



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

February 8, 2018

Mr. William R. Goodwine  
Director, WW Reg. Affairs  
Division of Janssen Pharmaceutica NV  
Janssen PMP  
1125 Trenton-Harbourton Road  
Titusville, NJ 08560

Subject: Label Amendment – minor label changes  
Product Name: Fungaflor 75 SP  
EPA Registration Number: 43813-4  
Application Date: October 26, 2017 & December 8, 2017  
Decision Numbers: 537953 & 536454

Dear Mr. Goodwine:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. 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 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.

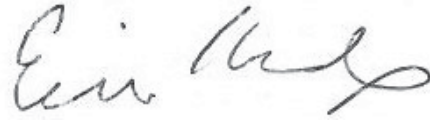
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded 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.

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

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with FIFRA section 6. If you have any questions, please contact BeWanda Alexander by phone at (703)347-0313, or via email at [alexander.bewanda@epa.gov](mailto:alexander.bewanda@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Erik Kraft". The signature is fluid and cursive, with a large initial "E" and a long, sweeping tail.

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

Enclosure

# FUNGAFLOR<sup>®</sup> 75 SP

Soluble powder for manufacturing use only

ACTIVE INGREDIENT: (w/w)

Imazalil sulfate: 1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy) ethyl)-1H-imidazole sulfate\* .....100%

(Equivalent to 75% Imazalil base)

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

<b>FIRST AID</b>	
<b>If in eyes</b>	-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.
<b>If swallowed</b>	-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.
<b>If inhaled</b>	-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.
<b>If on skin or clothing</b>	-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.
<b>HOT LINE NUMBER:</b> 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.	
<b>NOTE TO PHYSICIAN</b> Probable mucosal damage may contraindicate the use of gastric lavage.	

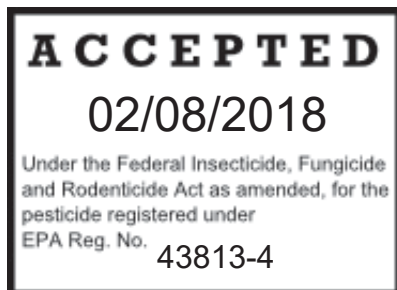
EPA REG. NO. 43813-4

EPA EST. NO. 43813-BL-2

NET CONTENTS: 55 lbs. (25 kg.)

**JANSSEN PMP**

a Division of Janssen Pharmaceutica NV  
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## **PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS**

### **DANGER**

Corrosive. Causes irreversible eye damage. May be fatal if swallowed or inhaled. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Do not breathe dust.

#### **PERSONAL PROTECTIVE EQUIPMENT (PPE)**

Handlers must wear goggles or face shield, long-sleeved shirt and long pants, shoes, socks, and chemical resistant gloves made of any waterproof material, such as natural rubber, polyethylene, PVC, neoprene rubber, nitrile rubber, or butyl rubber. Wear a minimum of a NIOSH approved filtering face piece respirator with any N filter (TC-84A). You can also use other NIOSH approved particulate respirators that offer more protection. For more information, see [www.epa.gov/pesticide-respirators](http://www.epa.gov/pesticide-respirators).

#### **USER SAFETY RECOMMENDATIONS**

Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. 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.

#### **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 DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows:

[For plastic containers  $\leq$  5 gallons in size] – Empty the remaining contents into application equipment or a mix tank. Fill the container  $\frac{1}{4}$  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.

For fiber drums or paperboard containers with plastic liners, triple rinse directions do not apply. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

**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).

**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 consistent with applicable 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.

\*Active Ingredient manufactured by Janssen Pharmaceutica NV  
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Date: 08Feb2018