

PM 2)

100-769

3/21/97

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

255549

Application for Pesticide - Section I

1. Company/Product Number 100-769	2. EPA Product Manager Welch	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Medallion Fungicide	PM# 21	
5. Name and Address of Applicant (Include ZIP Code) <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. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated 2/18/97
<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.

NOTIFICATION

MAR 21 1997

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

Submission of final printed labels and notification to add one pest (disease) and several ornamental plants to the Medallion label.

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	Unit 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
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<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"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Gregory T. Peters, Ph.D.	Title Senior Regulatory Manager	Telephone No. (Include Area Code) (910)632-2366
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 statement may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received (Stamped) 5/10/97
2. Signature 	3. Title Senior Regulatory Manager	
4. Typed Name Gregory T. Peters, Ph.D.	5. Date 3/5/97	

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March 5, 1997

Ms. Connie Welch, Team Leader (21)
Office of Pesticide Programs - H7504C
U.S. Environmental Protection Agency
401 M. Street (SW)
Washington, D.C. 20460-0001

**SUBJECT: SUBMISSION OF FINAL PRINTED LABELING FOR MEDALLION™
FUNGICIDE (EPA Reg. No. 100-769). NOTIFICATION FOR THE
ADDITION OF ORNAMENTAL PLANTS AND DISEASES CONTROLLED**

Dear Ms. Welch:

Enclosed please find five copies of final printed labeling for Medallion™ Fungicide (EPA Reg. No. 100-769) in response to your letter dated February 18, 1997. The label was revised according to your request that we add statements concerning chemigation systems connected to public water systems.

Via this notification, we added Alternaria spp. to the list of diseases controlled for ornamentals. We also added the following ornamental plants:

Soil Drench

At Seeding: Begonia, Petunia, Salvia, Snapdraggon

Transplants and Cuttings: Begonia, Carnation, Celosia, Impatiens, Salvia, Spathiphyllum, Snapdraggon, Vinca, Zinnia

Foliar Spray

Rhizoctonia control: Gomphrena

Botrytis control: African Violet, Chrysanthemum

Lastly, we added the note:

**IMPORTANT: (2) DO NOT APPLY MEDALLION FOR CONTROL OF
SEEDLING DISEASES OF PANSY.**

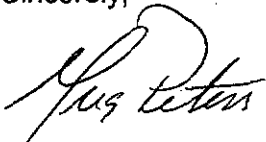
This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of

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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.

If you have any questions or comments concerning this notification, please contact me at (910) 632-2366. Thank you.

Sincerely,



Gregory T. Peters, Ph.D.
Senior Regulatory Manager

Enclosures: Five copies of final printed labeling
Application for Pesticide Form 8570-1

cc: Kathryn Scanlon

HIGHLIGHTED 4/8

PULL HERE TO OPEN ►

Medallion™

FUNGICIDE

For control of certain foliar and soilborne diseases in ornamentals grown in containers, greenhouses, and other enclosed structures

Active Ingredient:
4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile 50%

Inert Ingredients: 50%
Total: 100%

Medallion is a wettable powder.
EPA Reg. No. 100-769 EPA Est. 100-NC-2

**KEEP OUT OF REACH
OF CHILDREN.
CAUTION**

See additional precautionary statements and directions for use inside booklet.

This outer protective container contains Medallion in eight inner water-soluble packets. These inner packets dissolve in water, allowing contents to wet. After opening outer containers, immediately dump the required number of unopened inner packets into the partially filled sprayer or mix tank. Do not handle the soluble packets or expose them to moisture, since this may cause rupturing.

Do not offer individual packets for sale.
NCP 1981i 0297

8 x 1 Ounce 8 Ounces
Water-Soluble Packets Total Net Weight Per Bag



DIRECTIONS FOR USE AND CONDITIONS OF SALE AND WARRANTY

IMPORTANT: Read the entire **Directions for Use** and the **Conditions of Sale and Warranty** before using this product. If terms are not acceptable, return the unopened product container at once.

Conditions of Sale and Warranty

The **Directions for Use** of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application all of which are beyond the control of Novartis Crop Protection, Inc. or the Seller. All such risks shall be assumed by the Buyer.

Novartis warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions for Use** subject to the inherent risks referred to above.

Novartis makes no other express or implied warranty of Fitness or Merchantability or any other express or implied warranty. In no case shall Novartis or the Seller be liable for consequential, special, or indirect damages resulting from the use or handling of this product. Novartis and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing **Conditions of Sale and Warranty**, which may be varied only by agreement in writing signed by a duly authorized representative of Novartis.

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.

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 12 hours.

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

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Do not enter treated areas without protective clothing until sprays have dried.

NOTIFICATION

MAR 21 1997

FAILURE TO FOLLOW THE DIRECTIONS FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN POOR DISEASE CONTROL OR PLANT INJURY.

