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Printed: 07:45:55 Tuesday, 13 Jul, 1999 # 37 / 3548

Systems Integration Group, Inc.



100-769 6/8/99 1 of 16
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 8 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUN 8 1999

Richard Pence
Senior Regulatory Manager
Novartis Crop Protection, Inc.
P O Box 18300
Greensboro, NA 27419-8300

Dear Mr. Pence:

Subject: 100-769; Medallion™ Fungicide
Labeling Amendment
Submission Dated April 20, 1999

The labeling referred to above, submitted in connection with the registration under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable provided you make the following changes:

1. Delete "overhead" from the second line of last paragraph on page 5.
2. Delete "Avoid breathing spray mist" from the last paragraph, as it is not required, because the inhalation toxicity of Medallion formulation is Category IV.

A stamped copy of the label is enclosed for your records. Submit one copy of the final printed labeling before you release the product for shipment. Should you have any questions, do not hesitate to contact Dr. S. (Oonni) Oonnithan at 703-605-0368.

Sincerely,

Mary L. Waller

Mary L. Waller
Product Manager 21
Fungicide Branch
Registration Division (7505C)

Encl.

DRAFT
Booklet Label

Medallion™

FUNGICIDE

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

Active Ingredient:	
Fludioxonil (CAS No. 131341-86-1)50.0%
Other Ingredients:	50.0%
Total:	100.0%

ACCEPTED
with **COMMENTS**
In EPA Letter Dated:
06/08/99
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
100-769

Medallion is a wettable powder.

KEEP OUT OF REACH OF CHILDREN.

CAUTION

See additional precautionary statements and directions for use inside booklet.

EPA Reg. No. 100-769

EPA Est. 67545-AZ-1

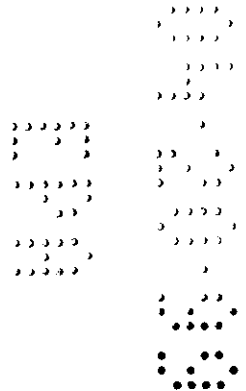
This outer protective container contains Medallion in eight inner water-soluble packets. These inner packets dissolve in water, allowing contents to wet. After opening outer containers, immediately dump the required number of unopened inner packets into the partially filled sprayer or mix tank. Do not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

Do not offer individual packets for sale.

8 x 1 OUNCE
Water-Soluble Packets

8 OUNCES
Total Net Weight Per Bag

NCP



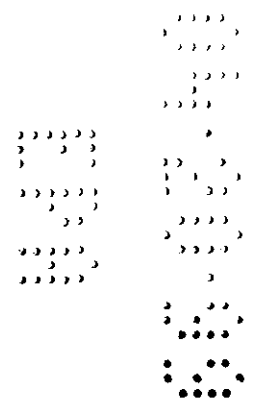
DIRECTIONS FOR USE AND CONDITIONS OF SALE AND WARRANTY

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.

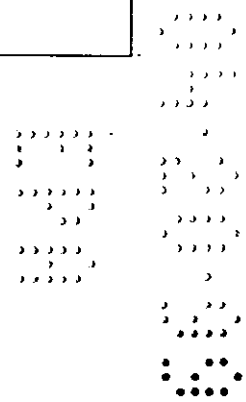
AGRICULTURAL USE REQUIREMENTS

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. Exception: If the product is applied by drenching, 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



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.

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

GENERAL INFORMATION

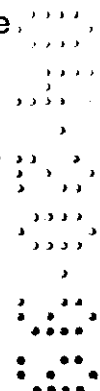
Mixing Instructions

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: Use with oils or adjuvants may cause plant damage.

Medallion Alone: Add 1/3 of the required amount of water to the spray or mixing tank. With the agitator running, drop all the required number of **unopened** soluble packets of Medallion into the spray tank. 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 compatible with Banner®, MAXX™, Subdue® MAXX™, and Subdue 2X WSP. Medallion is usually compatible with other commonly used fungicides and insecticides; if in doubt, run a "jar compatibility test" or consult with Novartis company representatives, other users, university or extension personnel before



proceeding.

