



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

February 18, 2015

William Goodwine
Director, WW Regulatory Affairs and Risk Assessment
Janssen PMP
Janssen Pharmaceutica NV
1125 Trenton-Harbourton Road
Titusville, NJ 80560-0200

Subject: PRIA Label Amendment- adding new use on pomegranate (post-harvest, in-line dip/drench, wash tanks)
Product Name: Penbotec 400 SC
EPA Registration No. 43813-32
Application Date: 9/12/2013; Resubmission Date: 2/11/2015
Decision No. 484375

Dear Mr. Goodwine:

The application referred to above, submitted under the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable under FIFRA sec 3 (c)(5). You must submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) 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 18 months from the date of this letter. After 18 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.

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.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Tamue L. Gibson by phone at (703) 305-9096 or via email at gibson.tamue@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to be 'HJ', written over a circular scribble.

Hope Johnson, Product Manager 21
Fungicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Attachment

PENBOTEC® 400 SC

For postharvest use on citrus, pome and stone fruit crop groups and pomegranates

Active Ingredient:

Pyrimethanil: 4,6-dimethyl-N-phenyl-2-pyrimidinamine* 37.14%

Other Ingredients: 62.86%

Total: 100.00%

Contains 3.27 lbs. active ingredient per gallon (400 g/L)

KEEP OUT OF REACH OF CHILDREN

CAUTION

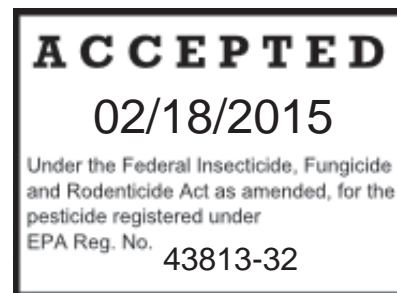
FIRST AID	
If on skin	-Take off contaminated clothing. -Rinse skin immediately with plenty of water for 15-20 minutes. -Call a poison control center or doctor for treatment advice.
If inhaled	-Move person to fresh air. -If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. -Call a poison control center or doctor for further treatment advice
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.
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.	

NET CONTENTS: 33.8 fl. oz. (1 liter)

EPA REG. NO. 43813-32
EPA EST. No.: 074263-DEU-001

Manufactured for:

JANSSEN PMP
a Division of Janssen Pharmaceutica NV
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200



PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Harmful if absorbed through skin, inhaled or swallowed. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE)

Wear long-sleeved shirt and long pants, socks, shoes and chemical-resistant gloves (Natural Rubber, Selection Category A).

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.

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.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Apply this product only as specified on this label.

STORAGE AND DISPOSAL

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

STORAGE: Store in original containers only. Keep container closed when not in use. Do not store near food or feed. In case of spill of spill on floor or other hard surfaces, mop and remove to chemical waste storage area until proper disposal can be made if product cannot be used according to the label. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Nonrefillable container. 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. Offer for recycling, if available, 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.

PRODUCT INFORMATION:

Pome Fruit: For the control of blue mold (*Penicillium expansum*), gray mold (*Botrytis cinerea*), Phacidiopycnis rot (*Phacidiopycnis piri*), and bull's eye rot (*Neofabraea perennans* & *N. malicorticis*).

Citrus Fruit: When applied in aqueous treating systems or when applied in diluted storage wax PENBOTEC 400 SC provides control of blue mold (*Penicillium italicum*) and green mold (*Penicillium digitatum*). In citrus pack waxes, PENBOTEC 400 SC provides suppression of both green and blue mold.

Stone Fruit: For the control of brown rot (*Monilinia*) and gray mold (*Botrytis cinerea*).

Pomegranate: For the control of Botrytis fruit rot (*Botrytis cinerea*).

Use of PENBOTEC 400 SC should be integrated into an overall disease management program within each packinghouse.

FUNGICIDE RESISTANCE MANAGEMENT

GROUP 9 FUNGICIDE

PENBOTEC 400 SC is an anilinopyrimidine fungicide that does not exhibit cross-resistance to sterol-inhibiting or benzimidazole fungicides. PENBOTEC 400 SC interferes with the secretion of enzymes necessary for infection by several postharvest pathogens, therefore, preventative applications soon after harvest or injury is necessary for optimal product performance. Fungal pathogens can develop resistance to products with the same mode of action when used repeatedly. Because resistance development cannot be predicted, use of postharvest resistance management strategies should be practiced. These may include rotating and/or tank mixing with products having different modes of action. Responsible resistance management practices are necessary to ensure the long-term effectiveness for decay control.

MIXING INSTRUCTIONS

Fill tank with half of the required amount of water or water wax and start mechanical agitation. Add the required amount of PENBOTEC 400 SC and then add the remaining volume of water or water wax. Maintain agitation after mixing and 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 PENBOTEC 400 SC with all tank mix partners and wax types has not been fully investigated. This product cannot be mixed with any product containing a label prohibition against such mixing. Follow the more restrictive labeling requirements of any tank mix partner. No label dosage rates for the individual products may be exceeded. Prior to tank mixing with PENBOTEC 400 SC, 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 water 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. THE CROP SAFETY OF ALL POTENTIAL PESTICIDE TANK MIXES WITH

PENBOTEC 400 SC INCLUDING ANTI-SCALD AGENTS AND WAXES, HAS NOT BEEN TESTED ON ALL CROPS AND VARIETIES. BEFORE APPLYING ANY TANK MIXTURE, CONFIRM SAFETY TO THE TARGET CROP BEFORE USE.

