



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 15, 2020

Michael Peplowski
Manager Product Registrations
ISK Biosciences Corporation
7470 Auburn Road, Suite A
Concord, OH 44077

Subject: Notification per PRN 98-10 – additional diseases to the grape section of label
Product Name: Isofetamid-TEB 475SC Fungicide
EPA Registration Number: 71512-31
Application Date: May 12th, 2020
Decision Number: 563521

Dear Peplowski:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, you may contact please contact Andrés Garzón at (703) 347-8547 or by email at GarzonMoreno.Andres@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed in a hand-drawn oval.

Kable Bo Davis
Acting Senior Advisor
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

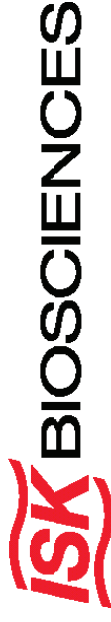
NOTIFICATION

71512-31

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

12/15/2020

GROUP	3	FUNGICIDE
GROUP	7	FUNGICIDE



ISOFETAMID-TEB 475SC

FUNGICIDE

ACTIVE INGREDIENT: Isofetamid* 25.0%
ACTIVE INGREDIENT: Tebuconazole** 18.2%
OTHER INGREDIENTS: 56.8%
Total..... 100.0%

*N-[1,1-dimethyl-2-[2-methyl-4-(1-methylethoxy)phenyl]-2-oxoethyl]-3-methyl-2-thiophenecarboxamide

** α -[2-(4-chlorophenyl)ethyl]- α -(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol

Contains 2.29 pounds isofetamid per gallon (275 grams per liter)
Contains 1.67 pounds tebuconazole per gallon (200 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.

EPA Reg. No. 71512-31

EPA Est. No.

Net Contents:

FIRST AID	
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 a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
HOT LINE NUMBER	
For 24-Hour Medical Emergency Assistance (Human or Animal) Call 1-888-484-7546 .	
For Chemical Emergency , Spill, Leak, Fire or Accident, Call CHEMTREC 1-800-424-9300 .	

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

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.

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.

User Safety Recommendations

Users should:

- Wash hands 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.
- 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.

ENVIRONMENTAL HAZARDS

Isotefamid is toxic to oysters. Tebuconazole is toxic to mammals, fish and aquatic invertebrates. DO NOT apply directly to water, or 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 washwaters or rinsate. Do not apply when weather conditions favor drift from the treated areas. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas.

Ground Water Advisory: Tebuconazole is known to leach through soil into ground water under certain conditions as a result of label use. Use of

this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

Surface Water Advisory: Tebuconazole may contaminate water through drift of spray in wind. Tebuconazole has a high potential for runoff for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to runoff that contains this product. A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted within 48 hours.

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

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container, in a secured, dry, cool place separate from fertilizer, food, and feed. Avoid cross-contamination with other pesticides.

PESTICIDE DISPOSAL: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Nonrefillable container (equal to or less than 5 gallons). DO NOT reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration or, if

allowed by state and local authorities, by burning. If burned, stay out of smoke.

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. To the extent consistent with applicable law, 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. To the extent consistent with applicable law, 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.

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 twelve (12) hours.

PPE required for early entry into 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.

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

PRODUCT INFORMATION

ISOFETAMID is a broad-spectrum fungicide with preventative, systemic and curative properties for foliar and soil-borne diseases. ISOFETAMID must be applied in scheduled protective programs and used in rotation with products with a different mode of action.

TEBUCONAZOLE is a broad-spectrum fungicide with preventative and locally systemic properties for foliar and soil-borne pathogens. TEBUCONAZOLE must be applied in scheduled protective programs and used in rotation with products with a different mode of action.

MIXING AND SPRAYING

This product can be used effectively in dilute or concentrate sprays. Thorough, uniform coverage is essential for disease control.

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

Dosage rates on this label indicate fluid ounces of formulated product per acre, unless otherwise stated. Under conditions highly favorable for

disease development, the highest rate specified and shortest application interval should be used.

This product may be applied with all types of spray equipment normally used for ground and aerial applications. Aerial application is prohibited in the State of New York. Do not apply this product through any type of irrigation system.

The required amount of this product should be added slowly into the spray tank during filling. With concentrate sprays, pre-mix the required amount of this product in a clean container and add to the spray tank as it is being filled. Keep agitator running when filling spray tank and during spray operations. DO NOT allow spray mixture to stand overnight or for prolonged periods. Prepare only the amount of spray required for immediate use. Spraying equipment should be thoroughly cleaned immediately after the application.

Apply this product in sufficient water to obtain adequate coverage of the foliage. Gallonage to be used will vary with crop and amount of plant growth. Spray volume will usually range from 20 to 100 gallons per acre (200 to 1000 liters per hectare) for dilute sprays, and 5 to 10 gallons per acre (50 to 100 liters per hectare) for concentrate ground sprays. For aerial applications, apply this product in a minimum of 5 gallons of water per acre.

TANK MIX COMPATIBILITY

This product is physically compatible (no nozzle or screen blockage) with many products labeled for control of diseases and insects on crops and other additives. Read and follow all manufacturer's label precautions and restrictions 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. This product is generally compatible with other insecticides, fungicides, adjuvants, fertilizers and micronutrient products provided sufficient free water is available for dispersion of all the tank mix products. Under some conditions, the use of adjuvants and surfactants at the rate of 0.025% to 0.1% of the spray tank volume may improve the performance of this product. However, not all crop varieties have been tested with all possible tank mix combinations. Thus the combination should be tested for crop safety on a small portion of the crop to ensure that a phytotoxic response will not occur. In addition, the physical compatibility of this product with tank mix partners must be evaluated before use. Conduct a jar test 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 for 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 this product should not be used in the tank-mix.

