



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

December 21, 2021

William Goodwine  
Regulatory Fellow  
Janssen PMP  
1125 Trenton-Harbourton Rd,  
Titusville, NJ 08560-0200

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Add  
“persimmons” to description; Add previously approved booklet  
Product Name: FYSIUM  
EPA Registration Number: 43813-57  
Application Date: 07/14/2021  
OPP Case Number: 00310739

Dear Goodwine:

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.

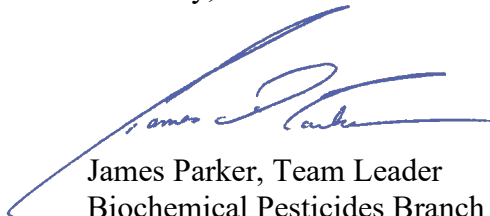
The labeling submitted with this application has been stamped “Notification” and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications.

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.

If you have any questions, please contact Susannah Powell via email at [powell.susannah@epa.gov](mailto:powell.susannah@epa.gov).

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Sincerely,

A handwritten signature in blue ink, appearing to read "James Parker", is written over a horizontal line.

James Parker, Team Leader  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)  
Office of Pesticide Programs

Enclosure

**NOTIFICATION**

43813-57

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:

12/21/2021

[Booklet Label]



For counteracting many of the undesirable effects of both internal and external sources of ethylene on the following harvested fruit: APPLES, PEARS, ASIAN PEARS, AVOCADOS, KIWIFRUIT, **PERSIMMONS**, PEACHES, NECTARINES, APRICOTS, PLUMS, AND PLUMCOTS.

Active Ingredient: 1-Methylcyclopropene (1-MCP)\* .....98.0%  
 Other Ingredients:.....2.0%  
 Total:.....100.0%

\*1-MCP gas produced in situ upon activation of the FYSIUM® Proprietary Generating Technology

**EPA Reg. No. 43813-57****EPA Est. No**

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**

**Refer to booklet for precautionary statements, and storage and disposal statements, and directions for use**

<b>FIRST AID</b>	
If in Eyes	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.
If on Skin or Clothing	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.
If Swallowed	Call 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.
<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, 6:30 AM to 4:30 PM Pacific time, seven days a week. During other times, call the poison control center at 1-800-222-1222. For chemical emergency assistance (spill, leak, fire, or accident), call CHEMTREC® 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.	

Manufactured for:



FYSIUM® is a registered trademark of Janssen Pharmaceutica.

1125 Trenton-Harbourton Road  
Titusville, NJ 08560

{Net Contents:}  
{Batch No.: }

PMP 2107/L/US/FYSIUM

2101-059-7516

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through skin. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear long-sleeved shirt, long pants, chemical-resistant gloves, and safety glasses when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**PERSONAL PROTECTIVE EQUIPMENT (PPE)**

Applicators of this product must wear:

- Coveralls over long-sleeved shirt and long pants
- Chemical-resistant footwear plus socks
- Chemical-resistant gloves made of any waterproof material
- Protective eyewear

Applicators and handlers must follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

**Non-Agricultural Use Requirements**

The requirements in this box apply to uses of this product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170).

Do not enter enclosed areas until the enclosed area has been vented unless wearing the appropriate PPE.

Ventilate for at least thirty (30) minutes using fans or other mechanical ventilating systems.

PPE required for early entry into enclosed areas prior to venting is:

- Coveralls over long-sleeved shirt and long pants
- Chemical-resistant footwear plus socks
- Chemical-resistant gloves made of any waterproof material
- Protective eyewear
- Respirator with an organic-vapor removing cartridge with a pre-filter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G) or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P, or HE pre-filter.

Restricted Entry Interval (REI): The treated space must remain sealed for 12-24 hours after treatment depending on the crop being treated (see Directions for Use section of the label). After the 12-24 hours, the treated area must be vented for a minimum of 30 minutes, as described above. Reentry into treated spaces may occur 30 minutes after room has been vented.

Do not smoke during the FYSIUM® 1-MCP application.

**GENERAL INFORMATION**

The FYSIUM® Proprietary Cartridge contains three different components, which, when placed in the FYSIUM® Proprietary Generator and activated, produces the active constituent, 1-methylcyclopropene (1-MCP) gas. This purified gas is discharged into the fruit storage room/container where it inhibits the spoilage effects of ethylene on the fruits.

Each FYSIUM® Proprietary Cartridge is custom-prepared with the exact amounts of the three components corresponding to the volume of the storage room/enclosure to be treated in order to deliver the prescribed level of 1-MCP. Neither the FYSIUM® Proprietary Generator nor the FYSIUM® Proprietary Cartridges contains 1-MCP until activation.

The FYSIUM® Generating Technology provides a novel postharvest application technique for producing and delivering 1-MCP to fruit storage and other enclosures during transport and storage. Regulating ethylene production in storage and during transport provides benefits, such as:

- Maintaining fruit firmness and titratable acidity
- Reducing internal ethylene production, fruit respiration, peel greasiness, core flush, mealliness, and chilling injury in treated fruit
- Protection from external sources of ethylene
- Delaying ripening and senescence

FYSIUM® can be used to apply 1-MCP to fruit from just after harvest to just prior to sale. Treatment with 1-MCP is effective under both cool (below 55°F, 13°C) and warm temperature conditions. To realize maximum benefit in controlling senescence, fruit should be treated as soon as possible after harvest. Harvested fruit must be exposed to 1-MCP in enclosed areas, such as storage rooms, coolers, shipping containers, enclosed truck trailers, or ambient temperature, refrigerated, or controlled atmosphere food storage facilities. This product is not intended for use outdoors or in other non-enclosed areas. These enclosed treatment areas should be gas tight as leakage will reduce 1-MCP's effectiveness.

