1,12 138



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

MAR 4 1994

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Dennis L. McFadden GUSTAFSON, INC. P. O. Box 660065 Dallas, TX 75266

Subject:

Label Amendment Submission of 08/24/93 in Response to PR Notice 93-7

EPA Reg. No. 7501-141

GUSTAFSON VITAVA-THIRA-LINDANE FLOWABLE FUNGICIDE

IMPORTANT NOTICE: This Letter Requires You to Submit a Notification to the Office

of Compliance Monitoring within 20 Days.

Dear Registrant:

The labeling cited above and submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is accepted subject to the comments listed on the enclosed sheet. A copy of your proposed labeling stamped "ACCEPTED WITH COMMENTS" is enclosed.

SERIOUS ERROR(S) ON SUBMITTED LABELING:

EPA has determined that one or more of the errors on the labeling you submitted to the Agency is categorized as "serious" as defined in PR Notice 93-11. In general, serious errors are those that may create a potential for harm to workers, handlers, other persons, or the environment; or those that prevent the achievement of the basic goals of the Worker Protection Standard (WPS) or FIFRA.

YOU MUST NOT SELL OR DISTRIBUTE (INCLUDING RELEASE FOR SHIPMENT) ANY PRODUCT BEARING THE SUBMITTED LABELING. Sale or distribution of any product with the incorrect labeling is a violation of FIFRA that could result in initiation of an action for civil penalties and/or cancellation of your product. This matter has been referred to the Office of Compliance Monitoring (OCM) for further action.

YOU MUST SUBMIT A NOTIFICATION TO THE OFFICE OF COMPLIANCE MONITORING WITHIN 20 DAYS OF THE DATE OF THIS LETTER.



Each notification must include the following information:

- 1. Registrant's name and address.
- 2. EPA Registration number of the product for which the labeling was submitted.
- 3. Whether any product already has been sold or distributed (this includes released for shipment) bearing the submitted labeling.

In addition, the notification must include the following information, IF you have already sold or distributed any product bearing the submitted labeling:

- 1. Quantity of the product that has been sold or distributed.
- 2. EPA Producing Establishment number.
- 3. Location of the product, if known.
- 4. Proposed plan for assuring that product with the incorrect labeling in your control, as well as that in the hands of dealers/distributors/users, will be corrected. The plan must include your proposal for assuring that the labeling is corrected as soon as possible.

Submit the notification to:

Michael Wood, Director Compliance Division, (7203) Worker Protection Notification Office of Compliance Monitoring U.S. Environmental Protection Agency 401 M Street SW Washington, DC 20460

Failure to submit a notification also may result in initiation of an action under FIFRA for civil penalties, if you sold or distributed (this includes released for shipment) product bearing the incorrect labeling.

IN ADDITION, YOU SHOULD CONTACT IMMEDIATELY THE PERSONS TO WHOM YOU SOLD OR DISTRIBUTED YOUR PRODUCT AND INFORM THEM NOT TO SELL OR DISTRIBUTE ANY PRODUCT WITH THE INCORRECT LABELING.

WHAT THIS ACCEPTANCE MEANS:

Based on your certification, the Agency has accepted the labeling changes that are necessary to comply with the WPS labeling requirements of 40 CFR part 156, subpart K, described in PR Notices 93-7 and 93-11. Any other labeling changes submitted in connection with this amendment application but not directly related to compliance with the WPS have neither been reviewed nor accepted by the Agency. If you wish to make such changes, you must submit a separate amendment application proposing them. If your product is currently suspended, the acceptance of this labeling amendment does not affect the suspension in any way.

WHAT YOU NEED TO DO NEXT:

Submit the required notification. Then by the next label printing make all the specified changes to your labeling. Send to EPA one (1) copy of the final printed labeling:

 BEFORE selling or distributing any product bearing the final printed labeling as amended

AND

• WITHIN one year from date of this acceptance.