ROTATIONAL CROP RESTRICTIONS

Crops on this label may be planted immediately after the last treatment. Do not plant other crops not registered for this product within 120 days after the last application.

INTEGRATED PEST MANAGEMENT

This product is an excellent disease control agent when used according to label directions for control of labeled fungi. This product 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. This product 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. This product's mode/target site of action is complex II; succinate-dehydrogenase, FRAC Group 7 for the Isofetamid portion and C₁₄-demethylase in sterol biosynthesis, FRAC Group 3 for the Tebuconazole portion. A disease management program that includes alternation or tank mixes between this product and other labeled fungicides that have a different mode of action and/or control pathogens not controlled with this product is essential to prevent disease resistant pathogens populations from developing. This product should not be utilized continuously nor tank mixed with fungicides that have shown to have developed fungal resistance to the target disease.

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 this product in

programs that seek to minimize the occurrence of disease resistance. This product is not cross-resistant with other classes of fungicides that have different modes of action.

DIRECTIONS FOR USE			
Crop	Diseases	Use Rate Fl. Oz. Product Per Acre	Instructions
Almond	<p>Brown rot blossom blight (<i>Monilinia</i> spp.)</p> <p>Anthraxnose (<i>Colletotrichum</i> sp.)</p> <p>Green fruit rot (<i>Botrytis cinerea</i>)</p> <p>Shot hole (<i>Wilsonomyces carpophilus</i>)</p> <p>Scab (<i>Cladosporium carpophilum</i>)</p> <p>Alternaria leaf spot (<i>Alternaria alternata</i>)</p> <p>Suppression: Hull rot (<i>Monilinia</i> spp., <i>Rhizopus</i> spp.)</p>	12.5 to 15 fl oz	<p>Application Instructions: Initiate applications for brown rot blossom blight when conditions are favorable for disease development and continue on a 7-14 day interval. Typically applications are started preventatively at pink bud and continued through petal fall.</p> <p>Initiate application for control of anthracnose, gray mold, shot hole, scab, Alternaria leaf spot or suppression of hull rot preventatively and continue as needed on a 7-14 day interval. If disease pressure is severe use the higher rate and shortest interval.</p> <p>Apply this product in sufficient water to obtain adequate coverage of the foliage. Spray volume will usually be 50 to 100 gallons per acre for dilute sprays and 5 to 10 gallons per acre for aerial sprays. For aerial applications, apply this product in a minimum of 5 gallons of water per acre. For dilute sprays, if higher spray volumes are desired for improved coverage, do not exceed the maximum rate of 15 fl oz of product per acre.</p> <p>Resistance Management: Do not make more than 2 sequential applications of this product or other Group 3 or Group 7 containing fungicide before rotating to a fungicide with a different mode of action. Do not apply a third application of this product within 14 days of the second application.</p> <p>Restrictions: Do Not apply more than 63 fl oz/A/year. The pre-harvest interval (PHI) for this crop is 40 days. Do Not apply more than the maximum yearly rate from any combination of products containing Isofetamid (1.77 lb. a.i. per acre per year) or Tebuconazole (0.9 lb. a.i. per acre per year) to this crop.</p>

Crop	Diseases	Use Rate Fl. Oz. Product Per Acre	Instructions
Crop Subgroup 13-07F (Grapes)	Powdery mildew (<i>Erysiphe necator</i>) <u>Black rot</u> (<i>Guignardia bidwellii</i>) <u>Phomopsis cane and leaf spot</u> (<i>Phomopsis viticola</i>) <u>Suppression:</u> Botrytis bunch rot (<i>Botrytis cinerea</i>)	8.5 fl oz	<p>Application Instructions: For use on all types of grapes (wine, table, raisin, and juice).</p> <p>For powdery mildew, <u>black rot</u>, <u>Phomopsis cane and leaf spot</u>, begin fungicide applications preventatively and continue as needed on a 21-day interval. When disease pressure is severe use a shorter interval.</p> <p>For bunch rot make applications at critical timings for Botrytis suppression. Applications are typically made at early bloom, bunch closure, veraison and pre-harvest (at least 14 days apart). Apply with sufficient water to allow for penetration into the foliage to obtain complete coverage using 50 to 100 gallons of spray volume per acre. This product will need to be combined with another registered fungicide for full bunch rot control.</p> <p>Resistance Management: Do not make more than 2 sequential applications of this product or other Group 3 or Group 7 containing fungicides before rotating to a fungicide with a different mode of action. Do not apply a third application of this product within 28 days of the second application.</p> <p>Restrictions: Do Not apply more than 25.5 fl oz/A/year The Pre-Harvest Interval (PHI) for this crop is 14 days. This product may be applied via aerial application equipment except in the State of New York. Do Not apply more than the maximum yearly rate from any combination of products containing Isofetamid (1.72 lb. a.i. per acre per year) or Tebuconazole (0.9 lb. a.i. per acre per year) to these crops.</p>
Includes all members of the Fruit, Small Vine Climbing Crop Subgroup 13-07F, except fuzzy kiwifruit: Amur river grape; gooseberry; grape; kiwifruit, hardy; maypop; schisandra berry; and cultivars, varieties, and/or hybrids of these.			

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