



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

March 13, 2019

Casey Pehrson  
Authorized Agent to De Ceuster Meststoffen nv  
Technology Sciences Group, Inc.  
1150 18<sup>th</sup> Street NW  
Suite 1000  
Washington, DC 20036

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Adjust warranty statement, correct distributor address, make minor changes to the expiration statement  
Product Name: PMV-01  
EPA Registration Number: 92554-1  
Application Date: February 7, 2019  
OPP Decision Number: 548427

Dear Ms. Pehrson:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.


The labeling submitted with this application has been stamped “Notification” and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications.

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 the Federal Insecticide, Fungicide, and Rodenticide Act (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 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 Assurance.

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OPP Decision No. 548427

If you have any questions, please contact Daniel Schoeff by phone at (703) 347-0143 or via email at [schoeff.daniel@epa.gov](mailto:schoeff.daniel@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "SEIICHI MURASAKI". The signature is stylized and cursive.

Seiichi Murasaki, Senior Regulatory Advisor  
Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)  
Office of Pesticide Programs

Enclosure: Stamped Label

# PMV<sup>®</sup>-01

Virus inoculation of greenhouse tomatoes to prevent damage and yield loss caused by virulent *Pepino mosaic virus* isolates

Active Ingredient: <i>Pepino mosaic virus</i> , strain CH2, isolate 1906 <sup>1</sup> .....	0.00010 % w/w <sup>2</sup>
Other Ingredients.....	99.99990 % w/w
Total.....	100.00000 % w/w

<sup>1</sup>mild strain of *Pepino mosaic virus*  
<sup>2</sup>PMV<sup>®</sup>-01 contains a minimum of 5 x 10<sup>11</sup> virus particles per qt.

**KEEP OUT OF REACH OF CHILDREN**

**NOTIFICATION**

**CAUTION**

92554-1

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:

[See First Aid on the [left] [right] panel.]

03/13/2019

EPA Reg. No. 92554-~~R1~~

EPA Est. No.

Net Contents: 1 qt.

Do not sell or use ~~21 days after production~~ after the expiration date, which is 21 days after production. See the [bottom left of the front panel of this label] [cap of the bottle] [bottle] for the expiration date.

Batch Code: Expiration

Date:

**Manufactured for:**

De Ceuster Meststoffen ~~nyv~~  
Fortsesteenweg 30  
2860 Sint- Katelijne-Waver  
Belgium

**Distributed by:**

~~Biobest USA Inc.~~  
~~28777 Goddard Rd., Suite 206~~  
~~Romulus, MI 48174 USA~~  
~~Phone: 1-519-322-2178~~  
~~E-mail: customerservice@biobest.ca~~

**Distributed by:**

Biobest USA Inc.  
11700 Metro Airport Center Drive, Suite 110 Romulus,  
MI 48174 USA

PMV-01 (EPA Reg. No. 92554-1)

Notification of minor label changes - Label dated February 7, 2019

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Phone: 1-519-322-2178  
E-mail: [customerservice@biobest.ca](mailto:customerservice@biobest.ca)



<b>FIRST AID</b>	
If inhaled	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
If swallowed	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
If on skin or clothing	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, if present, after the first 5 minutes then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>HOTLINE NUMBER</b>	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p> <p>For general information on this product, contact the National Pesticide Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8 a.m. to 12 p.m. PST, or at <a href="http://npic.orst.edu">http://npic.orst.edu</a>. For medical emergencies, call your poison control center at 1-800-222-1222.</p>	

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

Harmful if inhaled, if swallowed, or if absorbed through skin. Causes moderate eye irritation. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Avoid contact with skin, eyes, or clothing. Remove and wash contaminated clothing before reuse.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Protective eyewear
- A NIOSH-approved particulate filter with any N, R, or P filter with NIOSH approval number prefix TC-84A; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. (Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.)

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 get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### 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.*

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

For early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear

### GENERAL INFORMATION

PMV<sup>®</sup>-01 is an agricultural control treatment, based on the mechanism of cross protection through virus inoculation. PMV<sup>®</sup>-01 protects greenhouse tomatoes against damage and yield loss caused by virulent *Pepino mosaic virus* isolates.

In case of questions, contact the distributor.

### APPLICATION INFORMATION

PMV<sup>®</sup>-01 is part of a vaccination strategy that also includes professional advice, strict hygiene protocols and examination of young seedlings/plantlets before and after vaccination.



### Hygiene measures

Apply the product only after complete and thorough clean up and disinfection of the greenhouse facility between production cycles. Thoroughly disinfect and rinse spraying equipment before and after use. After application of PMV<sup>®</sup>-01, strict hygiene measures must be followed throughout the entire growing season to minimize the risk of contamination and mixed infections as much as possible.

Heat drainage water to a minimum of 162 °F (72 °C) for 15 seconds (Pasteurization) or disinfect using UV, ozone, or other appropriate disinfection methods.

### Application details and rate

**Use site:** GREENHOUSE

**Crop:** Tomatoes

**Pest:** Virulent *Pepino mosaic virus* isolates

**Formulation type:** Suspension concentrate (SC)

**Rate:**

- In general: 1 qt. / 0.6 acre
- When rapid colonization is required: 1 qt. / 0.3 acre

### Mixing instructions

Calculate the required amount of PMV<sup>®</sup>-01 based on the area of the greenhouse to be treated. The total spray volume depends on the application equipment and the timing of treatment. After pouring the product, rinse the bottle with water and add to the spraying equipment. Dilute with the appropriate amount of water to reach the desired spray volume.

