

1043-104

12/7/2011

1 of 7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Jennifer Reeder
Manager, Regulatory Affairs
STERIS, Corp.
P.O. Box 147
St. Louis, MO 63 166-0647

DEC -7 2011

SUBJECT: PROCESS QDS®
EPA Registration Number: 1043-104
Application Dated: November 8 2011
Receipt Date: November 9, 2011

Dear Ms. Reeder:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

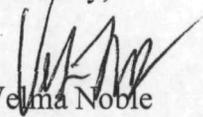
- To correct the Storage and Disposal section to reflect the language that Epa stated in the letter dated October 27, 2011

Based on a review of the submitted information, this notification is acceptable. A copy has been inserted in your file for future reference.

General Comments

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0109 or Velma Noble at (703) 308-6233.

Sincerely,



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

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

2097

EPA United States Environmental Protection Agency Washington, DC 20460	Registration Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 1043-104	2. EPA Product Manager Velma Noble	3. Proposed Classification
4. Company/Product (Name) Process QDS	PM # 31	<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (include Zip Code) STERIS Corporation P.O. Box 147 St. Louis, MO 63166-0147 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

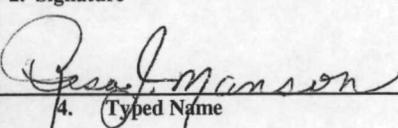
Amendment - Explain Below <input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>10/27/11</u> <input checked="" type="checkbox"/> Notification - Explain below.	Final printed labels in response to Agency letter dated "Me Too" Applicaton Other - Explain below.
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Explanation:
 Resubmitting the Notification of label change per PR Notice 2007-4 to correct the Storage and Disposal language as stated in the letter from the EPA dated 10/27/11. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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

Section - III

1. Material This Product will be Packaged In:				2. Type of Container	
Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging			
Yes* <input checked="" type="checkbox"/> No	Yes No <input checked="" type="checkbox"/>	Yes No <input checked="" type="checkbox"/>			Metal Plastic <input checked="" type="checkbox"/> 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 <input checked="" type="checkbox"/> Container	1 gallon and 55 gallon		On Label <input checked="" type="checkbox"/> On Labeling accompanying product <input checked="" type="checkbox"/>		
6. Manner in Which Label is Affixed to Product			Other		
			Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Resa Manson	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) 314-290-4633
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 Manager, Regulatory Affairs	
4. Typed Name Resa J. Manson	5. Date 11/8/2011	

4087

PROCESS QDS®
PROCESS DISINFECTANT/SANITIZER

Disinfectant - Sanitizer Fungicide - Deodorizer With Organic Soil Tolerance for Hospital, Institutional, Industrial, Dairy and other Farm Use

Active Ingredients

Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	3.00%
Octyl decyl dimethy ammonium chloride.	2.25%
Didecyl dimethyl ammonium chloride	1.35%
Diocetyl dimethyl ammonium chloride	0.90%
Inert Ingredients	92.50%
TOTAL	100.00%

NOTIFICATION
Date Reviewed: 12/2/11
Reviewed By: *acquerblich*

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID	
If in eyes	<ul style="list-style-type: none"> •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 the eye. •Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> •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	<ul style="list-style-type: none"> •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.
If inhaled	<ul style="list-style-type: none"> •Move person to fresh air. •If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. •Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

See Side panel for additional precautions

Net Contents:

STERIS Corporation
7501 Page Ave.
St. Louis, MO 63133 U.S.A.



EPA Reg. No. 1043-104

EPA Est. No. 1043-MO-2

11/11/2011

PRODUCT MADE IN U.S.A

PRECAUTIONARY STATEMENTS
Hazard to Humans and Domestic Animals
DANGER

Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wear goggles or face shield, protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS: (For 5 gallon containers or larger) Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water 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.

Apply Process QDS with a cloth, mop or mechanical spray device. When applied with a mechanical spray device, surface must be sprayed until thoroughly wetted. Treated surfaces must remain wet for 10 minutes. Fresh solution should be prepared daily or when the use solution becomes visibly dirty.

DISINFECTION IN HOSPITALS, NURSING HOMES AND OTHER HEALTHCARE INSTITUTIONS:

For disinfecting floors, walls, countertops, garbage pails and other hard non-porous surfaces. Add 3.5 oz. Process QDS to 4.5 gallons water. Apply to previously cleaned hard surfaces. At this use level, Process QDS is effective against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella enterica in the presence of 5% blood serum when evaluated by the A.O.A.C. Use-Dilution test.

