



## 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: PHILABUSTER 400 SC  
EPA Registration Number: 43813-38  
Case Number: 475031  
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](mailto:grogan.kelsi@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin Costello".

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.

HANDLER PERSONAL PROTECTIVE EQUIPMENT (PPE)

Wear protective eyewear (goggles, face shield, or safety glasses). Wear long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves.

PESTICIDE USER SAFETY REQUIREMENTS

Follow the 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. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

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 and wash contaminated clothing before reuse. If pesticide gets inside clothing PPE, remove immediately, wash thoroughly, and put on clean clothing. Wash the outside of gloves before removing.

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 water by cleaning of equipment, or disposal of wastes. Apply this product only as specified on this 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 in the original container away from food and feed.

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 EPA Regional Office for guidance.

CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) 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 1/4 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 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
PYRIMETHANIL	GROUP	9	FUNGICIDE

PHILABUSTER 400 SC combines the active ingredients imazalil sulfate and pyrimethanil, two fungicides with different modes of action, into a single product to facilitate adoption of resistance management strategies in postharvest disease control. Pyrimethanil is an anilinopyrimidine fungicide (Group 9 Fungicide) that interferes with the secretion of enzymes necessary for infection by several postharvest pathogens, while imazalil sulfate is an imidazole fungicide (Group 3 Fungicide) that inhibits sterol synthesis, 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 or Group 9 fungicides, may eventually dominate the fungal population if Group 3 or Group 9 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 imazalil or pyrimethanil or other Group 3 or Group 9 fungicides. A disease management program that includes alternation or tank mixes between PHILABUSTER 400 SC 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 imazalil or other Group 3 fungicides and pyrimethanil or other Group 9 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

IMAZALIL	GROUP	3	FUNGICIDE
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# PHILABUSTER™ 400 SC

For postharvest use on citrus fruits

Active Ingredient:

Pyrimethanil: 4,6-dimethyl-N-phenyl-2-pyrimidinamine*	17.21%
Imazalil sulfate: ±1-(2-(4-dichlorophenyl)-2-(2-propenyl)oxy)ethyl)-1H-imidazole sulfate	22.95%
Other Ingredients: .....	59.84%
<b>TOTAL</b>	100.0%

Contains 1.7 and 2.2 lbs. pyrimethanil and imazalil sulfate, respectively per gallon.

## 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.)

FIRST AID	
If 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.	If on skin - 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 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 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 ChemTrec 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. 43813-38

EPA EST. NO.

  
**JANSSEN PMP**  
PRESERVATION AND MATERIAL PROTECTION  
a division of Janssen Pharmaceutica NV  
1125 Trenton-Harbourton Rd.  
Titusville, NJ 08560-0200

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.

MIXING INSTRUCTIONS

Fill tank with half of the required amount of water or pre-diluted storage (water) wax and start mechanical agitation. Slowly add the required amount of PHILABUSTER 400 SC and then add the remaining volume of water or diluted storage wax. Slow addition of the PHILABUSTER 400 SC to the water or pre-diluted storage wax is important to achieve a high level of suspension. Maintain agitation after mixing and during application. Begin application with the treating solution only after the PHILABUSTER 400 SC has completely and uniformly dispersed into the mix carrier. Do not allow treating solution to stand overnight or for prolonged periods. For in-line injection systems better distribution will be achieved by injecting a larger volume of a more dilute solution per unit of time. The physical compatibility of PHILABUSTER 400 SC with all tank mix partners and storage waxes has not been fully investigated. Prior to tank mixing, conduct a jar test with the volumes and rates typically used for postharvest disease control. Add proportionate amounts of the products to a small container of water or diluted storage wax in the following order: Wettable powders and water-dispersible granules first, followed by liquid flowables, and emulsifiable concentrates last. After thorough mixing, let stand for at least 15 minutes. Separation, globules, sludge, flakes or other precipitates are indicative of physical incompatibility. Physical compatibility is indicated if the combination remains mixed or can be remixed readily. Once compatibility has been proven, use the same procedure for adding the required ingredients to the larger mix tank. THE CROP SAFETY OF ALL POTENTIAL PESTICIDE TANK MIXES WITH PHILABUSTER 400 SC INCLUDING STORAGE WAXES, HAS NOT BEEN TESTED ON ALL CROPS AND VARIETIES. BEFORE APPLYING ANY TANK MIXTURE, SAFETY TO THE TARGET CROP SHOULD BE CONFIRMED.

If using PHILABUSTER 400 SC in a tank mixture, observe all directions for use, crop/sites, use rates, dilution ratios, precautions, and limitations that appear on the tank mix product label. No label dosage rates should be exceeded, and the most restrictive label precautions and limitations should be followed. **Tank mixtures are permitted only in those states where the tank mix partner is registered.**

CROP USE DIRECTIONS

Citrus Fruit Crop Group - includes the commodities Calamondin, Citrus citron, Grapefruit, Kumquat, Lemon, Lime, Mandarin, Orange (sweet & sour), Pummelo, and Satsuma mandarin. Use PHILABUSTER 400 SC fungicide for the control of the following postharvest diseases caused by *Penicillium italicum* (blue mold), *Penicillium digitatum* (green mold), *Colletotrichum gloeosporioides* (anthracnose) and *Phomopsis citri* / *Diaporthe citri* (stem-end rot) on citrus fruits. Use of PHILABUSTER 400 SC should be integrated into an overall disease management program within each packinghouse. Provides curative and preventative activity - treat fruit within the same day of picking. For suppression of sporulation, use the highest labeled rate.

FOR USE IN DILUTED STORAGE WAX AND AQUEOUS APPLICATIONS ONLY. NOT FOR USE IN PACK OR FINISHING WAXES.

Dip and Wash Tank Application: Mix 16 - 48 fl. oz. of PHILABUSTER 400 SC in 100 gallons of water. Treating time should not exceed 2 minutes.

Drench: Mix 16 - 48 fl. oz. of PHILABUSTER 400 SC in 100 gallons of water. Drench cycle should not exceed 4 minutes.

Aqueous Line Spray Application: Mix 32 - 64 fl. oz. of PHILABUSTER 400 SC in 100 gallons of water and apply to fruit over conveyor rollers or brushes using T-jet, control droplet applicator (CDA), flood/shower, drip or similar systems. Apply at the rate of 1 gallon per 7,500 -10,000 lbs. of fruit.

Storage Wax Line Spray Application: Mix 64 - 128 fl. oz. of PHILABUSTER 400 SC in 100 gallons of diluted storage wax and apply to fruit over conveyor rollers or brushes using T-jet, control droplet applicator (CDA), drip or similar systems. Apply at the rate of 1 gallon per 3,800 lbs. of fruit.

Periodically measure the concentration of the active ingredients in the treating solutions from drenchers, dip and wash tanks, and recovery spray systems to maintain the proper level of active ingredient. Aqueous applications must be applied prior to fruit receiving any wax applications.

Citrus fruit from the same lot may not receive more than two treatment combinations.

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 OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

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\* Pyrimethanil manufactured by Bayer CropScience.

ACCEPTED

Jan 28, 2026

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under  
EPA Reg. No. 43813-38