USE RATES:

<i>CITRUS FRUITS: Calamondin, Citrus citron, Citrus hybrids (includes chironja, tangelo & tangor), Grapefruit, Kumquat, Lemon, Lime, Mandarin, Orange (sour & sweet), Pummelo, Satsuma mandarin, tangerine, and all cultivars and hybrids</i>			
Treatment Method	Rate fl.oz/100 gal	Treatment Time (min)	Concentration A.I. (ppm)
Dip, wash tanks	32	2	1000
Drenchers	16	2-4	500
Aqueous line spray	64	1	2000
Wax line spray: Storage & Pack Wax	64	1	2000

<i>POME FRUITS: Apples, Crabapple, Loquat, Mayhaw, Pear, Oriental pear, Quince</i>			
Treatment Method	Rate fl.oz/100 gal	Treatment Time (min)	Concentration A.I. (ppm)
Dip, wash tanks	16 – 32	1	500-1000
Drenchers	16 - 32	1	500-1000
Aqueous line spray	32	1	1000
Wax line spray	64	1	2000

<i>STONE FRUITS: Apricot, Cherry (sweet & tart), Nectarine, Peach, Plum (including Chickasaw, Damson, & Japanese), Plumcot, Prune (fresh)</i>			
Treatment Method	Rate	Treatment Time (min)	Concentration A.I. (ppm)
Dip tanks	16 fl. oz./100 gal	0.5 (30 sec)	500
High volume line spray nozzle or flood application (aqueous/ water-wax/wax-oil emulsion)	16 fl. oz./100 gal	0.5 (30 sec)	500
<i>STONE FRUITS EXCEPT CHERRIES: Apricot, Nectarine, Peach, Plum (including Chickasaw, Damson, & Japanese), Plumcot and Prune (fresh)</i>			
Low volume line spray nozzle application (i.e. CDA) (aqueous/water-wax/wax oil emulsion)	33.8 fl.oz per 80–120 gal	400 g AI per 200,000 lbs fruit (4 g AI/ton fruit)	

<i>POMEGRANATES</i>			
Treatment Method	Rate	Treatment Time (min)	Concentration A.I. (ppm)
In-line Dip/Drench, wash tanks	32 fl. oz./100 gal	1	1000

(aqueous/water-wax/wax oil emulsion)			
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Periodically measure the PENBOTEC 400 SC concentration of the treating solutions from drenchers, dips and wash tanks to maintain the proper level of PENBOTEC 400 SC. Clean citrus fruits treated by aqueous or wax line spray applications prior to application. Aqueous applications must be applied prior to fruit receiving any wax applications. Pre-dilute the citrus storage wax to the specified use rate of the wax prior to addition of the PENBOTEC 400 SC fungicide.

Restrictions

- PENBOTEC 400 SC may be applied to citrus fruits by a maximum combination of three application methods.
- For pome fruits, a maximum combination of two application methods may be used.
- For pomegranate and stone fruits, do not make more than a single application.

Acceptable treatment scenarios are presented below:

Treatment Scenario	PENBOTEC 400 SC Application Methods				
	Drench	Dip & Wash tanks	Aqueous spray	Storage Wax	Shipping Wax
CITRUS FRUITS: Calamondin, Citrus citron, Citrus hybrids (includes chironja, tangelo & tangor), Grapefruit, Kumquat, Lemon, Lime, Mandarin, Orange (sour & sweet), Pummelo, Satsuma mandarin, tangerine, and all cultivars and hybrids					
1	√			√	
2	√			√	√
3	√	√		√	
4				√	√
5		√		√	
6	√				√
7		√			√
8	√	√			
9	√	√			√
10			√		√
11	√		√		
12	√		√		√
POME FRUITS: Apples, Crabapple, Loquat, Mayhaw, Pear, Oriental pear, Quince					
1	√	√			
2	√		√		
3	√				√
4		√			√
5			√		√
6		√	√		

Treatment Scenario	Dip tanks	High volume line application (i.e. flooder)	Low volume line application (i.e. controlled droplet applicator)
STONE FRUITS: Apricot, Cherry (sweet & tart), Nectarine, Peach, Plum (including Chickasaw, Damson, & Japanese), Plumcot, Prune (fresh)			
1	√		
2		√	
3			√ (except cherries)
POMEGRANATES:			
Treatment Scenario	In-Line Dip/Drench wash tanks		
1	√		

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 other than as specified on the label, 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, handling, application, storage or disposal of this product or for damages in the nature of penalties, and the buyer and user waive any right that they may have to such damages. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, JANSSEN PMP MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OF IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

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* Pyrimethanil manufactured by Bayer CropScience AG

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