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

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	**Date of Issuance:**
92918-1	04/25/2019

Term of Issuance:
Unconditional

Name of Pesticide Product:
XylPhi-PD

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

EPA Form 8570-6

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 XylPhi-PD 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. 92918-1."

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.

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

Sincerely,

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.]

ACCEPTED
04/25/2019
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 92918-1

XylPhi-PD™

Bactericide for use in grapevines
{Biological control for {reduction}{decrease} of Pierce's Disease in grapevines}
{Biologically-based {reduction}{decrease} of Pierce's Disease in grapevines}
{Preventative reduction of the onset of Pierce's Disease in grapevines}
{Preventative and curative {reduction of}{decrease in} the symptoms of Pierce's Disease in grapevines}
{Bacteriophage designed to selectively target and reduce the bacteria in grapevines that cause Pierce's Disease}
{For Use in Organic Production}

{OMRI LISTED For Organic Use} **{Listed by Organic Materials Review Institute (OMRI)}**

Active Ingredient:
Bacteriophage active against *Xylella fastidiosa** 0.00013%
Other Ingredients: 99.99987%
Total: 100.00000%
*Contains a minimum of 5 x 10^9 plaque forming units (PFU) per milliliter of product

KEEP OUT OF REACH OF CHILDREN

{See {insert}{booklet} for {Precautionary Statements} {and} {Directions for Use}.}

[Note: The Signal Word (per 40 CFR 156.64) and First Aid Box (per 40 CFR 156.68) are not required because the 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-R
EPA Est. No. XXXX-XX-X

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

Net Contents: XXX
{Batch}{Lot} No.: XXX

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

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Applicators and other handlers must wear:

- Long-sleeved shirt
- Long pants
- Shoes plus socks

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS:

Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PRODUCT INFORMATION

{Bacteriophage selectively target and attack bacteria. Bacteriophage typically target specific ranges of bacteria. Once the phage come in contact with their targeted bacteria, they enter and

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destroy their targets, all while they are generating more phage that go on to attack more targeted bacteria.}

Pierce's Disease in grapevines is caused by the bacterium called *Xylella fastidiosa.* XylPhi-PD™ is comprised of bacteriophage that are designed to attack this bacterium. XylPhi-PD™ uses the specific nature of these phage to find and eliminate the bacteria within grapevines that the phage contact, decreasing the {amount}{level}{number} of *Xylella fastidiosa* that can cause the symptoms of Pierce's Disease in the grapevines.

XylPhi-PD™ can be used as a preventative and curative solution for {reducing}{decreasing}{lessening}{diminishing} the symptoms of Pierce's Disease in grapevines by targeting the bacterium that causes Pierce's Disease, *Xylella fastidiosa*.

XylPhi-PD™ can be applied as a preventative to protect growing vines, as a curative when disease symptoms become visible, or when conditions may lead to disease pressure. Apply XylPhi-PD™ with the specified injection device (see Application Instructions).

APPLICATION INSTRUCTIONS

Preparation of Plants for Application: Inject XylPhi-PD™ when uptake of water or product into the xylem vessels, the plant's vascular system, is optimal. Do not inject XylPhi-PD™ when plants' xylem is saturated or shortly after heavy rainfall or irrigation.

Application by Injection: XylPhi-PD™ applications are made by injection of the product into the vascular system of grapevines. Applications are made directly into the active xylem tissue of the plant. This section describes the following: the injection locations on the vines; the injection device to be used; the appropriate procedures to be followed to ensure optimal effectiveness of XylPhi-PD™; and the application process.

Injection Device: Applications of XylPhi-PD™ are to be made with a pressurized injection device that can deliver the application volumes described in this section, utilizing the needle gauge and length that enables consistent and effective delivery into the vascular systems of the treated plants.

[Note: Representative picture of injection device, with labels indicating the key components of the injection device, will be inserted here. An example of this graphic is provided in the figure below.]

