



Reg # 7501-37

PM - 13

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

FEB 24 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DENNIS L. MC FADDEN
GUSTAFSON, INC.
BOX 660065
DALLAS, TX. 75266

Subject: Label Amendment Submission of 9/9/93 In Response to PR Notice 93-7
EPA Reg. No. 7501-37
GUSTAFSON VITAVAX MANEB LINDANE 20-35-18-75

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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Recycled/Recyclable
Printed with Soy/Canola ink on paper that
contains at least 50% recycled fiber

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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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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.7501-37
GUSTAFSON VITAVAX MANEB LINDANE 20-35-18.75

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

Add the following statement to the "Personal Protective Equipment" section of your label: "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. 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." The exact location for this statement is shown in Section A on Part 1 of the Product Worksheet in Supplement Three to PR Notice 93-7.

The requirement under the heading "Personal Protective Equipment" must state: "Applicators and other handlers must wear:". Cross out your lead-in statement and replace it with correct one. EXCEPTION: If you have an entirely separate PPE section specifying what "Mixers and loaders must wear", the requirement under the heading "Personal Protective Equipment" must state: "Applicators and other handlers (other than mixers and loaders) must wear:". Cross out your lead-in statement and replace it with the correct one.

The bodywear requirement for early entry in the Agricultural Use Requirements box on your proposed labeling is missing or incorrect. Remove the incorrect requirement (if any) and add "Coveralls over long-sleeved shirt and long pants." The exact location is shown in Sections F and G on Part 2 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.

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GUSTAFSON, INC.
EPA Reg. Number: 7501-37
GUSTAFSON VITAVAX MANEB LINDANE 20-35-18.75
Application date: 09/09/93
Original Submission

Correct the typographical errors circled on your proposed label.

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RECEIVED
COMMENTS 798
EPA Letter Dated

FEB 24 1994

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
7501-37

Gustafson VITAVAX® Maneb Lindane

20-35-18.75 Fungicide-Insecticide Seed Protectant

**Only for Sale to, Use and Storage by
Agricultural or Commercial Applicator Personnel.**

A ready-to-use formulation for drill-box application to control smuts, seed decay and seedling blight and for temporary protection of seeds and seedlings against wireworms.

WHEAT--BARLEY--OATS--CORN

Active Ingredients:	By Wt.
Carboxin (5,6-Dihydro-2-methyl-1,4-Oxathiin -3-Carboxanilide)	20.00%
Maneb (Manganese ethylenebisdithiocarbamate)	35.00%
Lindane (Gamma isomer of Benzenehexachloride)	18.75%
Inert Ingredients:	26.25%
Total	100.00%

EPA Reg. No. 7501-37

EPA Est. 42056-IL-1

Net Contents: 7.5 Pounds

KEEP OUT OF REACH OF CHILDREN
WARNING AVISO
PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)
May be fatal if swallowed. May be absorbed through skin. Do not breathe dust. Do not get in eyes, on skin, or on clothing. Causes eye and skin irritation. Avoid contamination of feed and foodstuffs.
PERSONAL PROTECTIVE EQUIPMENT: Applicators and other handlers must wear: coveralls over long-sleeved shirt and long pants, waterproof gloves, chemical-resistant footwear plus socks, protective eyewear, chemical-resistant headgear for overhead exposure, chemical-resistant apron when cleaning equipment. Mixers and loaders must wear: coveralls over long-sleeved shirt and long pants, waterproof gloves, chemical-resistant footwear plus socks, chemical-resistant headgear, chemical-resistant apron when mixing or loading, and 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).
<small>Continued Next Column</small>

Engineering control statements: 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. 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.

STATEMENT OF PRACTICAL TREATMENT

If **swallowed**--Drink one or two glasses of water and induce vomiting by touching the back of the throat with finger. Repeat until vomit fluid is clear. Call a physician immediately. Do not induce vomiting or give anything by mouth to an unconscious person. If **inhaled**--Remove victim to fresh air. Apply respiration if indicated. If **on skin**--Remove contaminated clothing and wash affected areas with soap and water. If **in eyes**--Flush with plenty of water. Call a physician if irritation persists.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds, and other wildlife. 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 wastes. Apply this product only as specified on this label. Exposed treated seeds may be hazardous to birds and other wildlife. Dispose of all excess treated seeds by burial away from bodies of water.

STORAGE AND DISPOSAL

- 1. STORAGE:** Store in a cool dry place. Do not allow to freeze or become overheated.
- 2. PROHIBITION:** Do not contaminate water, food or feed by storage or disposal.
- 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 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:** Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.



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DIRECTIONS FOR USE

It is a violation of State and Federal Law to use this product in a manner inconsistent with its labeling. Read all directions before using and use only as specified on this label.

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 12 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 over short-sleeved shirt and short pants, waterproof gloves, chemical-resistant footwear plus socks, protective eyewear, and chemical-resistant headgear for overhead exposure.

VITAVAX-MANEB-LINDANE 20-35-18.75 Fungicide - Insecticide Seed Protectant is a dust base product especially formulated for seed treatment at planting time. This product is formulated to help lubricate the planter box and assure a smooth, even flow in the furrow. It is formulated for use in the treatment of seeds for protection against wireworms and certain other soil-borne insects as well as providing protection against stinking smut (bunt) of wheat, oat smuts, covered and false loose smuts of barley, and seed decay. Apply as a drill box treatment mixing thoroughly with the seed before planting. For best results, the following procedure is suggested. Fill the drill box only half full of seed; add half the required amount of product and mix thoroughly with a stick. Then add the remainder of seed to the drill box and add the rest of the required amount of product to the seed, again mixing thoroughly.

Good results are also obtained by premixing seed with the product in a suitable container, then pouring treated seed into the planter box.

- Wheat, Barley, Oats -- Use 2 ounces per bushel of seed
- Corn -- Use 3 ounces per bushel of seed

IF SOIL TEMPERATURE IS EXTREMELY HIGH (hot weather, midsummer planting, or other reasons) reduce recommended dosage by one-third. Avoid lengthy storage of treated seed to prevent loss of Lindane.

USE RESTRICTIONS

If this product is used on a crop, no other product containing a different EBDC active ingredient may be used on the same crop during the same growing season.

Treated seed must not be used for, or mixed with food or animal feed, or processed for oil. Do not graze or feed livestock on treated areas for six weeks after planting. Care must be exercised in the handling of treated seed. Treat only those seeds needed for immediate use minimizing the interval between treatment and planting. Do not store excess treated seeds beyond planting time.

READ ENTIRE LABEL USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

**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 OF ITS AGENTS OR REPRESENTATIVES TO MAKE ANY WARRANTY OF FITNESS OR MERCHANTABILITY, GUARANTY OR REPRESENTATION, EXPRESS OR IMPLIED, CONCERNING THIS MATERIAL. 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.

A quality product manufactured by:

Gustafson, Inc.
1400 Preston Road, Suite 400
Plano, Texas 75093
(214) 985-8877

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37(WPS)393090