DISINFECTION IN INSTITUTIONS, AND INDUSTRY: Add 2 oz. of Process QDS to 4.5 gallons of water. At 0.5 oz. to 2.25 gallons of water use level, the fungicidal effectiveness of Process QDS in the presence of 5% blood serum against Trichophyton mentagrophytes has been shown utilizing the A.O.A.C. Fungicidal Test. For fungicidal activity in areas such as locker rooms, dressing rooms, shower and bath areas, and exercise facilities.

DISINFECTION OF POULTRY EQUIPMENT, ANIMAL QUARTERS AND KENNELS: Remove all animals and feed from premise, vehicles, and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, poultry brooders, and other facilities and fixtures occupied and traversed by animals. Empty all troughs, racks, watering founts, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. For disinfection, saturate all surfaces with 2 ounces of Process QDS in 4.5 gallons of water for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers.

troughs, automatic feeders, fountains, and waterers with soap or detergent and rinse with potable water before reuse.

SANITIZING OF FOOD PROCESSING EQUIPMENT AND OTHER HARD NON-POROUS SURFACES IN FOOD CONTACT LOCATIONS: For sanitizing food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard non-porous surfaces. One-step sanitizer. DO NOT RINSE surface once sanitized.

Wash and rinse all articles thoroughly, then apply a solution of 1 oz. Process QDS in 4 gallons of water (150 ppm active). Allow surfaces to remain wet for at least one minute followed by adequate draining and air drying. DO NOT RINSE. Prepare fresh solution at least daily or when solution becomes diluted or soiled. For mechanical application, use-solution may not be reused for sanitizing applications.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard non-porous surfaces by cloth or brush or mechanical spray device. Let surface drain and dry. Sanitize Dishes, silverware, glasses, cooking utensils and other similar size food processing equipment by immersion in a 1 oz. per 4 gallon solution of Process QDS. After 1 minute, remove utensils and let drain and air dry. DO NOT RINSE.

DAIRIES: At 1 oz. / 4 gallons Process QDS fulfills the criteria of Appendix F of the grade "A" Pasteurized Milk Ordinances 1978. Recommendation of the U.S. Public Health Services in waters up to 800 ppm of hardness calculated as CaCO₃ when evaluated by the A.O.A.C. Germicidal and Detergent Sanitizer method against Escherichia coli and Staphylococcus aureus.

The udders, flanks and teats of dairy cows can be sanitized by washing with a solution of 1 oz. Process QDS in 4 gallons of warm water. DO NOT RINSE. Use a fresh towel for each cow. Avoid contamination of sanitizing solution by dirt and soil. Do not dip towel back into sanitizing solution. When solution becomes visibly dirty, discard and provide fresh solution.

SANITIZING SHELL EGGS INTENDED FOR FOOD: To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants, spray with a solution of 1 ounce of Process QDS in 4 gallons of warm water (150 ppm quat). The solution should be warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product shall be subjected to a potable water rinse only if they are to be broken immediately for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. Do not reuse the solution for sanitizing eggs.

ODOR CONTROL: Eliminates most odors by killing odor-causing bacteria and simultaneously chemically neutralizing their odors. Cleans unpleasant smelling soils. Apply use-solution of 2 oz. of Process QDS to 4.5 gallons of water to hard non-porous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge or sprayer. Allow surfaces to air dry.

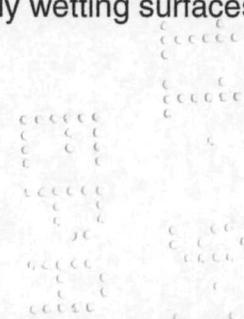
STORAGE AND DISPOSAL

(all sizes)

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

Pesticide Storage

For ≤5 gal:) Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.



(For > 5 gal.): Do not store on side. Avoid creasing or impacting of side walls.

Pesticide Disposal

(all sizes)

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:

(For ≤5 gal.): Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a 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. Empty the rinsate into application equipment or a mix tank. Follow pesticide disposal instructions for a rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

(For > 5 gal.): Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank. Follow pesticide disposal instructions for a rinsate disposal. Repeat this procedure two more times.