General Information

Mixing Instructions

Prepare no more mixture than is needed for the immediate operation. Thoroughly clean the spray equipment before using Medallion. Vigorous agitation is necessary to maintain uniformity of the spray mixture. Maintain maximum agitation throughout the spraying operation. It is not recommended that the spray mixture stand overnight in the spray tank. Flush the spray equipment thoroughly following each use and apply the rinsate to a previously treated area.

Note: Do not use with oils or adjuvants.

Medallion Alone: Add 1/3 of the required amount of water to the spray or mixing tank. With the agitator running, drop the required number of unopened soluble packets of Medallion into the spray tank all at once. Continue agitation while adding the remainder of the water. Begin application of the spray solution after the packets have dissolved, and the material has completely dispersed into the mix water. Maintain agitation until all of the mixture has been applied.

Medallion + Tank Mixtures: Medallion is usually compatible with Subdue®, Subdue II, and other commonly used fungicides or insecticides.

Add 1/3 of the required amount of water to the spray or mixing tank. With the agitator running, drop the required number of unopened soluble packets of Medallion into the tank all at once. If tank mixing with Subdue II, drop the required number of unopened soluble packets of Subdue II into the tank before adding the remainder of the water. Continue agitation while adding the remainder of the water. Allow the packets of Medallion to dissolve and the product to completely disperse into the mix water. Then add the desired amount of other products recommended for tank mixture and allow them to become completely dispersed. Continue agitation to maintain a uniform suspension until all of the spray solution has been applied.

Note: Do not let the spray mixture stand overnight in the spray tank. Rinse the spray tank at the end of the day.

Precaution: Water-soluble packets of Medallion must be completely dissolved and dispersed in water before any other tank mix partner, including micronutrients or other liquid or dry fertilizers, are added to the spray solution.

If using Medallion in a tank mixture, observe all directions for use, crops/sites, use rates, dilution ratios, precautions, and limitations which appear on the tank mix product label. No label dosage rate should be exceeded and the most restrictive label precautions and limitations should be followed. This product should not be mixed with any product which prohibits such mixing. Tank mixtures are permitted only in those states where the tank mix partner is registered.

Application Instructions for Use in Irrigation Systems

Overhead, Microjet, or Drip Irrigation Application: Medallion alone or in tank mixture with other pesticides which are registered for overhead, microjet, or drip application may be applied in irrigation water at rates recommended on this label. Apply this product only through an overhead, microjet, or drip irrigation system. Do not apply this product through any other type of irrigation system. Plant injury or lack of effectiveness can result from nonuniform distribution of treated water. If you have questions about calibration, you should contact State Extension specialists, equipment manufacturers, or other experts. Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place. A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise. **Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.**

Added

Operation Instructions

1. The system must contain a functional check-valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water-source contamination from backflow. **Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, back-flow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.**
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check-valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.

Added

Added

6. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Do not apply when wind speed favors drift beyond the area intended for treatment. Avoid spray overlap as injury may result.
8. Prepare a mixture with a minimum of 1 gal. of water to one packet of Medallion and inject this mixture into the system. Injecting a larger volume of a more dilute mixture per hour will usually provide more accurate calibration of metering equipment. Maintain sufficient agitation to keep the fungicide in suspension.
9. Meter into irrigation water during the beginning of the irrigation cycle.
10. With overhead or microjet systems, apply additional water after irrigation is completed to remove residues from the foliage. Apply enough supplemental water to set the root zones of the plants.

Precaution for irrigation applications: Where distribution patterns do not overlap sufficiently, unacceptable control may result. Where distribution patterns overlap excessively, injury to desirable plants may result.

Ornamentals

Medallion is a protectant fungicide for control of certain foliar and soilborne diseases in ornamentals grown in containers, greenhouses, and other enclosed structures. Medallion controls damping-off and root and stem rot diseases caused by *Rhizoctonia* spp. For control of other damping-off and root and stem rot diseases caused by *Pythium* spp. and *Phytophthora* spp., use Subdue or Subdue II. Use Medallion as a soil drench on ornamentals at the time of seeding or transplanting, or on established plants. Medallion can also be used as a foliar spray for control of *Botrytis* spp., foliar *Rhizoctonia* spp., and *Alternaria* spp.; apply Medallion as a foliar spray only to ornamentals grown in greenhouses or other enclosed structures.

Added

NOTICE TO USER: Plant tolerance to Medallion has been found to be acceptable for the specific genera and species listed on this label. Due to the large number of species and varieties of ornamentals and nursery plants, it is impossible to test every one for tolerance to Medallion. Neither the Manufacturer nor the Seller has determined whether or not Medallion can be used safely on ornamental plants not specified on this label. The professional user should determine if Medallion can be used safely prior to commercial use. In a small area, test the recommended rates on unlabeled plants for phytotoxicity prior to widespread use.

SOIL DRENCH

At Seeding (*Begonia*, *Celosia*, *Impatiens*, *Marigold*, *Petunia*, *Salvia*, *Snapdragon*, *Zinnia*)

Added

For control of soilborne *Rhizoctonia* spp., mix 1 packet/100 gals. of water. Apply sufficient solution to thoroughly wet the growing media (up to a maximum of 1 pt./sq. ft.). Make only one application to the seedling crop prior to transplanting or transfer to larger containers.