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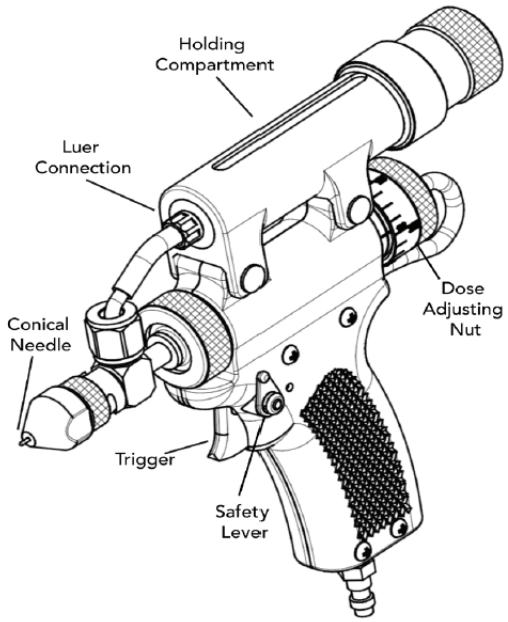

An injection device such as a Pulse *Xyleject*™ Injection System (Pulse Biotech, LLC; Lenexa, KS), or an equivalent, as configured to accept a needle using an 18- or 20-gauge conical needle is required. A 20-gauge needle is typically only needed when injecting into a newly planted vine or within newly grown suckers of severely affected plants. For the remainder of applications, use an 18-gauge needle. The injection device must be able to inject XylPhi-PD™ into the vine using pressurized injections at a needle penetration depth between 0.08 in. (2 mm) and 0.16 in. (4 mm), depending on the diameter and age of the plant tissue as detailed in this section.

Priming Holding Compartment and Injection Device: Introduce XylPhi-PD™ into the injection device's holding compartment as specified by the manufacturer. The entire capacity of the holding compartment does not need to be filled with XylPhi-PD™ if the anticipated number of injections is limited. In such cases, the amount of XylPhi-PD™ added to the holding compartment may match the number of injections to be performed with the device, with addition of extra liquid volume as necessary to fill the injection device fluid path and prime the injection device.

Prime Holding Compartment: Once XylPhi-PD™ is within the injection device's holding compartment, air must be removed from the holding compartment. Position the holding compartment's outlet port upward, and manually press the holding compartment plunger to expel excess air from the holding compartment until all air pockets in the holding compartment are filled with XylPhi-PD™. It is important to remove all air from the holding compartment before installing the holding compartment on the injection device.

Prime Injection Device: After the primed holding compartment is installed on the injection device following the manufacturer's directions, the injection device must be primed. Set the injection device dose volume to the maximum dose volume. Place the injection

device upward (needle pointed upward) and compress the trigger or actuate the injection device several times until a steady stream of liquid is expelled out of the needle. Once a steady stream of liquid is expelled, hold the injection device in its normal position. Select the desired injection device dose volume setting. The injection device is now ready to inject XylPhi-PD™ into the vines.

Injection Site Locations: Select the application locations for XylPhi-PD™ based on the age of the plant, pruning style, and the training system utilized for the plant. Inject XylPhi-PD™ into the active xylem vascular tissue, and only inject XylPhi-PD™ above ground. An overview of the appropriate locations for injections into grapevines for different types of grapevine training and age is provided in the first table below. Apply 2 or 3 injections in the arms based on the vine pruning style. Two injections can be applied at the crown of the trunk in mature vines, where pruning and branching have occurred. It is most critical, however, to apply XylPhi-PD™ in the cordons and spurs, per the details on pruning style, where there are active xylem vessels.

Cordon Training: Apply 1 injection in each cordon above the bifurcation but within the cordon arm and before the first spur.

Alternative Training Methods (e.g., goblet or head, vertical cordon, 6-arm Kniffen or similar): Apply 1 injection into each 1-year spur at each arm. It is ideal to apply an injection at each arm; however, at a minimum, inject up to 3 arms per vine. If all arms are not covered in initial application, consider application into different arms upon subsequent treatments.

For young, recently planted, or radically pruned vines, apply 1 to 2 injections into the crown of the trunk approximately 180° apart.

Injection Depth and Pressure: Inject XylPhi-PD™ at a depth between 0.08 in. (2 mm) and 0.16 in. (4 mm), depending on the diameter and age of the plant tissue. Inject XylPhi-PD™ using the injection device's required pressure settings. After inserting the needle into the plant, hold the injection device firmly against the plant and depress the device actuator to deliver the injection. The depth of injection is controlled by changing the needle retention nut. A set of needle retention nuts is included with the device. The different needle retention nuts allow for varying lengths of the needle to be exposed beyond the needle retention nut. For deeper injections, select a needle retention nut that exposes a longer portion of the needle beyond the needle retention nut. For shallow injections, select a needle retention nut that exposes a shorter portion of the needle beyond the needle retention nut.

