

Reg # 7501-114

PM-23

File
198



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

AUG 8 1994

Dennis L. McFadden
GUSTAFSON, INC.
P.O. Box 660065
Dallas, TX 75266 19103

OFFICE OF
PREVENTION AND
TOXIC SUBSTANCES

Subject: Label Amendment Submission of 08/24/93 in Response to PR Notice 93-7
EPA Reg. No. 7501-114
GUSTAFSON RTU-VITAVAX-THIRAM SEED PROTECTANT

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.



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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.

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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:

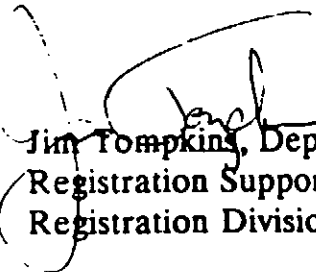
Document Processing Desk (FIN-LABEL)
Office of Pesticide Programs (7505C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460-0001

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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

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GUSTAFSON, INC.
GUSTAFSON RTU-VITAVAX-THIRAM SEED PROTECTANT
7501-114 08/24/93

Original Submission

The eyewear requirement for applicators and other handlers and early entry in the Agricultural Use Requirements Box on your proposed labeling is missing or incorrect. Remove the incorrect requirement (if any) and add "Protective Eyewear". The exact location is shown in Section F & G on Part 2 of the Product Worksheet in Supplemental Three-A to PR Notice 93-7.

There is a typographical error(s) in the PPE statements that you added to the Precautionary Statements.

ACCEPTED
with COMMENTS
in EPA Letter Dated

6 7 8.1

JAN 28 1994

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

Gustafson

RTU® - VITAVAX® - THIRAM

7501-114

Seed Protectant Fungicide

Active Ingredients:

Carboxin (5,6-Dihydro-2-methyl-N-phenyl-1,4-oxathin-3-carboxamide)	10.0%
Thiram (Tetramethylthiuram disulfide)	10.0%
Inert Ingredients:	80.0%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Immediately flush eyes with plenty of water. See a physician.

IF SWALLOWED: Call a physician or Poison Control Center immediately. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger or blunt object. Do not induce vomiting or give anything by mouth to an unconscious person.

IF INHALED: See a physician if an abnormal reaction occurs.

IF ON SKIN: Wash thoroughly with soap and warm water.

SYMPTOMS OF POISONING: No specific symptoms. Acute poisoning is accompanied by general depression and illness. Consumption of alcoholic beverages with exposure to thiram may cause flushing, breathing difficulty, nausea, vomiting and low blood pressure. In case of poisoning, call a physician immediately. Have patient lie down and keep quiet.

NOTE TO PHYSICIAN: No specific antidote is available. Treat symptomatically. In the presence of consumed alcohol, thiram responds similarly to disulfiram.

SEE ADDITIONAL PRECAUTIONARY STATEMENTS.

EPA Reg. No. 7501-114

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS CAUTION

Causes eye and skin irritation. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid inhaling of spray mist. Do not use or store near food or feed. Consumption of alcoholic beverages increases the toxic effects of thiram.

Personal Protective Equipment:

Applicators and other handlers must wear: long-sleeved shirt and long pants, waterproof gloves, shoes plus socks and protective eyewear. Mixers and Loaders must wear long-sleeved shirt and long pants, waterproof gloves, shoes plus socks, protective eyewear. For exposures in enclosed areas mixers and loaders must wear a 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-14G); for exposures outdoors a 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.

When handlers use closed systems in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide product is toxic to fish. Do not contaminate water when disposing of equipment washwaters. Drift or runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

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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. 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 hours. 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, waterproof gloves, and shoes plus socks.

STORAGE AND DISPOSAL

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

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 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: 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.

DIRECTIONS FOR USE

RTU-VITAVAX-THIRAM Seed Protectant Fungicide is a ready-to-use seed treatment. Apply as a commercial seed treatment or as a pour-on hopper-box application. This product does not require the addition of water for application. RTU-VITAVAX-THIRAM Fungicide combines the systemic action of Carboxin with the surface action of thiram to control various seed and seedling diseases. It is particularly effective against *Rhizoctonia solani* and shows good activity against various *Helminthosporium*, *Fusarium* and *Pythium* species. This often results in increased and more uniform stands of seedlings with higher yield potential. Use the higher rate under conditions

of expected heavy disease pressure.

RECOMMENDATIONS FOR USE AS A HOPPER-BOX SEED TREATMENT

Mix well before use: Apply RTU-VITAVAX-THIRAM Fungicide directly to seed in hopper box. Partially fill hopper box with a pre-measured amount of seed. Apply the proper amount of RTU-VITAVAX-THIRAM Fungicide evenly over the surface of the seed. Mix with a stick or paddle until a uniform color is imparted to all seed. Repeat procedure until hopper box is filled.

BARLEY, WHEAT, OATS AND TRITICALE

In addition, loose smut (*Ustilago nuda*), and covered smut (*Ustilago hordei*), are controlled on barley and loose smut (*Ustilago tritici*), and common bunt (*Tilletia caries*) are controlled on wheat by RTU-VITAVAX-THIRAM Fungicide.

Use 5 to 6.8 fl. oz. of RTU-VITAVAX-THIRAM Fungicide per 100 lbs. of seed. The higher rate is recommended where smuts and bunt are severe.

Do not graze or feed livestock on treated areas for six weeks after planting.

DRY BEANS, SOYBEANS

Use 3.4 fl. oz. of RTU-VITAVAX-THIRAM Fungicide per bushel of seed or 6.8 fl. oz. per 100 lbs. of seed.

On soybeans, do not graze or feed livestock on forage and hay on treated areas. On dry beans, do not allow livestock to graze or feed on bean forage until 60 days after treated seed is planted.

COTTON

RTU-VITAVAX-THIRAM Fungicide provides systemic control of seed and seedling diseases of cotton. Seed rot, damping-off and sore-shin due to *Rhizoctonia solani* are reduced. RTU-VITAVAX-THIRAM Fungicide can be used on both machine and acid delinted cottonseed at the rate of 11 to 13.5 fl. oz. per 100 lbs. of seed.

RICE

Use 5 to 6.8 fl. oz. of RTU-VITAVAX-THIRAM Fungicide per 100 lbs. of seed. The higher rate is recommended for control of *Helminthosporium oryzae*.

RECOMMENDATIONS FOR USE AS A COMMERCIAL SEED TREATMENT

Application should be made using standard mechanical, slurry or mist-type seed treatment equipment. Uniform application is necessary to insure seed safety and best disease control. Seed should be sound and well cured prior to treatment.

USE RESTRICTIONS

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

COMPATIBILITY

RTU-VITAVAX-THIRAM Fungicide should not be tank mixed with any pesticide unless adequate physical compatibility and phytotoxicity tests have been completed and proved to be satisfactory.

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SEED LABELING (Commercial Seed)

1. "This seed treated with Carboxin and Thiram. Do not use treated seed for food, feed or oil purposes." Add appropriate information for any other chemical treatments.
2. "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."
3. "Augers used for handling treated seed should not be used to move grain for food, feed or oil processing."
4. "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 lot 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. NEITHER MAKES NOR AUTHORIZES ANY WARRANTY OF FITNESS OR MERCHANTABILITY, GUARANTY OR REPRESENTATION EXPRESS OR IMPLIED, CONCERNING THIS MATERIAL. 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.

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

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