#### **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 agency responsible for pesticide regulation. All applicable directions, restrictions, precautions, and conditions of sale and warranty are to be followed. This labeling must be in the user's possession during application.

#### Fruit Storage Conditions

FYSIUM® Technology is compatible with and complementary to fruit stored in both controlled atmosphere and regular air storage conditions. FYSIUM must be used in air-tight treatment areas.

#### Timing of Harvest and Application

FYSIUM® should be used in the treatment area containing fruit immediately after harvest, upon entering storage or in transit. For best results, do not use with fruit previously treated with ethephon. To realize the maximum benefit for optimum quality, pre-cool fruit promptly and apply FYSIUM in the treatment area as soon after harvest as possible and before the climacteric peak of respiration has occurred. Best results from FYSIUM are obtained with fruit at the optimum maturity level for long term storage. The response of the fruit to FYSIUM may also be affected by variety. Fruit may benefit from repeat application. After application, store the treated fruit not for immediate sale according to good standard commercial practices, in either refrigerated air or modified or controlled atmosphere. Storage in controlled atmosphere is recommended for fruit that are to be held longer than 6 months.

It must be emphasized that maintaining the cold chain (keeping the treated fruit cool at all times) and strict adherence to phytosanitary practices remain essential in maintaining safe and high-quality fruit. For optimum control of superficial scald on pome fruits, FYSIUM® must be applied within one week after harvest.

**Apples:** Apply FYSIUM soon after harvest. Best results are obtained when fruit is at the optimum maturity level for long term storage. For optimum quality, store apples that are to be held longer than six months in a controlled atmosphere.

**Pears, Asian pears:** Apply FYSIUM as soon after harvest as possible.

**Avocados:** Apply FYSIUM to the fruit soon after harvest at the physiological maturity stage or just prior to the "turning black" stage.

**Kiwifruit:** Apply FYSIUM either as soon after harvest as possible or after long term storage and before the fruit are transported and distributed.

**Peaches, Nectarines, Apricots, Plums and Plumcots:** Apply FYSIUM either as soon after harvest as possible or after long term storage and before the fruit are transported and distributed.

**Persimmons:** Apply FYSIUM as soon after harvest as possible.

#### FYSIUM® Application Method

Prior to application, ensure that the treatment area can be properly and promptly sealed following application.

The 1-MCP is produced in the FYSIUM Proprietary Cartridge by the use of a proprietary generator. The appropriate amount of the three components in the cartridge will be dispensed at the production facility as necessary for the individual application situation (size of the room and/or amount of fruit to be treated). Directions for using the Cartridge and Generator follow:

1. Seal the treatment room/storage location in preparation for treatment. Close all vents to outside air and turn off any scrubbing devices or ozone generating equipment. During the treatment, run the internal refrigerated air circulation to ensure good air circulation within the room.
2. After the area is sealed, post a sign on all of the entrances to the treatment area. The sign should read "CAUTION. Do not enter area. FYSIUM treatment in progress."
3. Connect FYSIUM generator to power supply and switch on
4. Install FYSIUM cartridge into the generator
5. Connect the tube from the outlet port of the FYSIUM Cartridge into the closed treatment room/storage location
6. Start the generator (push "START" button). It will now start to warm up. This generally takes 15 to 30 minutes. More warm-up time is required to heat larger quantities of reactants as are necessary to treat larger rooms. Refer to the unit manual for the generator for more information. After the warm-up time, the generator automatically switches to the gas production and dispersion mode (gassing phase)
7. After 2 hours of "gassing", the FYSIUM generator switches off automatically
8. Remove the FYSIUM cartridge and follow container handling directions. Disconnect the FYSIUM generator from the power supply.
9. At the end of the FYSIUM treatment period (12-24 hours depending on the crop), and before allowing workers to enter, vent the treated room by opening the doors for a minimum of thirty minutes with continued full internal ventilation.

The doors to the storage area must remain sealed for the following periods of time from pushing the "start" button to ensure effective FYSIUM treatment. Entrance to the room prior to this time will compromise the treatment.

Apple, pear, peach, nectarine, apricot, plum, and plumcot – 24 hours

Asian pear – 15 hours

Avocado, kiwifruit, and persimmon – 12 hours

#### FYSIUM Application Rates

Crop	Rate (ppb)
Apples	650 - 1,000
Pears	300 - 600
Asian Pears	650 - 1,000
Avocados	650 - 1,000
Kiwifruit	450 - 650
Peaches, Nectarines, Apricots, Plums, Plumcots	450 - 650
Persimmons	450 - 650

#### STORAGE AND DISPOSAL

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

Pesticide Storage: Store in original packaging in a cool, dry place.

Pesticide Disposal: Wastes resulting from the use of this product, such as spent, partially used, damaged, and excess full cartridges, shall be collected by the service company provider and disposed of at an approved waste disposal facility as hazardous waste by incineration.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Not for recycling or reconditioning. Service company provider shall collect all cartridges for disposal at a licensed hazardous waste disposal facility by incineration.

#### 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. 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 permitted by law, Janssen PMP disclaims any liability for consequential, special or indirect damages resulting from the use, handling, application, storage or disposal of this product or for damages in the nature of penalties, and the buyer and user waive any right that they may have to such damages. To the extent consistent with applicable law, Janssen PMP makes no warranties of merchantability or of fitness for a particular purpose or any other express or implied warranty except as stated above.

Brackets { } indicates container labeling and [ ] is for information only and will not be printed on final label.

[Booklet Label]



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**DANGER**

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**JANSSEN PMP**  
PRESERVATION AND MATERIAL PROTECTION  
a division of Janssen Pharmaceutica NV

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