Add 1/3 of the required amount of water to the spray or mixing tank. With the agitator running, drop all the required number of unopened soluble packets of Medallion into the tank. Allow the packets of Medallion to dissolve and the product to completely disperse into the mix water. Continue agitation while adding the remainder of the water. If tank mixing with Subdue II, drop the required number of unopened soluble packets of Subdue II into the tank at the same time as the Medallion. Allow all of the products packaged in water-soluble packets to dissolve and disperse before adding the remainder of the 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 and any other products packaged in water-soluble film, must be completely dissolved and uniformly 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
(For applications of Medallion as soil drench applications only. Do not use in overhead irrigated systems.)

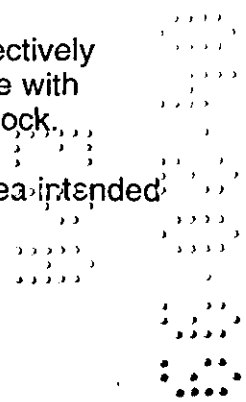
Microjet or Drip Irrigation Application: Medallion alone or in tank mixture with other pesticides which are registered for overhead, microjet, or drip application may be applied in irrigation water at rates recommended on this label. Apply this product only through a microjet, or drip irrigation system. 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.

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.
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 microjet systems, apply additional water after irrigation is completed to remove residues from the foliage. Apply enough supplemental water to wet the root zones of the plants and help clean lines.

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, stem and root diseases in ornamentals grown in greenhouses, containers, and other enclosed structures.

Medallion controls foliar diseases of ornamentals caused by *Rhizoctonia* spp., *Botrytis* spp., *Cercospora* spp., *Alternaria* spp., *Septoria* spp. and *Myrothecium* spp. when applied on a regular schedule as a full coverage spray.

Medallion also will provide control of stem and root diseases caused by *Rhizoctonia* spp., *Fusarium* spp. (e.g., oxysporum), *Cylindrocladium* spp., *Sclerotium* spp. and *Thielaviopsis* spp., when mixed with the potting media or as a drench to the root zone of plants.

For control of stem and root diseases caused by *Pythium* spp. and *Phytophthora* spp. tank mix Medallion with labeled rates of Subdue MAXX or Subdue 2XWSP. See mixing instructions for these tank mixes.

Maximum Use Rates

For indoor applications, use up to 30 oz. of Medallion per 1,000 sq. ft. (40 lb. a.i./a) per year or crop cycle. Applications to pre-potting mix can be made up to 4 oz. of Medallion per cu. yd.

California only: For indoor applications, up to 3.2 oz. of Medallion per 1,000 sq. ft. (4.4 lb. a.i.) per year or crop cycle may be used.

The high use rates recommended for greenhouses, containers and other

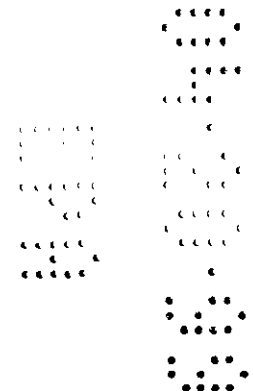


enclosed structures are due to the high organic matter soil mixes used in these systems and the high binding affinity of Medallion for organic matter.

Plant Species

Medallion has been tested and found to be safe on the ornamentals listed in this table at recommended rates. For plants not listed in the table, see the "Notice to User" box at the bottom of the table. Numbers in parenthesis refer to diseases controlled. See Table 1.

