

71512-13

7/29/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mike Peplowski
ISK Biosciences
7470 Auburn Road, Suite A
Concord, Ohio 44077

JUL 29 2009

**RE: Amendment Dated 8/8/08
PRIA Decision 399077
Cyazofamid 400SC Turf and Ornamental Fungicide
EPA Reg. No. 71512-13**

Dear Mr. Peplowski:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add new uses for residential turf is acceptable providing you submit the conditional data as listed below, and submit a final printed label within 45 days from the date of this letter, which makes the changes herein:

Conditional Data Requirements – the following must be submitted by 7/31/2012:

1. As part of the new 40CFR §158 Guidelines, a functional immunotoxicity study in rats and/or mice is required (Guideline 870.7800).
2. As part of the new 40CFR §158 Guidelines, a subchronic neurotoxicity study is required (Guideline 870.6200).

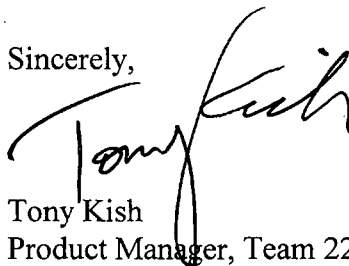
Label Changes

1. Change “professionally managed turf areas such as golf courses (including greens, tees, and fairways), sod farms, seed farms, college and professional sports fields, residential and commercial lawns” to the following, “turf areas associated with golf courses (greens, tees, and fairways), sod farms, seed farms, college and professional sports fields, residential and commercial lawns”. Note that “Professionally managed” is undefined and therefore non-enforceable terminology. Also “such as” is open ended and not defined. Add page numbers.
2. On page 3, under the turf use directions add “Use only with ground applications”.
3. By separate amendment or notification as appropriate (not as a final printed label), harmonize the “Container Disposal” with PR Notice 2007-4.

4. In the warranty section, add "To the extent consistent with applicable law" prior to "Buyers and users of this product assume the risk...directions"; and prior to Buyers and users of this product are responsible for all loss...practices".

Attach a copy of this letter with your final printed label. Enclosed please find a copy of the label stamped "Accepted With Comments". If you have questions concerning this letter, please contact me at 703-308-9443.

Sincerely,



Tony Kish
Product Manager, Team 22
Fungicide Branch
Registration Division (7505P)



CYAZOFAMID 400SC

TURF AND ORNAMENTAL FUNGICIDE

ACTIVE INGREDIENT: Cyazofamid* 34.5%
 OTHER INGREDIENTS: 65.5%
 Total 100.0%

*4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide (CA)

Contains 3.33 pounds Cyazofamid Per Gallon (400 grams per liter)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side panel for additional precautionary statements.

Read entire label carefully and use only as directed.

Manufactured in France

ISK Biosciences Corporation
 7470 Auburn Road, Suite A
 Concord, Ohio 44077 U.S.A.

EPA Reg. No. 71512-13

Net Contents: 5 Gallons

ACCEPTED
 with **COMMENTS**
 In EPA Letter Dated
 JUL 29 2009

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act
 as amended, for the pesticide
 registered under EPA Reg. No.
 EPA Est. No. 71512-13

FIRST AID	
If on skin	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of soap and water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
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 swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
<p>HOT LINE NUMBER</p> <p>For 24-Hour Medical Emergency Assistance (Human or Animal) Call 1-888-484-7546.</p> <p>For Chemical Emergency, Spill, Leak, Fire or Accident, Call CHEMTREC 1-800-424-9300.</p>	

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Avoid breathing spray mist. DO NOT take internally.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear long-sleeved shirt and long pants, socks, shoes, and chemical resistant gloves made of any waterproof material.

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. Do not allow contact of contaminated clothing with unprotected skin. 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.

Engineering Control Statements

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.

User Safety Recommendations

Users should:

- * Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.
- * Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

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 waters when disposing of equipment wash waters or rinsate.

AVOIDING SPRAY DRIFT AT THE APPLICATION SITE IS THE RESPONSIBILITY OF THE APPLICATOR. The interaction of many equipment- and weather-related factors determines the potential for spray drift. The applicator is responsible for considering all these factors when making decisions. Where states have more stringent regulations, they should be observed.

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE STORAGE: Store in original container, in a secured, dry place separate from fertilizer, food, and feed.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, pesticide spray 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: DO NOT reuse empty container. Triple rinse (or equivalent) and 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.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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

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 twelve (12) hours.

