

7182-1

7/20/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUL 20 2009

Ms. Susan Price
3M
3M Center, Bldg 220-6E-03
St. Paul, MN 55144-1000

Subject: 3M Steri-Gas Cartridges
EPA Registration No.: 7182-1
Notification Dated: July 2, 2009
EPA Receipt Dated: July 8, 2009

Dear Ms. Price,

This letter acknowledges receipt of your notification submitted in connection with registration under FIFRA section 3(c)9 and PR Notice 98-10.

Proposed Notification

- Delete whole and ground spices and other seasoning materials
- Revise Container Disposal Statement by adding the phrase, "offer for recycling"

General Comments

Based on a review of the submitted materials, your notification to revise the label with the changes mentioned above is acceptable. A copy has been placed in our records for future reference.

Should you have any questions regarding this letter, please call Jacqueline Campbell at (703) 308-6416.

Sincerely,

Velma Noble
Product Manager (31)

Regulatory Management Branch I
Antimicrobials Division (7510B)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

2096

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 7182-1	2. EPA Product Manager Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) 3M Steri-Gas Cartridges	PM# Team 31	
5. Name and Address of Applicant (Include ZIP Code) 3M 3M Center, Bldg 220-6E-03 St. Paul MN 55144-1000 <input type="checkbox"/> 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

<input type="checkbox"/> Amendment - Explain Below	<input type="checkbox"/> Final printed labels in response to Agency Letter dated _____
<input type="checkbox"/> Resubmission in response to Agency Letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - explain below.

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

This notification incorporates two label changes requested by EPA which are on the package insert: 1) delete the use on "whole and ground spices and other seasoning materials (see 40CFR180.151)" per ethylene oxide RED [2008] a2) add "offer for recycling" to the directions for container disposal as per PR Notice 2007-4. No other changes have been made to labelling or 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 PRN 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted.		If "yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 3 sizes (100, 127, 170 grams)		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other (_____)		


Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Susan M Price	Title Sr. Regulatory Specialist	Telephone No. (Include Area Code) 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 Sr Regulatory Specialist	
4. Typed Name Susan M Price	5. Date July 2 2009	

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I assume these changes are considered "minor" and not subject to a processing fee since both are at the request of US EPA and are not substantive changes requiring data review. If you have any questions or need anything else, please let me know.

Sincerely,



Susan M Price
Sr. Regulatory Specialist
3M Materials Environmental Health and Safety
3M Center Bldg 220-6E-03
St. Paul MN 55144-1000
Tel: 651 733 3461
Email: smprice1@mmm.com

50g Insert 50g
Actual size 13 5/8 x 17"
9 languages on 2 sides

3M™ Steri-Gas™ Cartridges
(English USA)
KEEP OUT OF REACH OF CHILDREN

**EXTREMELY FLAMMABLE – DO NOT USE NEAR FLAME
CAUSES EYE AND SKIN BURNS. MAY CAUSE NERVOUS SYSTEM DAMAGE.
CANCER HAZARD AND REPRODUCTIVE HAZARD**

Use Only in Accordance With Manufacturer's instructions in
3M™ Steri-Vac™ Gas Sterilizers

Users must follow the 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 for 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 for 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 for 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.

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 OVER EXPOSURE: 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

6096



Steri-Gas™ EO Gas Cartridge 4-134

Active Ingredient: Ethylene Oxide 100%
• Net wt. 127 g (4.47 oz.)

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 In Accordance With Manufacturer's Instructions in Steri-Vac™ Gas Sterilizer Model 400B.

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

SEE PACKAGE INSERT FOR DIRECTIONS FOR USE, STORAGE AND DISPOSAL AND ENVIRONMENTAL HAZARDS.

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.

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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.

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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/irradiation 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.

SHELF LIFE: Shelf life is five years from date of manufacture as printed on the cartridge.

Made in U.S.A. for 3M Health Care, St. Paul, MN 55144-1000 ©3M 2004
EPA Reg. No. 7182-1
EPA Est 36736-SC-01

top of tube

INSERT THIS END

38#: 38-9016-0123-7
78# 78-8078-7184-9
Supersedes 38-9001-5187-9
Creator: deZinnia, S Barker
Date: 8/18/04