with methanol. All cleanup material should be collected for disposal.

No levels have been established for stack emissions. Specific disposal procedures have been developed. Avermectin B₁ has been shown to be toxic to certain aquatic species. Do not flush into drains or natural waterways or areas draining into potable water supplies.

Environmental Control of Merck will advise on specific measures to be taken for disposal and spill control.

Floor areas that have become contaminated with avermectin B₁ oil solution may be decontaminated by the use of absorbent materials, confined and disposed of following proper procedures.

It is required that the absorbent material be capable of incineration in order to follow Merck & Co. procedures. Any of the botanical carriers including corn cob grits may be used.

During such cleanup procedures, suitable protective clothing including gloves and goggles are required.

Final cleanup of the dry floor area is provided as described above for the AFFIRM Technical.

If the AFFIRM 0.011% (active ingredient) end use product should require cleanup, only sweeping followed by proper containerization and disposal is required.

