



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

August 12, 2024

Casey Pehrson
Authorized Agent for Otsuka Pharmaceutical Co., Ltd
1150 Connecticut Ave. NW Suite 1100
Washington, DC 20036

Subject: Pesticide Registration Improvement Act (PRIA) Labeling Amendment – To support the use of new containers, to modify product storage and disposal language, and to add a producer to the label
Product Name: OPC-721
EPA Registration Number: 92918-2
EPA Receipt Date: 12/23/2023
Action Case Number: 00497179

Dear Casey Pehrson:

The amended labeling 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 terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or 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 (1) copy of the final printed labeling before you release this 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 your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the 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 EPA find or if it is brought to our attention that a website contains or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

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Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Hector Andres Maldonado by phone at (202) 566-1373 or via email at maldonado.hector@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Cody Kendrick". The signature is written in a cursive, flowing style.

Cody Kendrick, Senior Regulatory Advisor
Microbial Pesticide Branch
Biopesticides and Pollution
Prevention Division (7511M)
Office of Pesticide Programs

Enclosure (EPA's Science Memorandum dated July 23, 2024)

{Note: Text in curly brackets indicates optional text.} [Note:
Text in square brackets is a note to the reviewer.]

OPC-721

NOT TO BE USED DIRECTLY FOR TREATMENT OF PESTS FOR MANUFACTURING USE ONLY

Active Ingredient: Bacteriophage active against *Xylella fastidiosa**0.00013%
Other Ingredients99.99987%
Total:100.00000%

*Contains a minimum of 5×10^9 plaque forming units (PFU) per milliliter of product

KEEP OUT OF REACH OF CHILDREN

[Note: The Signal Word (per 40 CFR 156.64) and First Aid Box (per 40 CFR 156.68) are not required because product is classified as Toxicity Category IV for all routes of exposure and is negative for dermal sensitization.]

HOTLINE NUMBER

For general information on this product, call 1-650-337-0350 during normal business hours, 9 am to 5 pm (Pacific Time). Contact 1-800-222-1222 for emergency medical treatment information.

EPA Reg. No.: 92918-2

Net Contents: XX

{Batch}{Lot} No: XXXX

EPA Est. No.: XXXXX-XX- X

Produced {For:

Otsuka Pharmaceutical Co., Ltd.

2-9 Kanda-Tsukasamachi

Chiyoda-ku, Tokyo,

101-8535 Japan}

{By:

A&P Inphatec, LLC

1060 E Meadow Circle

Palo Alto, CA 94303}

ACCEPTED

Aug 12, 2024

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

92918-2

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PRECAUTIONARY STATEMENTS

[Note: The Hazards to Humans and Domestic Animals section is not required per 40 CFR 156.70 because product is classified as Toxicity Category IV for all routes of exposure and is negative for dermal sensitization.]

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.

FOR MANUFACTURING USE ONLY. For further manufacturing into end-use products only. Not for direct treatment of pests. Do not use from damaged, punctured or unsealed containers. End-use products formulated from this product must be registered by the EPA.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in original container. Always store this product in a dark location under refrigerated conditions (36 – 46°F, 2 – 8°C) in a locked area inaccessible to children or pets when not in use. Inappropriate storage may cause degradation of the product and that would decrease product efficacy.

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. Offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and

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Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed. However, it is impossible to eliminate all risks associated with the use of this product.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Otsuka Pharmaceutical Co., Ltd. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Otsuka Pharmaceutical Co., Ltd. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Otsuka Pharmaceutical Co., Ltd. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Otsuka Pharmaceutical Co., Ltd.'s election, the replacement of product.