Submit the final printed labeling via the U.S. Postal Service to:

Document Processing Desk (FIN-LABEL)
Office of Pesticide Programs (7505C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460-0001

Page 4

Hand or courier deliveries of final labeling may be made to:

Document Processing Desk (FIN-LABEL)
Office of Pesticide Programs
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Sincerely,

Jim Tompkins, Deputy Chief Registration Support Branch Registration Division (7505W)

Attachment

cc: Office of Compliance Monitoring

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division

Dennis L. McFadden GUSTAFSON, INC. BOX 660065 DALLAS TX 75266

Comment for: EPA Reg Nr.7501-141
GUSTAFSON VITAVA-THIRA-LINDANE FLOWABLE FUNGICI

The following specific comments pertain to your WPS labeling submission concerning the product cited above:

Add the following User Safety Recommendation to the label in the location shown in Section A on Part 1 of the Product Worksheet in Supplement Three-A to PR Notice 93-7: "Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

The respirator requirement for "applicators and other handlers" in the "Personal Protective Equipment" section on your proposed labeling is missing or incorrect. Remove the incorrect requirement (if any) and add "Dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

The exact location is shown in Sections A and B on Part I of the Product Worksheet in Supplement Three-A to PR Notice 93-7.

Delete the crossed-out statements on your proposed label. They are redundant statements or phrases.

Gustafson Gustafson Under the Federal Inaccticide, and Rudenticide Act as amended, for the posticide registered under EPA Ray, No. VITAVAX®-Thiram-Lindane

Flowable Fungicide - Insecticide

Active Ingredients: (% by weight)	
Carboxin (5,6-dihydro-2-methyl-N-phenyl-1,4-oxathiin	1-3-
carboxamide)	
Inert Ingredients:	
Total:	100%

Contains 1.37 lbs. carboxin, 1.17 lbs. Thiram and 0.78 lbs. Lindane per U.S. gallon

KEEP OUT OF REACH OF CHILDREN CAUTION

See additional precautionary statements.

EPA Reg. No. 7501-141

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if swallowed, absorbed through the skin or inhaled. Avoid breathing vapor or spray mist. Avoid contact with skin, eyes or clothing. This product should be applied in a well ventilated area. Consumption of alcoholic beverages increases the toxic effects of thiram.

PERSONAL PROTECTIVE EQUIPMENT:

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers (other than mixers and loaders) must wear: long-sleeved shirt and long parts, chemical-resistant gloves, such as barrier laminate or nitrile rubber or neoprene rubber or Viton, and shoes plus socks. Mixers and Loaders must wear: long-sleeved shirt and long pants, chemical-resistant gloves, such as barrier laminate or nitrile rubber or neoprene rubber or Viton, shoes plus socks, and dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C).

Follow manufacturer'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.

Continued Next Column

USER SAFETY RECOMMENDATIONS:

Users should wash hands before eating, drinking, chewing gum, using tobacco or using toilet.

STATEMENT OF PRACTICAL TREATMENT

If on skin — Remove-contaminated clothing and wash affected areas with soap and water. Get medical attention if irritation develops. If In eyes — Flush eyes with plenty of water. Get medical attention if irritation develops. If swallowed — Call a physician or Poison Control Center immediately. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Repeat until vomit fluid is clear. Avoid alcohol. Do not induce vomiting or give anything by mouth to an unconscious person. If Inhaled — Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention.

SYMPTOMS OF POISONING: Consumption of alcoholic beverages with exposure to thiram may cause flushing, breathing difficulty, nausea, vomiting and low blood pressure. Lindane is a central nervous system stimulant. In case of poisoning, call a physician immediately. Have patient lie down and keep quiet.

NOTE TO PHYSICIAN: Treat symptomatically. In the presence of consumed alcohol, thiram responds similarly to disulfiram.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds and wildlife. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Exposed treated seeds may be hazardous to birds or other wildlife. Dispose of all excess treated seed by burial away from bodies of water. Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL

- 1. STORAGE: Store in a cool, dry place. Do store in direct sunlight. Keep container closed when no se.
- 2. PROHIBITIONS: Do not contaminate w by storage or disposal or by cleaning of dumping is prohibited.
- 3. PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be

Gustafson (%)

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.

4. CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DIRECTIONS FOR USE

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

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistances. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard. Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hou 5. Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated. PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: coveralls, chemical-resistant gloves, such as barrier laminate or nitrile rubber or neoprene rubber or Viton, and shoes plus socks.

