

7501-209

01 6-15-2004

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Use read instructions on reverse before completing form. Form Approved, OMB No. 2070-0060, Approval expires 2-28-95



United States Environmental Protection Agency Washington, DC 20460

Registration Amendment Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 7501-209
2. EPA Product Manager L. Arrington
3. Proposed Classification None Restricted
4. Company/Product (Name) Raxil MD-W Seed Treatment
5. Name and Address of Applicant (Include ZIP Code) Gustafson LLC 1400 Preston Rd., Suite 400 Plano, TX 75093
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. Product Name

Section - II

Amendment - Explain below. Resubmission in response to Agency letter dated. Notification - Explain below. Final printed labels in response to Agency letter dated. "Me Too" Application. Other - Explain below.

NOTIFICATION

JUN 15 2004

Explanation: Use additional page(s) if necessary. (For section I and Section II.) Remove the following sentence from the label since the product is not currently registered in California. In California - Registered only for use in commercial seed treating establishment. Not allowed for "on-farm" use.

This notification is consistent with the provisions of FR Notice 90-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of facts 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 FR Notice 90-10 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 13 and 14 of FIFRA. Dennis McFadden

Section - III

1. Material This Product Will Be Packaged In: Child-Resistant Packaging, Unit Packaging, Water Soluble Packaging, 2. Type of Container, 3. Location of Net Contents Information, 4. Size(s) Retail Container, 5. Location of Label Directions, 6. Manner in Which Label is Affixed to Product

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Dennis McFadden Title Mgr. Tox & Reg Affairs Telephone No. 972-985-8877
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.
2. Signature Dennis McFadden 3. Title Mgr. Tox & Reg Affairs
4. Typed Name Dennis McFadden 5. Date 6/8/04
6. Date Application Received (Stamped)

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NOTIFICATION

JUN 15 2004

RAXIL[®] MD-W Seed Treatment

ACTIVE INGREDIENTS:

Imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine).....	1.538%
Tebuconazole (Alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethyl-ethyl)-1H-1,2,4-triazole-1-ethanol).....	0.461%
Metalaxyl N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester	0.615%
INERT INGREDIENTS	97.386%
TOTAL	100.00%

EPA Reg. No. 7501- 209
EPA Est. 7501-ID-1

NET CONTENTS: 5 gallons

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wear protective eye wear. Wash thoroughly with soap and water after handling and before eating, drinking chewing gum or using tobacco.

PERSONAL PROTECTIVE EQUIPMENT (PPE): Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for Category C on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt, long pants, shoes plus socks, chemical resistant gloves (such as nitrile rubber > 14 mils, butyl rubber > 14 mils, neoprene rubber > 14 mils, barrier laminate > 14 mils, polyvinyl chloride (PVC) > 14 mils and Viton > 14 mils) and protective eyewear.

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.

Manufactured by:



Gustafson LLC
1400 Preston Rd., Suite 400
Plano, TX 75093
Questions? (972) 985-8877

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 clothes. 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.

FIRST AID

If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IN CASE OF AN EMERGENCY ENDANGERING LIFE OR PROPERTY INVOLVING THIS PRODUCT, CALL:

CHEMTREC: (800) 424-9300 (Toll free – US)

CHEMTREC: (703) 527-3387 (Domestic and International)

ENVIRONMENTAL HAZARDS

This product is highly toxic to birds and aquatic invertebrates and toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Exposed treated seeds may be hazardous to birds. In the event that treated seeds are spilled and cannot be salvaged, completely cover them with soil. Do not contaminate water when disposing of equipment washwaters or rinsate.

Groundwater Advisory: Metalaxyl is known to leach through soil into groundwater under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

PRODUCT INFORMATION

RAXIL®MD-W is a combination of the insecticide, imidacloprid and the systemic fungicides, Tebuconazole and Metalaxyl that aid in the control or suppression of the following seed, seedling and soilborne diseases of wheat and barley: stinking smut, flag smut, loose smut, early season *Septoria* disease complex, general seed rots, *Pythium* damping-off, early season *Rhizoctonia* root rot, early season common root rot, seedborne *Fusarium* scab, early season *Fusarium* foot rot, early season suppression of powdery mildew and rust. Imidacloprid offers suppression of wireworm activity on seed and young seedlings.