Application Locations, Frequency, Timing and Rates: XylPhi-PD™ applications are made by direct injection into grapevines, as summarized in the following tables:

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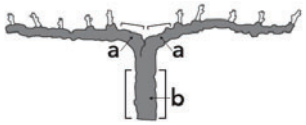
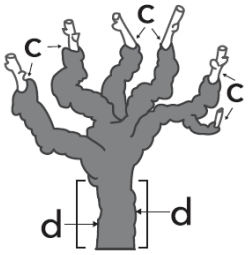
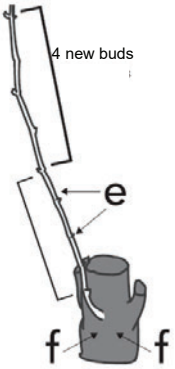
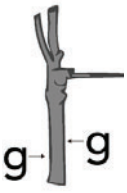
Types of Grapevine Training	**Diagrams of Grapevines**	**Number of Applications Needle Size Injection Locations Injection Volume**
Uni-, Bi-, and Quadri-Lateral Cordon Vines; Cain-Pruned Vines		•Make 3 applications of XylPhi-PD™ per year •Use an 18-gauge needle •For each application, apply a minimum of 1 injection into each cordon just after the T (a) plus 1 - 2 injections into the trunk (b) •Apply 0.0014 fl. oz. (40 µL) – 0.0027 fl. oz. (80 µL) of XylPhi-PD™ per injection
Head-Trained Vines		•Make 3 applications of XylPhi-PD™ per year •Use an 18-gauge needle •For each application, apply 1 injection into each arm at location of 1-year-old spur with a minimum of 3 arms (c) plus 2 injections at trunk 180° from each other (d) •Apply 0.0014 fl. oz. (40 µL) – 0.0027 fl. oz. (80 µL) of XylPhi-PD™ per injection
Cut Down, Retrained Vines		**For New Shoots:** •Make 3 applications of XylPhi-PD™ per year •Use a 20-gauge needle •For each application, apply 1 - 2 injections into each shoot event (e) •Apply 0.0014 fl. oz. (40 µL) of XylPhi-PD™ per injection **For the Trunk:** •Make 2 applications of XylPhi-PD™ per year •Use an 18-gauge needle •For each application, apply 2 injections into the trunk on both sides and below new shoot growth (f) •Apply 0.0027 fl. oz. (80 µL) of XylPhi-PD™ per injection
Replants; New Vines		•Make 2 applications of XylPhi-PD™ per year •Use a 20-gauge needle •For each application, apply 2 - 3 injections into shoot at 180° from each other (g) •Apply 0.0014 fl. oz. (40 µL) – 0.0027 fl. oz. (80 µL) of XylPhi-PD™ per injection

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Rate	Timing	Frequency
Use 0.0014 fl. oz. (40 µL) – 0.0027 fl. oz. (80 µL) of XylPhi-PD™ per injection. **For mature plants**, apply XylPhi-PD™ as detailed above. **For newly planted, young vines, or vines that have been trimmed to 2 in. (5 cm) – 6 in. (15 cm) above the ground,** apply XylPhi-PD™ as detailed above.	Primary Injection: 6 - 8 weeks after new flush from dormancy. Secondary Injection: 4 - 6 weeks after primary injection. Tertiary Injection: As appropriate, 4 - 6 weeks after second injection.	Conduct 2 - 3 treatments per growing season depending on disease pressure.

Cleaning Injection Device: Upon completion of applications or at the end of an application day, clean the injection device in accordance with the injection device instructions. These instructions will include cleaning the injection device to ensure that XylPhi-PD™ residue is thoroughly removed from the injection device, that the injection device is free of plant debris and that the injection device is stored appropriately in between uses.

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: To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

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.

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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 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. Ineffectiveness or other unintended consequences may result because of such factors as, including, but not limited to, the extent of the existing symptoms of Pierce's Disease in the treated grapevines, the pressure of further introduction of disease by vectors such as sharpshooters, the overall health of the grapevines, weather conditions, presence of other materials and the challenges of the method of application, all of which are beyond the control of Otsuka Pharmaceutical Co., Ltd. All such risks shall be assumed by the user or buyer.

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.