Transplants and Cuttings (*Begonia*, *Carnation*, *Celosia*, *Impatiens*, *Marigold*, *Poinsettia*, *Pothos*, *Salvia*, *Spathiphyllum*, *Snapdragon*, *Vinca*, *Zinnia*)

Added

For the control of soilborne *Rhizoctonia* spp., mix 2-4 packets/100 gals. of water. Apply sufficient solution to thoroughly wet the growing media (up to a maximum of 1 pt./sq. ft.). If needed, retreat transplants and cuttings with Medallion 21-28 days after the initial application.

Under severe disease conditions, use the higher rate on these ornamentals.

FOLIAR SPRAY

Under severe disease conditions, use the higher rate on these ornamentals.

Rhizoctonia spp. (*Poinsettia*, *Gomphrena*, *Pothos*)

Added

For control of foliar diseases caused by *Rhizoctonia* spp. and *Alternaria* spp., mix 4-8 packets/100 gals. of water. Spray to runoff. Repeat applications at 7 to 14-day intervals. Do not apply to poinsettia after bract formation.

Added

Botrytis spp. (*African Violet*, *Chrysanthemum*, *Cyclamen*, *Impatiens*, *Marigold*)

Added

For control of foliar diseases caused by *Botrytis* spp., mix 12-16 packets/100 gals. of water. Spray to runoff. Repeat applications at 7 to 14-day intervals.

IMPORTANT: (1) DO NOT APPLY MEDALLION TO GERANIUM (PELARGONIUM SPP.). (2) Do not apply Medallion for control of seedling diseases of pansy. (3) APPLY MEDALLION AS A FOLIAR SPRAY ONLY TO ORNAMENTALS GROWN IN THE GREENHOUSE OR OTHER ENCLOSED STRUCTURES.

Added (this will be upper case on the packaging)

Storage and Disposal

Storage

Store in a cool, dry place. Do not store this product under wet conditions. Handle outer container carefully to avoid breakage of inner soluble packets.

Pesticide Disposal

Do not contaminate water, food, or feed by storage or disposal, or cleaning of equipment. Improper disposal of unused pesticide, spray mixture, or rinse water is a violation of federal law. Pesticide, spray mixture, or rinsate that cannot be used according to label instructions must be disposed of according to federal, state, or local procedures. If these wastes cannot be used 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 in proper disposal methods.

Container Disposal

Do not reuse outer container. Dispose of empty outer container in a sanitary landfill or by incineration, or by open burning, if allowed by state and local authorities. If burned, keep out of smoke.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during clean up procedures and disposal of wastes. In the event of a major spill, fire, or other emergency, call 1-800-888-8372, day or night.

Precautionary Statements**Hazards to Humans and Domestic Animals****CAUTION**

Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing.

Statement of Practical Treatment

If in eyes: Flush with plenty of water. Call a physician if irritation persists.

If on skin: Wash with plenty of soap and water. Get medical attention.

If swallowed: Immediately drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person. Call a physician or Poison Control Center.

If inhaled: Move to fresh air.

Note to Physician: If ingested, induce emesis or lavage stomach. Treat symptomatically.

Personal Protective Equipment**Applicators and other handlers must wear:**

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

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.

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.

Environmental Hazards

This product is toxic to fish and aquatic invertebrates. 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 wash waters or rinsates.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

Medallion™ and Subdue®
trademarks of Novartis
U.S. Patent Nos. 4,151,299; 4,705,800

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Novartis Crop Protection, Inc.
Turf and Ornamental Products
Greensboro, NC 27419
NCP 198L1 0297

This booklet manufactured using
post-consumer, recycled paper.



Medallion™ FUNGICIDE

For control of certain foliar and soilborne diseases in ornamentals grown in containers, greenhouses, and other enclosed structures

Active Ingredient:
4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile 50%

Inert Ingredients: 50%

Total: 100%

Medallion is a wettable powder.

See additional precautionary statements and directions for use in attached booklet.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to supplemental labeling under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

EPA Reg. No. 100-769

EPA Est. 100-NC-2

This outer protective container contains Medallion in eight inner water-soluble packets. These inner packets dissolve in water, allowing contents to wet. After opening outer container, immediately dump the required number of unopened inner packets into the partially filled sprayer or mix tank. Do not handle the soluble packets or expose them to moisture, since this may cause rupturing.

Do not offer individual packets for sale.

8 x 1 Oz.
Water-Soluble
Packets

8 Oz.
Total Net
Weight



KEEP OUT OF REACH OF CHILDREN. CAUTION

Precautionary Statements

Hazards to Humans and Domestic Animals

Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing.

Statement of Practical Treatment

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Physical or Chemical Hazards
Do not use or store near heat or open flame.

Medallion™ trademark of Novartis

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NCP 198L1 0297