

400-115

3-28-2003

115

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

Application for Pesticide - Section I

1. Company / Product Name 400-115	2. EPA Product Manager Mary Waller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company / Product (Name) Vitavax®-25DB	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. NOTIFICATION Product Name 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."
- 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"/> 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

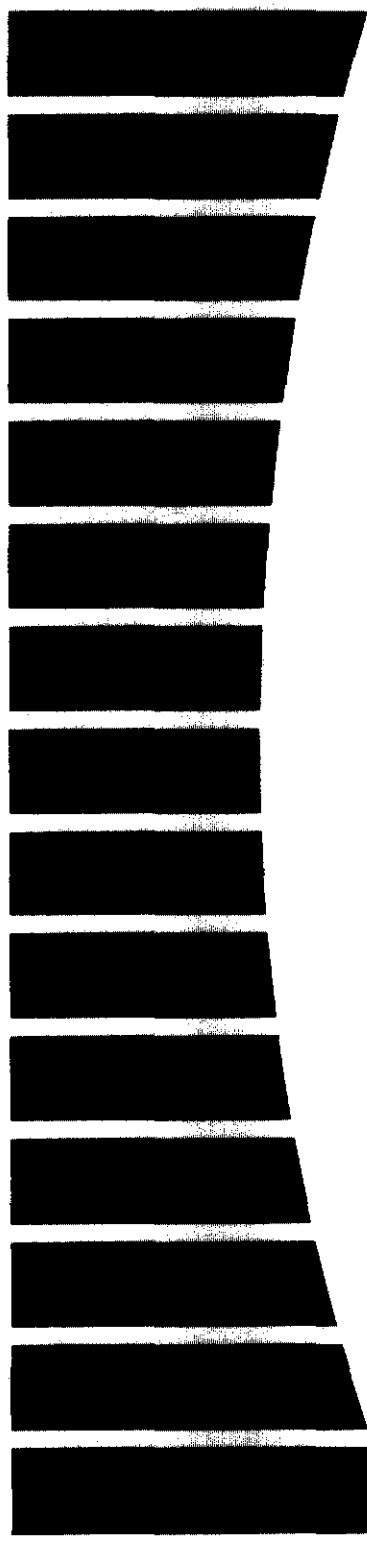
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Willard F. Cummings	Title Manager U.S. Registration	Telephone No. (Include Area Code) (203) 393-2163	
Certification I certify that the statements I have 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®-25DB Fungicide

Net
Contents:



Active Ingredients: (% by weight)

Carboxin (5,6-dihydro-2-methyl-N-phenyl-1,4-oxathiin-3-carboxamide)	25%
Inert Ingredients:	75%
Total:	100%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

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 glass 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 DANGER

Corrosive, causes eye damage. Harmful if swallowed, if swallowed, inhaled or absorbed through skin. Avoid breathing vapors or spray mist. Do not get in eyes, on skin or on clothing. Wear goggles or face shield when handling. Wash hands and face thoroughly with soap and water after use and before eating or smoking. Consumption of alcoholic beverages increases the possibility of harm.

ENVIRONMENTAL HAZARDS

This 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.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

EPA REG. NO. 400-115
EPA EST. NO.
001CM

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Middlebury, CT 06749

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subsidiary of Crompton Corporation



www.cromptoncorp.com

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-25DB Fungicide is a ready-to-use seed treatment fungicide. It has been formulated to be applied directly to seed in the planter. The recommended rate (see below) should be thoroughly mixed with the seed in the planter to insure proper coverage. Use the higher rate under conditions of expected heavy disease pressure.

CORN

VITAVAX-25DB Fungicide controls seed rots and provides systemic control of seedling diseases on corn. VITAVAX-25DB Fungicide should be applied directly to the seed in the planter at a rate of 4-6 ounces per 100 pounds of seed.

WHEAT, OATS AND BARLEY

Use 4 - 6 ounces of VITAVAX-25DB Fungicide per 100 pounds of seed as a planter box application for the control of various diseases and for loose and covered smut on wheat. For bunt control on wheat the higher rate is recommended.

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.

COMPATIBILITY

VITAVAX-25DB Fungicide can be applied to seed that has previously been treated with other seed protectant fungicides such as captan or thiram.

Observe all cautions and limitations on labeling of all products used in mixture with this product.

STORAGE AND DISPOSAL

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

STORAGE: Store in a dry location.

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: 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.

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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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®-25DB**
EPA Reg. No. 400-115
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®-25DB (400-115) label
- 6) One copy of the current Vitavax®-25DB (400-115) label.