

400-92

3-28-2003

116

EPA	United States	<input type="checkbox"/> Registration	OPP Identifier Number
	Environmental Protection Agency	<input type="checkbox"/> Amendment	
	Washington, DC 20460	<input checked="" type="checkbox"/> Other	

Application for Pesticide - Section I

1. Company / Product Name 400-92	2. EPA Product Manager Mary Waller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company / Product (Name) Vitavax®-T	PM# 21	
5. Name and Address of Applicant (Include ZIP Code) Crompton Corporation 74 Amity Road Bethany, Connecticut 06524-3402 <input type="checkbox"/> check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg No. <u> </u> Product Name <u> </u>	

NOTIFICATION
MAR 28 2003

Section II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

- This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

- Deletion of label statement: "This product contains the toxic inert ingredient Rhodamine B dye."

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Child Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
	If "Yes" Unit Packaging wgt	No. Per container	If "Yes" Packaging wgt	No. Per container	<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled Other		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Willard F. Cummings	Title Manager U.S. Registration	Telephone No. (Include Area Code) (203) 393-2163
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Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Manager U.S. Registration	6. Date Application Received (Stamped)
4. Typed Name Willard F. Cummings	5. Date February 25, 2003	

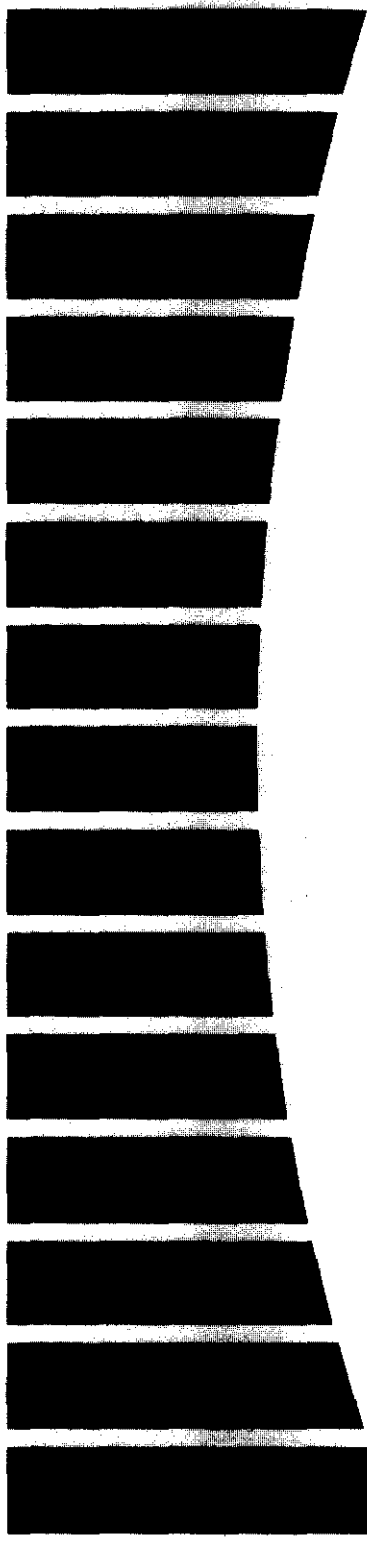
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NOTIFICATION
MAR 28 2003

Vitavax®-T Fungicide

(Vitavax with Thiram)

Net
Contents:



Active Ingredients: (% by weight)

Carboxin (5,6-dihydro-2-methyl-N-phenyl-1, 4-oxathiin-3-carboxamide) ...	37.5%
Thiram (tetramethylthiuram disulfide)	37.5%
Inert Ingredients:	25.0%
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN DANGER • PELIGRO

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.)

FIRST AID

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

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: Probable mucosal damage may contraindicate the use of gastric lavage. No specific antidote is available. All treatments should be based on observed signs and symptoms of distress in the patient. In the presence of consumed alcohol, thiram responds similarly to D-thiuram.

EPA REG. NO. 400-92
EPA EST. NO.
002CM

Crompton Manufacturing Company, Inc.
Middlebury, CT 06749

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Crompton
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**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER**

Corrosive. Causes irreversible eye damage. Do not get in eyes, or on clothing. Harmful if inhaled or swallowed. Avoid breathing dust or spray mist.

PERSONAL PROTECTIVE EQUIPMENT

Applicators and Other Handlers Must Wear: A long-sleeved shirt & long pants; waterproof gloves; shoes plus socks; protective eyewear; chemical-resistant headgear for overhead exposure; and chemical-resistant apron when cleaning equipment, mixing, or loading.

Follow manufacturer's instructions for cleaning and 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 by WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.
- 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.

ENVIRONMENTAL HAZARDS

This pesticide 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, to areas where surface water is present or to intertidal areas below the mean high water mark. Exposed treated seed may be hazardous to birds and other wildlife. Dispose of all excess treated seed and seed packaging by burial away from bodies of water.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

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 through any type of irrigation system.

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.

recommended amount of VITAVAX-T Fungicide. Stir this paste into the remainder of the water and provide enough agitation to maintain a uniform water suspension.

Use the higher rate under conditions of expected heavy disease pressure.

BARLEY, CORN, OATS AND WHEAT

VITAVAX-T Fungicide combines the systemic action of carboxin with the surface action of thiram to control various seed and seedling diseases of barley, corn, oats and wheat. It is particularly effective against *Rhizoctonia solani*.

