

400-116

3-28-2003

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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 400-116	2. EPA Product Manager Mary Waller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company / Product (Name) Vitavax®-R Flowable Fungicide	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: <b>NOTIFICATION</b> EPA Reg No. _____ Product Name <u>MAR 28 2003</u>	

**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."
- Updated "Do not apply directly to water..." statement.
- Added "First Aid" heading.

**Section - III**

1. Material This Product Will Be Packaged In:			
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	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt	No. Per container
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"/> On 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**

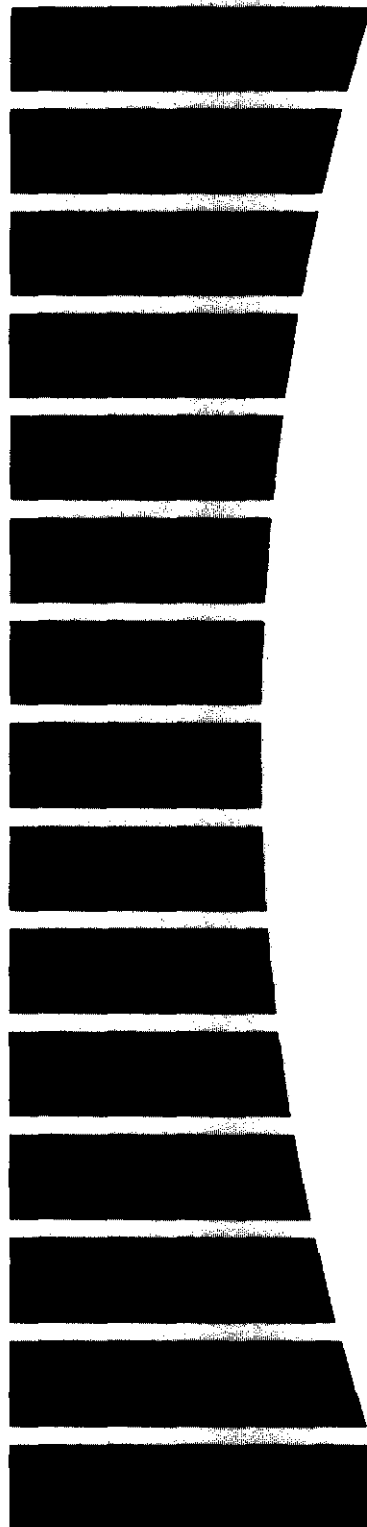
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Willard F. Cummings	Title Manager U.S. Registration	Telephone No. (Include Area Code) (203) 393-2163	
Certification I certify that the statements I have 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.			6. Date Application Received (Stamped)
2. Signature 	3. Title Manager U.S. Registration		
4. Typed Name Willard F. Cummings	5. Date February 25, 2003		

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[NOTIFICATION  
MAR 28 2003

# Vitavax®-R Flowable Fungicide

(Vitavax with Thiram)

Net Contents:



Active Ingredients: (% by weight)

Carboxin (5,6-dihydro-2-methyl-N-phenyl-1, 4-oxathiin-3-carboxamide) ...	17%
Thiram (tetramethylthiuram disulfide)* .....	17%
Inert Ingredients: .....	66%
Total: .....	100%

\*Contains 1.67 pounds of active thiram per gallon.

## KEEP OUT OF REACH OF CHILDREN CAUTION

### FIRST AID

- 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 water.

### 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. Wear goggles or face shield and rubber gloves when handling. Avoid inhalation of spray mist. Do not use or store near food or feed.

During commercial exposure in seed treatment and loading operations, wear goggles, clean rubber gloves, protective clothing, and a pesticide respirator jointly approved by the Mine Safety and Health Administration (formerly the U.S. Bureau of Mines) and by the National Institute of Occupational Safety and Health under provisions of 30CFR, Part 11. Wash hands, arms and face thoroughly with soap and water after handling and before eating or smoking. Routinely shower or bathe after work before reusing. Consumption of alcoholic beverages increases the toxic effects of thiram.

### ENVIRONMENTAL HAZARDS

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

### PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

EPA REG. NO. 400-116  
EPA EST. NO.  
001CM

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Middlebury, CT 06749

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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 through any type of irrigation system.

VITAVAX-R Flowable Fungicide is a ready-to-use seed treatment.

**RICE**

VITAVAX-R Flowable Fungicide combines the systemic action of carboxin with the surface action of thiram to control various seed and seedling diseases of rice. It is particularly effective against *Rhizoctonia solani* and *Helminthosporium oryzae*. Use 3-4 fluid ounces of VITAVAX-R Flowable Fungicide per 100 pounds of seed applied as a slurry treatment by machine. The higher rate is recommended for control of *Helminthosporium oryzae*.

**USE RESTRICTIONS**

Do not use treated seed for food or feed purposes.

**USE PRECAUTIONS**

The purchaser of this product is responsible for insuring that all seed treated with this product are adequately dyed with a suitable color to prevent accidental use as a food for man or feed for animals. Refer to 21 CFR, Part 2.25. All dye added to treated seed must be cleared for use under 40 CFR, Part 180.1001.

**COMPATIBILITY**

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

**SEED LABELING**

"This seed is treated with carboxin and thiram (VITAVAX-R) at the manufacturer's recommended rate. Do not use treated seed for food, feed or oil purposes." Add appropriate information for any other chemical treatments.

**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 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.

**IMPORTANT NOTICE**—Seller warrants that this product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with the directions and instructions specified on the label under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product, contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

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**Crompton**  
**Unroyal 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®-R Flowable Fungicide**  
**EPA Reg. No. 400-116**  
**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. 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®-R Flowable Fungicide (400-116) label
- 6) One copy of the current Vitavax®-R Flowable Fungicide (400-116) label.