- African Violets (1-12)
- Ageratum (1-10)
- Alyssum (1-12)
- Aster (1-12)
- Azalea (4, 11, and 12)
- Begonia (1-12)
- Bleeding Heart* (1-12)
- Bridal Veil* (1-12)
- Caladium (1-12)
- Carnation (1-12)
- Calendula (1-12)
- Celosia (1-12)
- Centrosa* (1-12)
- Chenille* (1-12)
- Christmas Cactus (1-12)
- Chrysanthemums (1-12)
- Coleus (1-12)
- Coreopsis* (1-12)
- Cyclamen (1-12)
- Daisy* (1-12)
- Dahlia* (1-12)
- Fern (1-12)
- Fushia* (1-4)
- Geranium (1-12)
- Gerbera Daisy (1-12)
- Gomphrena (1-12)
- Lantana* (1-12)
- Marigold (1-12)
- Mexican Heather* (1-7)
- Nephthytis* (1-12)
- Pansy (1-12)
- Petunia (1-12)
- Poinsettia* (9-12)
- Protulaca* (1-12)
- Pothos (1-12)
- Rose (1, 4, and 9)
- Salvia (1-12)
- Snapdragon (1-12)



- Spathiphyllum (1-12)
- Sunflower* (1-12)
- Tobacco, flowering* (1-12)
- Verbena (1-12)
- Vinca (1-12)
- Wandering Jew*(1-12)
- Zinnia (1-12)

*Indicates that only foliar applications have been tested for plant safety.

Note: Drench or at seedling applications to impatiens or New Guinea Impatiens may cause stunting and/or chlorosis.

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 a small number of plants for phytotoxicity prior to widespread use.

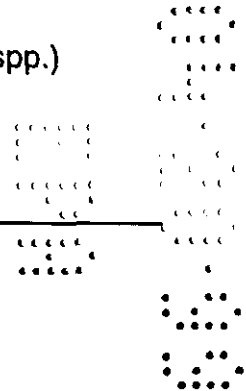
Table 1: Diseases Controlled by Medallion

Foliar Diseases

-
1. Aerial Blight (*Rhizoctonia* spp.)
 2. Alternaria Leaf Blight (*Alternaria* spp.)
 3. Alternaria Leaf Spot (*Alternaria* spp.)
 4. Botrytis Blight (*Botrytis* spp.)
 5. Cercospora Leaf Spot (*Cercospora* spp.)
 6. Myrothecium Leaf Spot and Blight (*Myrothecium* spp.)
 7. Septoria Leaf Spot (*Septoria* spp.)

Stem, Crown, and Root Rots

8. Cylandrocladium Stem and Root Rot (*Cylandrocladium* spp.)
 9. Fusarium Stem and Root Rot (*Fusarium* spp.)
 10. Rhizoctonia Stem and Root Rot (*Rhizoctonia* spp.)
 11. Southern Blight (*Sclerotium rolfsii*)
 12. Black Root Rot (*Thielaviopsis* spp.)
-



FOLIAR SPRAY

For control of *Rhizoctonia* spp., *Alternaria* spp., *Septoria* spp., *Myrothecium* spp., and *Cercospora* spp., use 1-2 packets per 100 gals. of water and spray to runoff at 7-14 day intervals while conditions are favorable for disease development.

For control of *Botrytis* spp. use 2-4 packets per 100 gals. of water and spray to runoff at 7-14 day intervals while conditions are favorable for disease development.

Note: (1) Under severe conditions, use the highest rate and/or the shortest application interval. (2) Spray applications can be made with up to 200 gals. per acre.

PRE-POTTING GROWING MEDIA MIX

Medallion can be mixed with the potting media before seeding or transplanting by uniformly mixing 0.5-4 oz. per cu. yd. of potting media. The desired amount of Medallion should be mixed with 0.5-1 gal. of water and applied to 0.5 oz. per cu. yd. of potting media. It is recommended that Medallion treatment should be made just before the plants are seeded or potted up. Uniform mixing can be accomplished by placing the potting mix in a rotating drum and spraying the Medallion solution onto the mix while the drum is rotating.

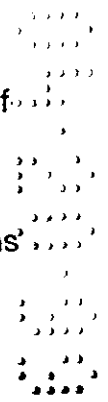
GROWING MEDIUM DRENCH

At Seeding

For the control of damping off, root and stem diseases, mix 1-2 packets/100 gals. of water. When using Medallion for control of *Rhizoctonia* spp., apply sufficient mix to wet the upper one-half of the growing medium. For control of other root and stem diseases, completely drench the growing medium. Make only one application to the seeding crop prior to transplanting or transfer to larger containers.