In addition, loose smut, covered smut, flag smut, common bunt and barley stripe are controlled by VITAVAX-T Fungicide.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR 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 assistance. 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
- shoes plus socks
- protective eyewear

DOSAGE INSTRUCTIONS

Crop	Diseases Controlled	Amount of Vitavax-T Fungicide per 100 Pounds of Seed
BARLEY	Seed rots Seedling Diseases Barley Stripe Loose smut Covered smut	3 - 4 ounces
CORN	Seed rots Seedling diseases	4 ounces
OATS	Seed rots Seedling diseases Loose smut Covered smut	2 ounces
WHEAT	Seed rots Seedling diseases Loose smut Common bunt Flag smut	3 - 4 ounces

VITAVAX-T Fungicide is a wettable powder seed treatment for use as a dry dust, spray mist or slurry seed treatment. In liquid systems, a thin paste should first be made using a portion of the required water and the

USE RESTRICTIONS

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. Care must be exercised in the handling of treated seed.

USE PRECAUTION

When using formulations that do not contain dye, to comply with 21 CFR2.25 and 40 CFR153.155, treated seed must be colored with an approved dye (40 CFR180.1001) to distinguish and prevent subsequent and inadvertent use as a food for man or feed for animals.

SEED LABELING

1. "This seed is treated with carboxin and thiram (VITAVAX-T) at the manufacturer's recommended rate. 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. Consult the manufacturer for additional tagging requirements.
2. "Augers used for handling treated seed should not be used to move seed for feed, food or oil processing."
3. "Do not re-use bags from treated seed to handle food or feed products".

EMERGENCY ASSISTANCE:

CROMPTON EMERGENCY PHONE	800-292-5898
SAFETY DATA AND INFORMATION	203-573-3303
TRANSPORTATION EMERGENCY (CHEMTREC)	800-424-9300

**NOTICE - READ CAREFULLY
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 of 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 Crompton, no claims are made to guarantee germination of carry-over seed.

Crompton warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label only when used in accordance with directions and instructions specified on the label. Crompton neither makes, nor authorizes any agent or representative to make any other warranty of **FITNESS** or **MERCHANTABILITY**, guarantee or representation, expressed or implied, concerning this material. In the event of any breach of this limited warranty, Crompton shall not be liable for consequential damages.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal. **PESTICIDE STORAGE:** Store in a cool, dry location. Do not store in direct sunlight. Protect from extreme temperatures.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. 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:

Bag: 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.

Fiber Drum: 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.

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Unlroyal Chemical

February 25, 2003

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Attention: Ms. Mary Waller, PM 21
Registration Division (7505C)

Subject: **Vitavax®-T**
EPA Reg. No. 400-92
Removal of List 1 Required Label Wording

Dear Ms. Waller:

Enclosed is amended labeling for the above referenced product. This label change was submitted on November 18, 2002. We hereby request to make the label change via the notification method. Only one change is requested in this label. Since the dye in the seed treatment product, Rhodamine B dye, has been moved from EPA List 1 to EPA List 4B, we request to delete the following label statement.

"This product contains the toxic inert ingredient Rhodamine B dye."

Background: In 1987 EPA announced its policy on toxic inert ingredients in the FR of April 22, 1987 (52FR13305). EPA encouraged the use of the least toxic inerts available and required the development of data necessary to determine the conditions of safe use of products that contained the toxic inerts. At that time, Rhodamine B dye was placed on List 1, Inerts of Toxicological Concern. Being a list 1 inert, it also was subject to the labeling requirement in the paragraph above. A copy of the FR notice is attached as item 1.

A task force composed of seed treatment companies developed data during the 1990's to demonstrate that under the conditions of use, the chemical is not likely to result in residues in food or feed. In part, as a result of that effort, the EPA created a new subpart E in 40CFR part 180. The subpart is titled: "Pesticide chemicals not requiring a tolerance or an exemption from a tolerance." Rhodamine was placed in the new subpart 180.2020. Rhodamine B is now limited to uses as a dye for seed treatment, and must meet the limits stated in 180.2020: "Not to exceed 2% by weight of the formulated product and 60 ppm on the treated seed." The Final rule was published in 66FR66769. A copy of the Final Rule is attached as item 2.

Crompton Corporation

74 Amity Road, Bethany, CT 06524-3402 (203) 393-2163 (203) 393-2290 fax

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Ms. Mary Waller, PM-21
February 25, 2003
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Then in March 2002, the EPA reclassified Rhodamine B from List 1 to List 4B. This notice was published in **67FR10718**. List 4B inerts are "inerts for which EPA has sufficient information to reasonably conclude that the current use pattern in pesticide products will not adversely affect public health or the environment." A copy of that Federal Register notice is attached as item 3.

Kerry Leifer agrees that the List 1 required label statement is no longer appropriate and may be removed from applicable labels. Feel free to contact me if you have any questions.

Sincerely,

CROMPTON CORPORATION



Willard F. Cummings
U.S. Registration Manager
Crop Protection
Research & Development

Attachments:

- 1) Federal Register - 52FR13305
- 2) " " - 66FR66769
- 3) " " - 67FR10718
- 4) Application for Pesticide Label Notification (form 8570-1).
- 5) Five copies of the revised Vitavax®-T (400-92) label
- 6) One copy of the current Vitavax®-T (400-92) label.

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