7182-1 8/5/2014 1/8

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Linda Murray
Regulatory Specialist
3M Health Care
2510 Conway Ave.
St. Paul, MN 55144-1000

AUG 5 2014

SUBJECT: 3M Steri-Gas Cartridges
EPA Registration Number: 7182-1
Application Date: April 29, 2014
Receipt Date: July 8, 2014

Dear Ms. Murray:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

Proposed Notification

- Add model number of 3M sterilizer equipment for product use
- Add CE mark and address for 3M as required by Medical Device directive in Europe for import to Germany

Based on a review of the submitted information, this notification is acceptable and will be made part of the record for this file.

General Comments

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Tracy Lantz

for Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060 Print Form 2/8

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
7182-1	Velma Noble	☐ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
3M Steri-Gas Cartridges	31	

5. Name and Address of Applicant *(Include ZIP Code)*

3M Health Care, 2510 Conway Ave.
St. Paul, MN 55144-1000

☐ *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Addition of new model number of 3M Sterilizer equipment and the addition of "CE" mark and 3M Germany address for export purposes under Medical Device Directive in Europe. Please see label changes which are highlighted on enclosed label copy.

See cover letter for complete description of label revisions.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☒ Yes ☐ No	☐ Yes ☒ No	☒ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☒ Container		☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☒ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Linda Murray	Regulatory Specialist	651-733-3461

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Linda Murray	Regulatory Specialist
4. Typed Name	**5. Date**
Linda Murray	04/29/2014

3/8

3M Material Environmental Health and Safety
3M Center 220-6E-03
St. Paul, MN 55144-1000

(651) 733-3461 Telephone
(651) 733-1773 Fax
ljmurray@mmm.com

April 29, 2014

Registration Division
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

RE: Notification of minor label change to Steri-Gas Cartridge, EPA Reg. No. 7182-1

To Whom It May Concern:

3M would like to submit a notification of a non-substantive label change to the Steri-Gas Cartridge, EPA Reg. No. 7182-1 label.

Changes to the label include:

- The addition of a second model number of 3M sterilizer equipment in which the product must be used;
- The addition of "CE" mark and also an address for 3M Deutschland as is required per the Medical Device Directive in Europe for this product when it is imported into Germany.

Documents included supporting this request:

- Completed 8570-1 EPA notification form;
- One copy of revised label (changes highlighted in yellow).

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of

FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Best regards,

Linda Murray

Linda Murray
Regulatory Specialist
3M Material Environmental Health, Safety and Regulatory Affairs

3M Steri-Gas™ Cartridges

EO Gas Cartridge [8-170] [4-134] [4-100]

Active Ingredient: Ethylene Oxide 100%

• Net wt. 170 g (5.99 oz.) [127 g (4.47 oz.)] [100 g (3.52 oz.)]

[redacted]
NOTIFICATION
Date Reviewed: 8/5/14
Reviewed by: T. Lantz

Keep Out of Reach of Children

DANGER

Extremely Flammable–Do Not Use Near Flame
Causes Eye and Skin Burns. May Cause Nervous System Damage
CANCER HAZARD AND REPRODUCTIVE HAZARD
USE ONLY AFTER READING DIRECTIONS FOR USE
Use Only in Accordance With Manufacturer's instructions in Steri-Vac™ Gas Sterilizer Model 8XL and GS8 [5XL and GS5]

Users must follow requirements of the OSHA Occupational Exposure Standard for Ethylene Oxide (29 CFR 1910.1047).

FIRST AID:

IN ALL CASES GET MEDICAL ATTENTION IMMEDIATELY.
TAKE PERSON TO A DOCTOR OR EMERGENCY TREATMENT FACILITY AT ONCE.

IF INHALED: Move exposed person to fresh air. Keep warm. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. If breathing is difficult, give oxygen. Call a poison control center or doctor immediately for further treatment advice. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.
IF ON SKIN OR CLOTHING: Immediately flush skin with plenty of water for 15-20 minutes while removing contaminated clothing and shoes. Call a poison control center or doctor immediately for treatment advice. Aerate, wash or clean contaminated clothing and discard leather goods.
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 SWALLOWED: Call a 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.
NOTE TO PHYSICIAN: Persons exposed to ethylene oxide may develop severe and intractable vomiting, requiring the use of antiemetics given intravenously. Prolonged or high vapor concentration exposure may result in respiratory tract irritation and the development of pulmonary edema after a latent phase of several hours. Skin exposure to Ethylene Oxide will commonly result in skin irritation with extensive blister formation, which may be delayed. At high concentrations, severe conjunctivitis can occur. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination, and cardiac irregularities. Treatment is symptomatic.