PPE required for early entry to the 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), and
- shoes plus socks.

Sod and seed farms, commercial greenhouses and nurseries are within the scope of the Worker Protection Standard.

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. Turf grasses on golf courses and to other non-residential turf areas such as industrial parks, tank farms, professionally managed college and professional sports fields, commercial lawns and ornamental landscapes are not within the scope of the Worker Protection Standard. Keep children, pets, and unprotected persons out of the treated area until sprays have dried.

GENERAL INFORMATION

Cyazofamid 400SC is a flowable suspension concentrate for control of Pythium and Downy mildew diseases on professionally managed turf areas such as golf courses (including greens, tees and fairways), sod farms, seed farms, college and professional sports fields, residential and commercial

lawns. Cyazofamid 400SC can also be used to control Pythium, Phytophthora and Downy mildew diseases on ornamental plants in landscapes and those grown in commercial greenhouses and nurseries. Application by home-owners to residential turf is prohibited.

INTEGRATED PEST MANAGEMENT

Cyazofamid 400SC is an excellent disease control agent when used according to label directions for control of several Oomycete fungi. Although Cyazofamid 400SC has limited systemic activity, it should be utilized as a protectant fungicide and applied before the disease infects the crop.

Depending upon the level of disease pressure, good protection of the crop against disease can be expected over a period of 7 to 28 days.

Cyazofamid 400SC is recommended for use as part of an Integrated Pest Management (IPM) program, which may include the use of disease-resistant crop varieties, cultural practices, crop rotation, biological disease control agents, pest scouting and disease forecasting systems aimed at preventing economic pest damage. Practices known to reduce disease development should be followed. Consult your state cooperative extension service or local agricultural authorities for additional IPM strategies established in your area. Cyazofamid 400SC may be used in State Agricultural Extension advisory (disease forecasting) programs that recommend application timing based upon environmental factors that favor disease development.

RESISTANCE MANAGEMENT

Some plant pathogens are known to develop resistance to products used repeatedly for disease control. Cyazofamid 400SC's mode/target site of action is complex III of fungal respiration: ubiquinone reductase, Qi site (Fungicide Resistance Action Committee code 21). A disease management program that includes alternation and/or tank mixes between Cyazofamid 400SC and other labeled fungicides that have a different mode of action and/or control pathogens not controlled by Cyazofamid 400SC is essential to prevent disease resistant pathogen populations from developing. Cyazofamid 400SC should not be utilized continuously nor tank mixed with fungicides to which the target diseases have developed resistance.

Since pathogens differ in their potential to develop resistance to fungicides, follow the directions outlined in the "Directions For Use" section of this label for specific resistance management strategies for each crop. Consult

with your Federal or State Cooperative Extension Service representatives for guidance on the proper use of Cyazofamid 400SC in programs that seek to minimize the occurrence of disease resistance. Cyazofamid 400SC is not cross-resistant with other classes of fungicides that have different modes of action.

PLANT TOLERANCE

Note to User: Although Cyazofamid 400SC has been evaluated on several plants with no indication of phytotoxicity, neither the manufacturer nor seller has determined whether or not Cyazofamid 400SC can be used safely on ornamental and nursery plants not specified on this label. The professional user should determine if Cyazofamid 400SC can be used safely prior to commercial use by testing a small number of the type of plants to be treated at recommended rates for that particular group for phytotoxicity.

MIXING INSTRUCTIONS

NOTE: Slowly invert Cyazofamid 400SC container several times to assure uniform mixture of formulation before adding this product to the spray tank.

Fill the mixing tank with half of the required amount of water. The required amount of Cyazofamid 400SC should be added slowly into the spray tank during filling to the required volume. Keep agitator running when filling spray tank and during spray operations. Do not allow spray mixture to stand overnight or for prolonged periods of time. Prepare only the amount of the spray mixture required for immediate use. Spraying equipment should be thoroughly cleaned immediately after the application is completed.

Apply Cyazofamid 400SC in sufficient water to obtain adequate coverage of the foliage. Gallonage to be used will vary with crop and amount of plant growth.

