



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

January 28, 2026

Billie Espejo
Regulatory Fellow
Janssen PMP
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Subject: Label Amendment - Registration Review Mitigation for Imazalil and Imazalil Sulfate
Product Name: FUNGAFLOR 500 EC
EPA Registration Number: 43813-6
Case Number: 482653
Application Dates: June 22, 2021

Dear Billie Espejo:

The Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Imazalil and Imazalil Sulfate Interim Decision, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

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 Assurance.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling and must be used at your next label printing. You must

submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 12 months from the date of this letter. After 12 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

If you have any questions about this letter, please contact Kelsi Grogan by phone at 202-566-2228, or via email at grogan.kelsi@epa.gov.

Sincerely,

A handwritten signature in dark ink, appearing to read "Kevin Costello", is positioned above the typed name.

Kevin Costello, Branch Chief
Risk Management and Implementation Branch 2
Pesticide Re-Evaluation Division
Office of Pesticide Programs

ENCLOSURE: Stamped label

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

DANGER

PELIGRO

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE):

All mixers, loaders, applicators, and other handlers must wear:

- Protective eyewear (goggles, face shield, safety glasses)
- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical resistant gloves, except for bag sewers, seed planters, truck drivers, and sorters.
- Chemical resistant apron when mixing/loading, cleaning up spills, cleaning equipment, or otherwise exposed to the concentrate.

Some materials that are chemical-resistant to this product are butyl rubber, nitrile rubber, neoprene rubber, PVC, viton, or barrier laminate.

USER SAFETY REQUIREMENTS:

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, 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. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should 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

This chemical is toxic to fish. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff from the treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when cleaning equipment or disposing of equipment wash waters or rinsate. Apply this product only as specified on the label.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool dry place.

PESTICIDE DISPOSAL: Pesticide wastes are acutely 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 Regional Office for guidance.

CONTAINER DISPOSAL

Non-refillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows:

[For containers ≤ 5 gallons in size] - 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.

[For containers > 5 gallons in size] - Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

DIRECTIONS FOR USE:

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

FUNGICIDE RESISTANCE MANAGEMENT:

| | | | |
|----------|-------|---|-----------|
| IMAZALIL | GROUP | 3 | FUNGICIDE |
|----------|-------|---|-----------|

FUNGAFLOR 500 EC is an imidazole fungicide in the Group 3 class of fungicides that inhibits sterol biosynthesis which results in disruption of membrane structure and function, thus affecting cell wall permeability. Because resistance development cannot be predicted, postharvest resistance management strategies and sanitation practices should be followed. Fungal isolates with acquired resistance to Group 3 fungicides, may eventually dominate the fungal population if



IMAZALIL

GROUP

3

FUNGICIDE

Fungaflo[®] 500 EC

An Emulsifiable Concentrate for
Post-harvest treatment of Citrus Fruits

ACTIVE INGREDIENT: (w/w)

IMAZALIL: 1-(2-(2,4-dichlorophenyl)-
-2-(2-propenyloxy)ethyl)-1H-imidazole*..... 44.6%

INERT INGREDIENTS: (w/w)..... 55.4%

TOTAL..... 100.0%

Contains 4.17 lbs. active ingredient/gal.

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

Si usted no entiende la etiqueta, busque a alguien
para que se la explique a usted en detalle.
(If you do not understand the label, find someone
to explain it to you in detail)

See side panel for additional precautionary statements

| FIRST AID | |
|--|--|
| If in eyes | - 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 eye. - Call a poison control center or doctor for treatment advice. |
| If swallowed | - 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. |
| If on skin or clothing | - Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for treatment advice. |
| If inhaled | - Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. - Call a poison control center or doctor for further treatment advice. |
| HOT LINE NUMBER: For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents) call the National Pesticide Telecommunications Network at 1-800-858-7378. For chemical emergency assistance (spill, leak, fire, or accident), call Chem Trec at 1-800-424-9300. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| NOTE TO PHYSICIAN Probable mucosal damage may contraindicate the use of gastric lavage. | |

NET CONTENTS:

EPA REG. NO. 43813-6

EPA EST. No.