Bracketed text [X] is optional.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER! CAUSES EYE AND SKIN BURNS. HARMFUL IF INHALED.
MAY CAUSE NERVOUS SYSTEM DAMAGE.
DANGER! CANCER HAZARD AND REPRODUCTIVE HAZARD

EFFECTS OF OVEREXPOSURE: May be fatal if inhaled in high concentrations. May cause irritation of respiratory tract, chest tightness, headache, nausea, vomiting, diarrhea, light-headed feeling, dizziness, weakness, drowsiness, cyanosis, loss of coordination, convulsions, coma, delayed lung injury (fluid in the lungs), immediate or delayed skin irritation or blisters, allergic skin reaction.

OTHER POSSIBLE DELAYED HEALTH EFFECTS: May cause nervous system injury, cataracts, adverse reproductive effects, chromosomal and mutagenic changes, and cancer.

PEL: 1 PPM TWA (as per the Ethylene Oxide Standard 29 CFR 1910.1047)
EL: 5 PPM – excursion limit 15 minutes

ODOR: Ether-like in high concentrations. Exposure to toxic levels may occur without warning or detection by the user.

PRECAUTIONS: Do not breathe vapor. Do not swallow. Do not get in eyes, on skin, or on clothing. Store and use with adequate ventilation in accordance with 29 CFR 1910.1047.

PHYSICAL AND CHEMICAL HAZARDS: DANGER! FLAMMABLE LIQUID AND GAS UNDER PRESSURE.
Contents under pressure. Do not use near flame, electrical sparks or hot surfaces, or allow sources of ignition near the sterilization/fumigation area. Ethylene Oxide is extremely flammable and reactive. Ground all equipment to prevent static sparks. Do not puncture or incinerate container. Exposure to temperatures above 150°F may cause bursting.

LEAK: In case of leak evacuate area and keep personnel upwind. Shut off all sources of ignition. Use self-contained breathing apparatus and protective clothing, and shut off leak if without risk.

FIRE: In case of fire move container away from fire if without risk. Use water spray or fog nozzle to keep container cool.

EXPIRATION DATE: Not for sale or use after date printed on cartridge.

Personal Protection Equipment (PPE):
A material that is chemical-resistant to this product is butyl rubber.
All handlers must wear at a minimum:
- Long sleeved shirt and long pants.
- Shoes plus socks.
- Chemical-resistant gloves.
- When the ambient ETO concentration is 1 to 50 ppm:

o Full-facepiece respirator with ETO approved canister, front or back mounted.

- When the ambient ETO concentration is 50 to 2,000 ppm:

o (1) Positive-pressure supplied-air respirator equipped with full-facepiece, hood, or helmet: or (2) continuous-flow supplied-air respirator (positive pressure) equipped with hood, helmet, or suit.

- When the ambient ETO concentration is > 2,000 ppm or unknown (e.g. emergency situations):

o (1) Positive-pressure self-contained breathing apparatus equipped with full-facepieces; or (2) positive-pressure full-facepiece supplied-air respirator equipped with an auxiliary positive-pressure self-contained breathing apparatus.

When handlers could have eye or skin contact with ETO or ETO solutions, such as during maintenance and repair, vessel cleaning, or cleaning up spills, they must wear:
- Chemical-resistant attire, such as an apron, protective suit, or footwear that protects the area of the body that might contact ETO or ETO solutions, and
- Face-sealing goggles, a full face shield, or a full-face respirator.

Bracketed text [X] is optional.

When wearing respirators:
1. Follow the respirator manufacturer's user's instructions for changing canisters.
2. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134).
3. Respirator users must be trained using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134).
4. Respirator users must be examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status or respirator use conditions change (see 29 CFR Part 1910.134).
Follow manufacturer's instructions for cleaning/maintaining PPE. If no such Instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations
- **Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.**
- **Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.**
- **Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash.**

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.