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.

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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 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 seed is treated with the product and the treated seed 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, chemical-resistant gloves made of any waterproof material, shoes plus socks.

APPLICATION DIRECTIONS

Wheat, Barley:

Use 5 fluid ounces of RAXIL MD-W per 100 pounds of seed. Applications should be made using standard slurry or mist-type seed treatment equipment. In some cases, a water and chemical slurry dilution may enhance coverage. A 1part RAXIL MD-W with 1part water dilution may be used. This product is for commercial or on-farm application. This product is not intended for direct application into a planter box. Uniform application to seed is necessary to ensure seed safety and best pest control. Seed should be sound and well cured prior to treatment. Consult your area agronomist regarding planting depth recommendations for the particular variety to be planted.

Federal law requires that bags containing treated seeds shall be labeled with the following information: "This seed has been treated with Raxil MD-W seed treatment insecticide/fungicide (imidacloprid, tebuconazole, and metalaxyl). Do not use for feed, food, or oil purposes. Store away from feeds and foodstuffs." Use with an EPA-approved dye that imparts an unnatural color to the seed.

ROTATIONAL CROPS: Treated areas may be replanted with any crop specified on the RAXIL MD-W label, or for any crop for which a tolerance exists for imidacloprid, as soon as practical following the last application. The following plant-back intervals should be observed for listed crops:

ROTATIONAL PLANT-BACK INTERVALS*				
IMMEDIATE PLANT-BACK				30-DAY PLANT-BACK
Artichoke	Cranberry	Mustard seed	Sugar beet	Cereals (Including buckwheat, millet, oats, popcorn, rice, rye and triticale) Safflower Soybean
Barley	Cucurbits	Okra	Tomatillo	
Brassica (cole) leafy veg.	Eggplant	Pepinos	Tomato	
Canola	Ground cherry	Pepper	Turnip greens	
Cilantro	Leaf petiole veg.	Popcorn	Veg. Root and Tuber	
Corn, Field	Leafy veg.	Potato	Watercress	
Corn, Sweet	Legume veg. (succulent or dried, except Soybean)	Rapeseed	Wheat	
Cotton		Sorghum		
		Strawberry		

* Cover crops for soil building or erosion control may be planted any time, but do not graze or harvest for food or feed.
* All other crops not listed on an Imidacloprid label, or for crops for which no tolerance for the active ingredient have been established, a 12-month plant-back interval should be observed.

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited. Do not reuse empty containers.

PESTICIDE STORAGE: Keep pesticide in original container. Do not put concentrate or dilute into food or drink containers. Store in a cool dry location. Protect from excessive heat.

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 Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Contact Gustafson or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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, 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 LLC, no claims are made to guarantee germination of carry-over seed.

As its sole express warranty, Gustafson LLC 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 LLC SHALL NOT BE LIABLE FOR CONSEQUENTIAL DAMAGES. SUBJECT TO APPLICABLE LAW, GUSTAFSON LLC 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 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 LLC. If these terms are not acceptable, return all products to the place of purchase, unopened for a full refund.

Gustafson (logo) is a registered trademark of Gustafson LLC, Plano, Texas
RAXIL® is a registered trademark of Bayer AG, Germany

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June 8, 2004


Ms. Linda Arrington, Notifications
Office of Pesticide Programs
Document Processing Desk (NOTIF)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Subject: Raxil MD-W Seed Treatment, 7501-209
Label Notification

Dear Ms. Arrington,

Gustafson LLC is submitting a notification to remove the sentence, "In California-Registered only for use in commercial seed treating establishments. Not allowed for on-farm use." This sentence is being removed to avoid confusion since the product is not registered in California at this time.

Sincerely,


Dennis McFadden

Manager, Toxicology and Regulatory Affairs