TANK MIX COMPATIBILITY

Cyazofamid 400SC is physically compatible (no nozzle or screen blockage) with many products recommended for control of diseases and insects on turf grass and ornamental plants. Read and follow all manufacturer's label recommendations for the tank mix companion product. It is the applicator's responsibility to ensure that the companion product is EPA approved for use on the intended crop. Cyazofamid 400SC is generally compatible with other insecticides, fungicides, fertilizers and micronutrient products provided sufficient free water is available for dispersion of all the tank mix products. However, the physical compatibility of Cyazofamid 400SC with tank mix partners should be evaluated before use. A jar test should be conducted with intended tank-mix pesticides prior to preparation of large volumes. Use the following procedure: 1) Pour the recommended proportions of the products into a suitable container of water, 2) Mix thoroughly and 3) Allow to stand 5 minutes. If the combination remains mixed or can be re-mixed readily, it is considered physically compatible. Any physical incompatibility in the jar test indicates that Cyazofamid 400SC should not be used in the tank-mix.

TURF

Cyazofamid 400SC controls Pythium blight and Pythium damping-off and Pythium root dysfunction in turf. Within the rate range given for turf, use the lower rate for the shortest interval and higher rate for the longest interval. Under severe disease conditions, use the highest rate and shortest interval.

Do not apply more than three applications of Cyazofamid 400SC at the high use rate during any growing season. Do not apply more than two consecutive applications of Cyazofamid 400SC. Subsequent applications should be alternated with another registered fungicide with a different mode of action. Do not apply more than 2.7 fl oz/1000 square feet/year (3.0 lb a.i./acre/year).

Disease	Use Rate Fl. Oz. Product per 1,000 sq. ft.	Application Interval (Days)	Remarks
Pythium blight, Pythium damping-off, Pythium root dysfunction	0.45 to 0.9 fl. oz.	14 to 21	Apply as a preventative treatment at 0.45 to 0.9 fl oz in 2 to 4 gallons of water per 1,000 sq. ft. On established turf apply as a preventative treatment when conditions are favorable for disease development, or when first visible disease symptoms appear. During periods of prolonged favorable conditions use 0.45 fl oz on a 14-day interval. For newly seeded areas use 0.45 fl oz in 2 to 4 gallons per 1,000 sq. ft. immediately after seeding. Under severe conditions use the highest rate and the shortest interval.

ORNAMENTALS

Container Grown Plants – Soil Application

For control of damping-off, root and stem rot diseases of ornamentals, including conifers, grown in containers in greenhouses, outdoor nurseries and landscapes, apply Cyazofamid 400SC as a soil drench or soil surface spray. Do not make more than 2 applications of Cyazofamid 400SC per crop cycle for control of Pythium or Phytophthora soil borne diseases. Cyazofamid 400SC may also be applied via irrigation systems as noted below.

For drench applications to containerized plants, use enough of the specified water solution to wet the root zone with minimal run-through. Do not exceed 5% run-through. In general 1 pint of the solution/sq. ft. is sufficient for ornamentals growing in a container with 4-inch depth of growth media. Containers greater than 4-inch depth generally require from 1½ to 2 pints of the solution/sq. ft.

Field Grown (Bed) Plants – Soil Application

For control of damping-off, root and stem rot in field-grown (bed) plants, including forest tree nurseries, with drench applications, use sufficient water solution to allow for penetration into the root zone. For soil surface

applications made in outdoor nurseries, irrigate with at least ½ inch of water if rainfall does not occur within 24 hours. For all field grown (bed) plant applications, apply Cyazofamid 400SC only to the root zone area of the plant at the rate of 6 fl. oz. of Cyazofamid 400SC per 100 gallons. Do not exceed 1000 gallons of this mixture per acre per application (1.56 lbs. a.i./A). Do not make more than 2 applications of Cyazofamid 400SC per year to field grown (bed) plants (3.12 lbs. a.i./A/yr.). Applications may also be applied via drip irrigation as noted below.

Container and Field Grown (Bed) Plants - Foliar Application

For foliar applications, apply sufficient spray solution to thoroughly wet the foliage to the point of run-off (generally not to exceed 100 gallons per acre). Do not apply more than two consecutive applications of Cyazofamid 400SC during any growing season. Cyazofamid 400SC should then be alternated with another registered fungicide with a different mode of action. Do not make more than 4 applications of Cyazofamid 400SC per crop cycle for control of downy mildews or Phytophthora foliar diseases.