Employers in facilities that use ETO must comply with all of the requirements for ETO use specified in 29 CFR 1910.1047. This product may be used only in facilities that meet requirements of 29 CFR 1910.1047 in 3M™ Steri-Vac™ Gas Sterilizers designed for use with 3M™ Steri-Gas™ EO Gas Cartridges containing 100% ethylene oxide. This product may be used only by persons who have been trained in accordance with 29 CFR 1910.1047. In hospital and healthcare facilities, sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO. After February 28, 2010, a single chamber process is required for ETO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities. In contract sterilization facilities, including facilities treating medical equipment and supplies, musical instruments, library/museum artifacts, and cosmetics, the following requirements must be followed:
Sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO.
Safety and awareness training is required for all employees including office staff. Information and training must be provided to all employees in the facility at the time of initial assignment and annually thereafter. The safety training must include, at a minimum, the following information:
1. The most recent monitored ambient levels of ETO in the facility;
2. The potential health effects from the levels of ETO in the facility;
3. The emergency response plan and how to respond in an emergency;

Bracketed text [X] is optional.

4. The availability of the Material Safety Data Sheet and other materials related to the health hazards of exposure to ETO.

In order to reduce ambient levels of ethylene oxide, lengthy facility aeration is encouraged. Achieving an ambient level of 0.25 ppm (measured as a daily time-weighted average) greatly reduces potential, long-term risks to employees not directly involved in the ethylene oxide applications. Air monitoring should include the entire facility including office space, break areas, and loading/unloading areas. For complete use directions (including type of surfaces, objects, or items/products recommended for treatment, pre-cleaning instructions, concentration of gas per unit volume of closed space to be treated, exposure time/temperature, relative humidity, ventilation/aeration time, and method of monitoring to be used) refer to the ethylene oxide gas sterilizer manufacturer's Operators Manuals.

Always remove plastic cap prior to use. Remove the cap by hand. Do not use tools to remove cap.

This product may be used only to sterilize medical or laboratory items, pharmaceuticals, and aseptic packaging (see 21 CFR 201.1(d)(5)), or to reduce microbial load on cosmetics, and artifacts, archival material or library objects.

Sterilization /fumigation with Ethylene Oxide must be performed only in vacuum or gas tight chambers designed for use with Ethylene Oxide.

Ethylene Oxide cycle parameters depend on several sterilizing/fumigating variable factors: pre-conditioning (if any); exposure time; chamber air pressure; gas concentration; types and quantities of items to be sterilized/fumigated; packaging; load configuration in the chamber; microbial challenge method; desired degree of disinfection; and the desired performance of the sterilized/fumigated product and package. The sterilization/fumigation cycle parameters should be those prescribed by the equipment manufacturer. If other cycle parameters are used, the safety and efficacy of the alternate cycle parameters must be validated and are the responsibility of the user.

NEVER USE PARAMETERS WHICH ALLOW FLAMMABLE MIXTURES OF ETHYLENE OXIDE AND AIR TO ENTER THE CHAMBER.

STORAGE AND DISPOSAL: Do not contaminate food, feed or water by storage and disposal.
Pesticide Storage: Store at room temperature. Store in accordance with 29 CFR 1910.1047.

Pesticide Disposal: Pesticide Wastes are acutely hazardous. Improper disposal of excess pesticide, spray, or mixture of rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Do not puncture or incinerate unused cartridges. Aerate empty cartridges according to instructions in equipment manual. After aeration offer for recycling or dispose of with nonincinerated waste.

Cap Disposal: Dispose of plastic cap in regular trash or according to your facility's policy.

EPA Reg. No. 7182-1
EPA Est. 36736-SC-01

Made in USA for:
3M Health Care
2510 Conway Ave.,
St. Paul, MN 55144-1000

[For export (as per Medical Device Directive for Europe):]

CE
Made in U.S.A. for
3M Health Care
2510 Conway Ave.,
St. Paul, MN 55144

EC REP
3M Deutschland GmbH
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss, Germany

EPA Reg. No. 7182-1
EPA Est 36736-SC-01
DOT 20 M5706

34-8713-7885-6

Bracketed text [X] is optional.