Janssen PMP
Preservation and Material Protection
A division of Janssen Pharmaceutica NV
1125 Trenton-Harbourton Rd.
Titusville, NJ 08050

Group 3 fungicides are used repeatedly or in successive years as the primary method of disease control for the targeted pathogens. This may result in partial or total loss of control of those fungal species with imazali or other Group 3 fungicides. A disease management program that includes alternation or tank mixes between FUNGAFLOR 500 EC and other labeled fungicides that have a different mode of action, may prevent pathogen populations from developing resistance.

To delay fungicide resistance, take one or more of the following steps:

- Rotate the use of imazali or other Group 3 fungicides, during a growing season sequence, such as long-term storage and prior to extended transport conditions, with different fungicide groups that control the same pathogens and in which the pathogen population is still highly sensitive to that fungicide or fungicide Group.
- Use tank mixtures or alternate with combination products containing fungicides from different fungicide groups that are equally effective when such use is permitted. Use at least the minimum application rate as labeled by the manufacturer.
- Adopt an integrated disease management program for fungicide use that includes monitoring fungal populations in the packinghouse and fruit storage rooms for resistance development using different available sensitivity monitoring techniques, historical information related to pesticide use, impact of packinghouse storage conditions on disease development and thresholds, as well as cultural, biological and other chemical control practices.
- Where possible and practical, make use of predictive disease models to effectively time fungicide applications. Note that using predictive models alone is not sufficient to manage resistance.
- Contact your local service company, Janssen PMP, or your local extension specialist for information on packinghouse spore monitoring programs and for any additional resistance management and/or Integrated Pest Management (IPM) recommendations for specific crops and pathogens.
- For further information, or to report suspected resistance contact Janssen PMP at info@janssenpmp.com. You can also contact your pesticide distributor service company or university extension specialist to report resistance.

GENERAL PRECAUTIONS AND RESTRICTIONS:

Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application.

Application Restrictions for Citrus Drench:

Do not enter or allow others to enter the treatment area until the citrus is treated and completely drained.

The windows and doors of the transport vehicle must be closed prior to and during treatment.

Citrus Fruits: Intended for post-harvest control of Penicillium digitatum (green mold), Penicillium italicum (blue mold), Diaporthe citri (phomopsis stem and rot), Diplodia natalensis (diploia rot) and Alternaria citri on citrus fruits.

Used as directed, FUNGAFLOR 500 EC has curative and preventative action as well as antisporeulation properties.

DOSE RECOMMENDATIONS:

In dips, wash tanks, and drenchers: Apply FUNGAFLOR 500 EC at rates of 12.8-19.2 fl. oz. per 100 gallons water (500-750 ppm active ingredient). The treatment solutions should be inspected periodically to insure the proper concentration of active ingredient. Length of dip time should not exceed two minutes.

In non-recovery spray: Apply FUNGAFLOR 500 EC at 25.5 fl.oz. per 100 gal water (1000 ppm a.i.). Apply to freshly-cleaned citrus immediately prior to waxing.

For water spray brush application: After washing, apply FUNGAFLOR 500 EC at 25.5 fl.oz. per 100 gal water (1000 ppm a.i.). Apply prior to storage wax application.

In citrus wax: Apply 51.1 fl.oz. of FUNGAFLOR 500 EC to 100 gal of citrus wax (2000 ppm a.i.). Use without further dilution in conventional waxing equipment.

Remark 1: Combinations of above-listed treatments are possible, but never more than two treatments should be carried out on the same citrus lot.

Remark 2: In waxes, sporulation control can be obtained, at the rate of 102.2 fl.oz. FUNGAFLOR 500 EC per 100 gallons citrus wax or diluted "ready to use" detergent material (4000 ppm a.i.). When this dilution is used, combinations of treatments are not allowed.

Remark 3: AFTER DILUTION OF FUNGAFLOR 500 EC IN WAX, STIR THOROUGHLY FOR AT LEAST 15 MINUTES WITH A MIXING DEVICE AT 1500 RPM.

NOTICE OF WARRANTY

Janssen PMP, a Division of Janssen Pharmaceutica NV warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with the directions under normal use conditions. It is impossible to eliminate all risks inherently associated with the 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 Janssen PMP. To the extent permitted by law, Janssen PMP disclaims any liability for consequential, special or indirect damages resulting from the use or handling of this product. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, JANSSEN PMP MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OF IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

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