



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 30, 2015

William R. Goodwine
Director, WW Regulatory Affairs & Risk Assessment
Janssen PMP, Preservation & Material Protection Division
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – To state the percentages of the ingredients to one decimal place (to read 98.0% and 2.0%, instead of 98% and 2%) and to line up with the 100.0% per the request of New York State Department of Environmental Conservation.

Product Name: Fysium®
EPA Registration Number: 43813-57
Application Date: June 24, 2015
OPP Decision Number: 506254

Dear Mr. 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.

If you have any questions, please contact Colin G. Walsh of my team by phone at (703) 308-0298 or via email at walsh.colin@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Andrew C. Bryceland".

Andrew C. Bryceland, 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:

07/30/2015

FYSIUM

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

KEEP OUT OF REACH OF CHILDREN

DANGER

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

FIRST AID	
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.
HOT LINE NUMBER: 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.	

EPA Reg. No. 43813-57

EPA Est. No.



Manufactured for:

JANSSEN PMP
PRESERVATION AND MATERIAL PROTECTION
a division of Janssen Pharmaceutica NV
1125 Trenton-Harbourton Road
Titusville, NJ 08560

FYSIUM® is a registered trademark of Janssen Pharmaceutica.

PMP 1506/L/US/FYSIUM

525005

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 pre-fix 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 24 hours after treatment. After 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.

GENE

The following active ingredients are contained in this product:

Each of the Gene Pesticides listed below is a fruit and vegetable protectant.

- M
- R_t
- Pr
- D_t

FYSIUM is effective against fruit and vegetable pests as stated on the label. Food crops should be harvested and stored as directed on the label.

Directions

It is essential that you read and understand the complete directions for use on the label. Do not use this product in a manner inconsistent with the label directions.

Apply FYSIUM as directed on the label.

Timing

FYSIUM may be applied to fruit and vegetable crops at any time during the growing season. Do not apply FYSIUM to crops that are to be stored for long periods of time.

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-methylcyclopropane (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 of apples, pears, and Asian pears.

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 up to the maximum level of 1 ppm 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 apples, pears and Asian pears. 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, mealiness, 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 apples, pears and Asian pears 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 apples and pears 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.

Apple, Pear, and Asian Pear Storage Conditions

FYSIUM® may be used 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 apples, pears, or Asian pears 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 apples 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 apples, pears, and Asian pears may also be affected by variety. Fruits 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 controlled atmosphere. Storage in controlled atmosphere is recommended for fruit that are to be held longer than 6 months.

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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.

FYSIUM® Application Method

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

The 1-MCP produced in the FYSIUM® Proprietary Cartridge is applied 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
2. Connect FYSIUM® generator to power supply and switch on
3. Install FYSIUM® cartridge into the generator
4. Connect the tube from the outlet port of the FYSIUM® Cartridge into the closed treatment room/storage location
5. Start the generator. It will now start to warm up. This generally takes 15 to 20 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.
6. After 2 hours of run time, the FYSIUM® generator switches off automatically
7. Remove the FYSIUM® cartridge and follow container handling directions Disconnect FYSIUM® generator
8. Keep the treatment area closed for 24 hours from the start of the Run time

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." The doors to the storage area must remain sealed for 24 hours to ensure effective 1-MCP treatment. Entrance to the room prior to 24 hours will compromise the treatment. During the treatment, run the internal refrigerated air circulation to ensure good air circulation within the room. Close all vents to outside air and turn off any scrubbing devices or ozone generating equipment. At the end of the FYSIUM® treatment period, vent the treated room by opening the doors for a minimum of thirty minutes with continued full internal ventilation before allowing workers to enter. Store treated apples not intended for immediate sale according to good, standard commercial practices, in either refrigerated air or controlled atmosphere. Storage in controlled atmosphere conditions is recommended for fruit stored longer than 6 months.

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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.

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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.

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