DIRECTIONS FOR USE

Gustafson VITAVAX-Thiram-Lindane Flowable Fungicide - Insecticide is a ready-to-use seed treatment containing the systemic fungicide, VITAVAX®, and the protectant fungicide, Thiram, plus the insecticide, Lindane.

BARLEY, WHEAT AND OATS

Gustafson VITAVAX-Thiram-Lindane Flowable provides systemic protection against loose smut (Ustilago nuda) and covered smut (Ustilago hordei) on barley; loose smut (Ustilago tritici) and common bunt (Tilletia caries) on wheat; and loose smut (Ustilago avenae) on oats.

Gustafson VITAVAX-Thiram-Lindane Flowable also protects

seeds against seed decay and damping off while providing protection to seeds and seedlings against damage from wireworms and seed corn maggots.

Apply Gustafson VITAVAX-Thiram-Lindane Flowable at the rate of 5 fluid ounces on wheat and oats and 6 fluid ounces on barley per 100 pounds of seed. Apply as a ready-to-use seed treatment by machine ensuring uniform seed coverage.

Do not graze or feed livestock on treated areas for six weeks after planting. Care must be exercised in the handling of treated seed.

USE RESTRICTIONS

This product contains a dye which imparts an unnatural color to the seed to prevent the inadvertent use of treated seed for food, feed or oil use. Treated seed must not be used for or mixed with food or animal feed, or processed for oil. Treat only those seeds needed for immediate use, minimizing the interval between treatment and planting. Do not store excess seeds beyond planting time.

USE PRECAUTIONS

- IMPORTANT: Federal Law requires that bags containing treated seed shall be labeled with the following information: This seed treated with Carboxin, Thiram and Lindane. Do not use treated seed for food, feed or oil purposes. Do not graze or feed livestock on treated areas for six weeks after planting. Add appropriate information for any other chemical treatments.
- Planting Note: Seed treated with this product does not flow as freely as untreated seed. The drill should therefore be adjusted to compensate for this restricted seed flow to prevent lower than desired seeding rates.
- Augers used for handling treated seed should not be used to move grain for food, feed or oil processing.
- Do not reuse bags from treated seed to handle food or feed products.

NOTICE - READ CAREFULLY CONDITIONS OF SALE AND LIMITED WARRANTY STATEMENT

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, except for the purposes of curative control of existing disease or insect pests, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed to a selected chemical treatment. Due to seed quality conditions beyond the control of Gustafson, Inc., no claims are made to guarantee germination of carry-over seed.

As its sole express warranty, Gustafson, Inc. warrants that this product conforms to the chemical description on the label and is reasonably fit for purposes stated on the label only when used in accordance with directions and instructions specified on the label, subject to the inherent risks set forth above. ONLY AS PERMITTED BY APPLICABLE LAW, IN THE EVENT OF A BREACH OF THIS LIMITED WARRANTY, GUSTAFSON, INC. SHALL NOT BE LIABLE FOR CONSEQUENTIAL DAMAGES. SUBJECT TO APPLICABLE LAW, GUSTAFSON, INC. NEI-THER MAKES NOR AUTHORIZES ANY OF ITS AGENTS OR REPRESENTATIVES TO MAKE ANY WARRANTY OF FIT-NESS OR MERCHANTABILITY, GUARANTY OR REPRESEN-TATION, EXPRESS OR IMPLIED, CONCERNING THIS MATE-RIAL. Buyer assumes the responsibility to handle, use and store this product in accordance with the safety instructions and use directions contained on the label

Buyer/User purchases this product subject to the foregoing Conditions of Sale and Limited Warranty, which, subject to applicable law, may be varied only by a written agreement signed by a duly authorized representative of Gustafson, Inc. If these terms are not acceptable, return all products to the place of purchase, unopened for a full refund.

Gustafson (logo) is a Reg. TM of Gustafson, Inc. VITAVAX is a Reg. TM of Uniroyal Chemical Company, Inc.

A quality product manufactured by: Gustafson, Inc.
1400 Preston Road, Suite 400
Plano, Texas 75093
(214) 985-8877

141(WPS)397060