Applications of Cyazofamid 400SC should begin when conditions are favorable for disease development or when plants first exhibit disease symptoms, from germination to mature crop.

For Application to Ornamental Plants:

Disease	Product Rate per 100 gallons	Comments
Pythium crown and root rots and damping-off	1.5 to 3.0 fl. oz.	Make applications on a 14 to 28 day interval using another registered fungicide with a different mode of action between applications of Cyazofamid 400SC. Within the rate range, use the lower rate and shortest interval and the higher rate at the longest interval. When disease is severe use the highest rate at the shortest interval. See the rate chart below for application volumes for container grown plants.
Phytophthora crown and root rots and foliar blights.	3.0 to 6.0 fl. oz.	Make applications on a 14 to 28 day interval using another registered fungicide with a different mode of action between applications of Cyazofamid 400SC. Use the shortest interval when disease conditions are severe. See the rate chart below for soil applications to container grown plants. For foliar applications, apply sufficient product to wet all foliage to the point of run-off (generally not to exceed 100 gallons per acre).
Downy mildews	2.1 to 3.5 fl. oz.	Apply on a 14 to 21 day schedule (refer to the additional directions given in the Foliar Application paragraphs above). Within the rate range, use the lower rate at the shortest interval and the higher rate at the longest interval. When disease conditions are severe use the highest rate and shortest interval. Apply sufficient volume (normally 50 to 100 gallons per acre) to wet all foliage to the point of run-off. If water volumes used are less than 50 gallons per acre, an organosilicone surfactant should be added when the disease infection is severe, or a non-ionic surfactant or a blend of an organosilicone and a non-ionic surfactant should be added when disease infection is moderate or light, according to the manufacturer's label recommendations.

For Container Grown Plants:

Pot Diameter (Inches)	Maximum Drench Volume (fl. oz. of drench mixture/pot)
4	2
5	3
6	4
8	10
10	20
12	30

APPLICATION AND CALIBRATION TECHNIQUES FOR DRIP IRRIGATION

Apply this product only through pressurized drip (trickle) systems or micro-irrigation systems such as spaghetti-tube or individual tube irrigation, or ebb and flow systems. DO NOT apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water.

If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.

DO NOT apply Cyazofamid 400SC through irrigation systems connected to a public water system. "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 per year.

Controls for both irrigation water and pesticide injection systems must be functionally interlocked, so as to automatically terminate pesticide injection when the irrigation water pump motor stops. A person knowledgeable of the irrigation system and responsible for its operation shall be present so as to discontinue pesticide injection and make necessary adjustments, should the need arise.

The irrigation water pipeline must be fitted with a functional, automatic, quick-closing check valve to prevent the flow of treated irrigation water back toward the water source. The pipeline must also be fitted with a vacuum relief valve and low-pressure drain, located between the irrigation

water pump and the check valve, to prevent back-siphoning of treated irrigation water into the water source.

Always inject Cyazofamid 400SC into irrigation water after it discharges from the irrigation pump and after it passes through the check valve. Never inject pesticides into the intake line on the suction side of the pump.

Pesticide injection equipment must be fitted with a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump. Interlock this valve to the power system, so as to prevent fluid from being withdrawn from the chemical supply tank when the irrigation system is either automatically or manually turned off.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump. The irrigation line or water pump must include a functional pressure switch that will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.

Spray mixture in the chemical supply tank must be agitated at all times, otherwise settling and uneven application may occur. DO NOT apply when wind speed favors drift beyond the area intended for treatment.

WARRANTY AND LIMITATION OF DAMAGES

Seller warrants to those persons lawfully acquiring title to this product that at the time of first sale of this product by Seller that this product conformed to its chemical description and was reasonably fit for the purposes stated on the label when used in accordance with Seller's directions under normal conditions of use, and Buyers and users of this product assume the risk of any use contrary to such directions. **EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESS REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.** In no event shall Seller's liability for any breach of warranty or guaranty exceed the purchase price of the product as to which a claim is made.

Buyers and users of this product are responsible for all loss or damage from use or handling of this product which results from conditions beyond the control of Seller, including, but not limited to, incompatibility with other products unless otherwise expressly provided in Directions for Use of this product, weather conditions, cultural practices, moisture conditions or other environmental conditions outside of the ranges that are generally recognized as being conducive to good agricultural and/or horticultural practices.

ISK Biosciences Corporation

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