- Application after planting: use 15 to 30 gallons of spray solution per acre.
- Application before/at planting: use 2 to 7 gallons of spray solution per acre.

It is advisable to perform a spray test with water before applying the product. Determine the sprayed volume of water per row to calculate the final volume of water needed to apply the product to the entire area. Pay special attention to the warming up of the spray solution due to the return of the pump of the sprayer. The temperature of the spray solution must be kept below 60 °F (15 °C).

The following directions need to be observed strictly:

- Shake the product well before diluting in order to create a suspension.
- Mix the diluted spray solution well in the spraying equipment before treatment.
- Spray as soon as possible after diluting into the appropriate concentration.
- Do not make more spray solution than can be sprayed in 2 hours.

### **Application instructions**

Using the labeled application rate, apply the product to young tomato plants free of *Pepino mosaic virus* as soon as possible (prior to first cluster flowering is the general rule). Use appropriate spraying devices, such as a spraying robot, spray tank wagon, hand-operated spraying machine or backpack sprayer. Do not apply this product through any type of irrigation equipment.

The following directions need to be observed strictly:

- Spray pressure: Use 72-87 psi with a minimum distance of 1 foot between the nozzle tip and the crop canopy. When choosing the spraying nozzles, take the optimal pressure ranges into consideration.
- Spray accurately: Make sure all the spray solution is sprayed directly on all plants. When using a sprayer boom for hedges, use only one nozzle. Obtain thorough leaf coverage.
- Clean the filters regularly (at least every 2 hours).
- Mix the spray solution frequently (at least every 15 minutes).
- To ensure an optimal effect, do some crop handling immediately after the application (between 4 and 24 hours). The crop handling will include a manual plant manipulation, so as to slightly injure the plant tissue and to spread the virus particles, which are superficially present on the leaf surface, from one plant to the other. Examples of this type of plant care treatment are training, twining, pruning or deleafing.

## STORAGE AND DISPOSAL

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

### **Pesticide Storage:**

Store the product at 39 °F (4 °C). Do not use after the expiration date printed on the bottom left of the front panel of this label, on the bottle, or on the cap of the bottle. Always store pesticide in the original container. Do not store PMV<sup>®</sup>-01 where food or medicine for human consumption is stored.

### **Product 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 the container. Triple rinse the container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into the application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into the application equipment or mix tank. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

## WARRANTY

~~De Ceuster Meststoffen nv warrants that PMV<sup>®</sup>-01 conforms to the description and conditions on this label and that it will perform as indicated when used under the directions and conditions of this label. To the extent consistent with applicable law, De Ceuster Meststoffen nv and/or Biobest USA Inc. makes no other expressed or implied warranty of fitness, merchantability, or otherwise.~~

## LIMITATIONS OF LIABILITY

~~To the extent consistent with applicable law, De Ceuster Meststoffen nv and Biobest USA Inc. shall not be responsible and shall not accept any liability for any damage caused by or resulting from—directly or indirectly—the use of PMV<sup>®</sup>-01 and/or the implementation of the vaccination strategy. To the extent consistent with applicable law, this exclusion of liability applies towards both the User and any potential third party. To the extent consistent with applicable law, only the User will be responsible for the consequences resulting from the use of PMV<sup>®</sup>-01 and from the decisions he or she takes by implementing the vaccination strategy. To the extent consistent with applicable law, the User expressly disclaims any liability on the part of De Ceuster Meststoffen nv and Biobest USA Inc. and shall keep them indemnified from this without limitation at all times. To the extent consistent with applicable law, the User declares to have been informed explicitly and in advance of this disclaimer and acknowledges to have accepted its content unconditionally.~~

## NO CHANGES AUTHORIZED

~~No one other than an authorized agent of De Ceuster Meststoffen nv is allowed to make any other warranty or change the conditions, disclaimers, or limitations stated on this label. Any authorization to make changes should be in writing and in specific reference to this label.~~

**CONDITIONS OF SALE AND USE AND  
LIMITATION OF WARRANTY AND LIABILITY**

BEFORE USING THIS PRODUCT, read the entire Directions for Use and the following Conditions of Sale and Use and Limitation of Warranty and Liability. By buying or using this product, the buyer or user accepts the following Conditions of Sale and Use and Limitation of Warranty and Liability, which no employee or agent of DE CEUSTER MESTSTOFFEN NV or BIOBEST USA INC. is authorized to vary in any way.

Follow the Directions for Use of this product carefully. It is impossible to eliminate all risks associated with using this product. Crop or other plant injury, ineffectiveness, or other unintended consequences may result from risks that are beyond the control of DE CEUSTER MESTSTOFFEN NV and BIOBEST USA INC., for example, using this product contrary to the label instructions or the advice of BIOBEST USA INC., failing to observe precautionary statements in this product's label, abnormal environmental conditions, or interference by unknown biological factors. To the extent consistent with applicable law, the buyer or user of this product assumes all such risks.

Subject to the foregoing risks, DE CEUSTER MESTSTOFFEN NV and BIOBEST USA INC. warrant that this product conforms to the ingredient statement on the label and is reasonably fit for the purposes stated in the Directions for Use when the product is used in strict accordance with such Directions for Use under normal conditions of use. EXCEPT AS WARRANTED IN THIS LABEL AND TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THIS PRODUCT IS SOLD "AS IS," AND DE CEUSTER MESTSTOFFEN NV AND BIOBEST USA INC. MAKE NO OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ELIGIBILITY OF THIS PRODUCT FOR ANY PARTICULAR TRADE USAGE.

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