

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 17, 2020

Mr. William R. Goodwine Regulatory Fellow Divison of Janssen Pharmaceutica, NV Janssen PMP 1125 Trenton – Harbourton Road Titusville, NJ 08560-0200

Subject: Label Notification per PRN 2007-4 – Container Label Statement Product Name: Fungaflor Technical EPA Registration Number: 43813-2 Application Date: March 18, 2020 Decision Number: 561778

Dear Mr. Goodwine:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 2007-4 and finds that the action requested falls within the scope of PRN-2007-4.

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

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on <u>non-refillable</u> containers. The code may appear either on the label (and can be added by non-notification via PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact BeWanda Alexander at (703)347-0313 or by email at alexander.bewanda@epa.gov.

Sincerely,

: the

Erik Kraft, Product Manager 24 Fungicide and Herbicide Branch Registration Division (7505P) Office of Pesticide Programs

FUNGAFLOR® Technical

ACTIVE INGREDIENT: (w/w) Imazalil: 1-[2-(2,4-dichlorophenyl) -2-(2-propenyloxy)ethyl]-1H-imidazole OTHER INGREDIENTS TOTAL

98.94 % 1.06 % 100.00 % NOTIFICATION

43813-2

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:

04/17/2020

FOR MANUFACTURING USE ONLY

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 detaile.

(If you do not understand the label, find someone to explain it to you in detail)

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.
lf on skin or	-Take off contaminated clothing.
clothing	-Rinse skin immediately with plenty of water for 15-20 minutes.
	-Call a poison control center or doctor for 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: 110 lbs./50 Kgs.

EPA Reg. No. 43813-2 EPA Est. No.

Manufactured for:

JANSSEN PMP

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

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes irreversible eye damage. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes, or on clothing. Avoid contact with skin. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

Wear goggles or face shield. Wear protective clothing and chemical resistant gloves made of any waterproof material. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

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.

Only for formulation into a fungicide for the following uses: postharvest application to citrus fruits. This product may be used to formulate products for any additional uses not listed on the manufacturing product label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses. Each formulator is responsible for obtaining EPA registration for his end use product(s).

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 EPA Regional Office for guidance.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse (or equivalent). Then offer for recycling or reconditioning, 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.

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. 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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