



U.S. ENVIRONMENTAL PROTECTION AGENCY  
 Office of Pesticide Programs  
 Biopesticides and Pollution Prevention Division (7511P)  
 1200 Pennsylvania Ave., N.W.  
 Washington, D.C. 20460

EPA Reg. Number:

92918-2

Date of Issuance:

04/25/2019

NOTICE OF PESTICIDE:

Registration  
 Reregistration  
 (under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

OPC-721

Name and Address of Registrant (include ZIP Code):

Otsuka Pharmaceutical Co., Ltd.  
 2-9 Kanda-Tsukasamachi  
 Chiyoda-ku, Tokyo  
 101-8535 Japan

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration or registration review of your product when the EPA requires all registrants of similar products to submit such data

Signature of Approving Official:

Jeannine Kausch, Product Manager 92  
 Microbial Pesticides Branch  
 Biopesticides and Pollution Prevention Division (7511P)  
 Office of Pesticide Programs

Date:

04/25/2019

2. For the production facility associated with Alternate Confidential Statement of Formula (CSF) #1, submit two (2) batches to equal the total number of batches generally submitted to satisfy the analysis of samples (Guideline 885.1400) data requirement. You have 18 months from the date of this registration to provide these data to the EPA.
3. Should the EPA receive substantive comments on the registration decision of OPC-721 during the comment period opened for the EPA's Public Participation Process for Registration Actions, submit any additional data/information requested by the EPA to support this registration (e.g., revised labeling) within a time frame that will be specified by the EPA at the time of the request.
4. Make the following labeling change before you release this product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 92918-2."
5. Submit one (1) copy of the final printed labeling for the record before you release this product for shipment.

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 EPA. 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 statements 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.

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. A stamped copy of the labeling is enclosed for your records. Please also note that the record for this product currently contains the following acceptable CSFs:

- Basic CSF dated 02/25/2019
- Alternate CSF #1 dated 02/25/2019

Any CSFs other than those listed above are superseded.

Page 3 of 3  
EPA Reg. No. 92918-2  
OPP Decision Nos. 527226 and 545718

If you have any questions, please contact Alex Boukedes by phone at (703) 347-0305 or via email at [boukedes.alexandra@epa.gov](mailto:boukedes.alexandra@epa.gov).

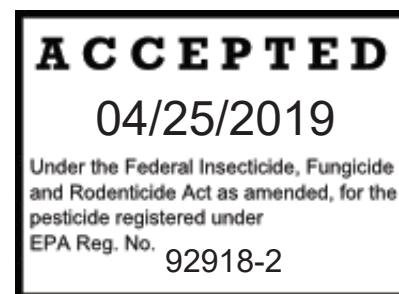
Sincerely,

A handwritten signature in black ink, appearing to read 'JKausch', written in a cursive style.

Jeannine Kausch, Product Manager 92  
Microbial Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)  
Office of Pesticide Programs

Enclosure

{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 Ingredients:** ..... 99.99987%  
**Total:** ..... 100.00000%

\*Contains a minimum of  $5 \times 10^9$  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, 8 am to 5 pm (Pacific Time). Contact 1-800-222-1222 for emergency medical treatment information.

**EPA Reg. No.:** 92918-E  
**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

{Note: Text in curly brackets indicates optional text.}

[Note: Text in square brackets is a note to the reviewer.]

## 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. Store this product in a dry area at either room temperature or under refrigerated conditions (36 – 80°F, 2 – 27°C), away from direct sunlight and extreme heat. 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

{Note: Text in curly brackets indicates optional text.}

[Note: Text in square brackets is a note to the reviewer.]

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.