

43813-32

08-06-2009

Sheet 1
7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

William Goodwine
Senior Director
Janssen PMP
Janssen Pharmaceutica NV
Titusville, NJ 80560-0200

AUG 06 2009

Subject: Penbotec 400 SC
EPA Registration No. 43813-32
Your Amendment dated April 10, 2008, New use stone fruit and citrus
PRIA Decision No. 393115

Dear Mr. Goodwine:

The labeling referred to above, submitted in connection with registration under section under 3(c)(7)(b) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is acceptable.

- 1) On page 4, in the third table, change "ALL STONE FRUITS" to "STONE FRUITS".
- 2) On page 5, revise the second bullet under "Treatment Schemes" to read "For pome fruits, a maximum combination of two application methods may be used."
- 3) On page 6, revise the last sentence by adding the word "makes" so that the sentence reads as follows: "To the extent consistent...Janseen PMP makes no..."

One copy of the label stamped "Accepted with Comments" is enclosed for your records. This label supersedes all labels previously accepted for this product. Please submit one copy of the final printed label before the product is released for shipment. 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 cursive script that reads "Mary L. Waller".

Mary L. Waller
Product Manager (21)
Fungicide Branch
Registration Division (7505P)

Enclosure

PENBOTEC® 400 SC

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

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

**ACCEPTED
with COMMENTS
In EPA Letter Dated:
AUG 06 2009**

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
43813-32**

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS**

CAUTION

Harmful if swallowed, inhaled or absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves (such as Natural Rubber, Selection Category A). Remove and wash contaminated clothing before reuse. Avoid breathing spray mist.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

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.

PESTICIDE STORAGE AND DISPOSAL

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

PESTICIDE 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 DISPOSAL: 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.

GENERAL INFORMATION:

Pome Fruit: For the control of blue mold (*Penicillium expansum*), gray mold (*Botrytis cinerea*) and Phacidiopycnis rot (*Phacidiopycnis pir*).

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*).

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:

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			
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

POME FRUITS: Apples, Crabapple, Loquat, Mayhaw, Pear, Oriental pear, Quince			
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

ALL STONE FRUITS: Apricot, Cherry (sweet & tart), Nectarine, Peach, Plum (including Ccickasaw, Damson, & Japanese), Plumcot, Prune (fresh)			
Treatment Method	Rate fl.oz/100 gal	Treatment Time (min)	Concentration A.I. (ppm)
Dip tanks	16	0.5 (30 sec)	500
High volume line application (i.e. flooder) (aqueous/ water-wax/wax-oil emulsion)	16	0.5 (30 sec)	500
STONE FRUITS EXCEPT CHERRIES: Apricot, Nectarine, Peach, Plum (including Ccickasaw, Damson, & Japanese), Plumcot and Prune (fresh)			
Low volume line application (i.e. CDA) (aqueous/water-wax/wax oil emulsion)	64 (½ gallon)	0.5 (30 sec)	2000

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.

Treatment Schemes

- PENBOTEC 400 SC may be applied to citrus fruits by a maximum combination of three application methods.
- Double treatment is the maximum allowed on pome fruits.
- For 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 Ccickasaw, Damson, & Japanese), Plumcot, Prune (fresh)			
1	√		
2		√	
3			√ (except cherries)

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 NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OF IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

® Registered trademark of Janssen Pharmaceutica N.V.

* Pyrimethanil manufactured by Bayer CropScience AG

Rev . 07/09