Transplants and Cuttings

For the control of root and stem diseases, mix 1-2 packets per 100 gals. of water. When using Medallion for control of *Rhizoctonia* spp., apply sufficient mix to wet the upper one-half of the growing medium. For control of other root and stem diseases completely drench the growing medium. If needed, retreat transplants and cuttings with Medallion as described above at 21-28 day intervals. Two applications per year during conditions



favorable for disease development are usually adequate to control diseases of ornamentals.

Note: (1) Under severe conditions, use the highest rates and/or the shortest application interval. (2) For control of *Pythium* and *Phytophthora* diseases in addition to *Rhizoctonia* spp., *Cylindrocladium* spp., *Thielaviopsis* spp., *Fusarium* spp. and *Sclerotium* spp., tank mix Medallion with labeled rates of Subdue MAXX or Subdue 2X WSP. (3) Drench applications can be made at up to 2 pts./sq. ft. to wet the root zone of plants.

STORAGE AND DISPOSAL

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.

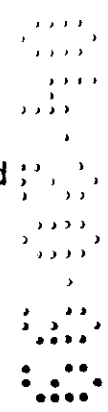
For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

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:

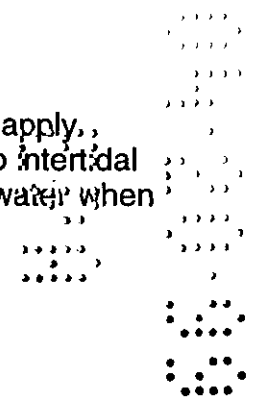
- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

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.

<p>User Safety Recommendations</p> <p>Users should:</p> <ul style="list-style-type: none"> • 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.

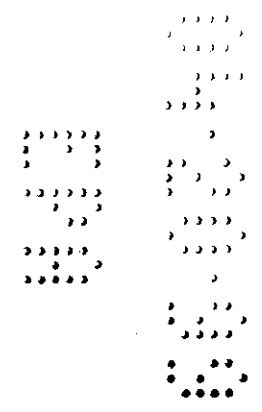
Banner® MAXX™, Medallion™, and Subdue® MAXX™ trademarks of
Novartis
U.S. Patent No. 4,705,800

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Novartis Crop Protection, Inc.
Turf and Ornamental Products
Greensboro, NC 27419

NCP

This booklet manufactured using post-consumer, recycled paper.



150816

BASE LABEL

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-carbonitrile50.0%

Inert Ingredients:	50.0%
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Total:	100.0%
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Medallion is a wettable powder.

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

AGRICULTURAL USE REQUIREMENTS

<p>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.</p>
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EPA Reg. No. 100-769

EPA Est. 67545-AZ-1

8 x 1 OUNCE
Water-Soluble Packets

8 OUNCES
Total Net Weight Per Bag

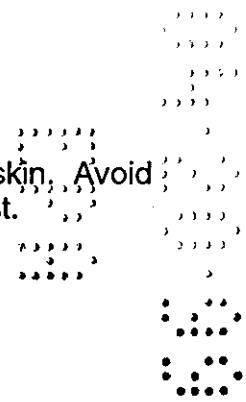
KEEP OUT OF REACH OF CHILDREN.

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. Avoid breathing spray mist.



Statement of Practical Treatment

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

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 on skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

If inhaled: Move to fresh air.

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

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.

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. In the event of a major spill, fire, or other emergency, call 1-800-888-8372, day or night.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

Medallion™ trademark of Novartis

©1999 Novartis

Novartis Crop Protection, Inc.
Turf and Ornamental Products
Greensboro, North Carolina 27419

NCP

[QUARK/MEDALLION/MEDALLION BOOKLET-F] - ccg - 3/30/99

