

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

September 25, 2019

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Cristina Griffin Authorized Agent for Process Cleaning Solution Ltd. Process Cleaning Solutions Ltd. c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

Subject: Notification per PRN 98-10 – Addition of optional language and error corrections Product Name: PCS 7000 EPA Registration Number: 90271-1 Application Date: June 14, 2019 Decision Number: 554351

Dear Ms. Griffin:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) 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 label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements 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 Agency 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.

If you have any questions, you may contact Melanie Bolden at (703) 347-0165 or via email at Bolden.Melanie@epa.gov.

Sincerely,

Melavie Bolden for

Demson Fuller, Product Manager 32 Antimicrobials Division (7510P) Regulatory Management Branch I Office of Pesticide Programs

NOTIFICATION

90271-1

PCS7000

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:

09/25/2019

[Alternate Brand Name: ECOGent 7000] _____09/2 [Alternate Brand Name: PCS 7000 Disinfectant Cleaner] [Alternate Brand Name: ECOGent 7000 Disinfectant Cleaner]

For use on pre-cleaned hard non-porous environmental surfaces in health care facilities, institutions, schools and hospitality industries, where organic soils may be present.

Kills Bacteria (Bactericide)

Kills Pseudomonas aeruginosa, Salmonella enterica and Staphylococcus aureus

Kills Clostridium difficile* (spores)

ACTIVE INGREDIENT:

Sodium Hypochlorite	2	0.735%
• •		
TOTAL		100.000%

Available Chlorine 0.7%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[See back panel for complete precautions] [See side panel for additional precautionary statements]

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 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. 	
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. 	
	uct container or label with you when calling a poison control center or doctor, or going In case of emergency, call poison control center 1-800-222-1222 for treatment advice.	

Manufactured for [by]: Process Cleaning Solutions Ltd 2060 Fisher Drive Peterborough, Ontario K9J8N4 877-745-7277 EPA Reg. No. 90271-1 EPA Est. No. 64900-CAN-001

Net Contents:

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Physical or Chemical Hazards

Dangerous fumes form when mixed with other products including ammonia, toilet bowl cleaner, rust remover or undiluted acids. This product is not intended for use on fabrics.

[In accordance with PR notice 95-1, use the following complete Environmental Hazards statement for containers 5 gallons and larger]

Environmental Hazards

This product is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public 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.

[For containers smaller than 5 gallons use the following:]

Environmental Hazards

This product is toxic to fish and aquatic organisms.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

DISINFECTION

To disinfect walls, tables, counter tops or other hard nonporous surfaces:

- Remove gross soil prior to cleaning and disinfecting surfaces.
- Apply undiluted with a clean mop, cloth or sponge to pre cleaned surfaces. (When applying with a saturated cloth or sponge, gloves should be worn.)
- Completely wet surface and keep wet for five *or* [5] minutes.
- Wipe with a clean damp cloth or paper towel or allow to air dry.
- Rinse with potable water surfaces that come in contact with food and surfaces or objects that come in contact with children at the mouthing stage of development. For all other surfaces, no rinsing is required.

Avoid contamination of food.

Special Instructions for Cleaning Prior to Disinfection against Clostridium difficile spores Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop and/or sponge saturated with this product *[or product name]*. Cleaning is to include vigorous wiping and/or scrubbing until all visible soil is removed. Special attention is needed for high touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner such as from right to left or left to right on horizontal surfaces and top to bottom on vertical surfaces to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

Disinfection Procedure: Apply with a clean cloth, mop and/or sponge saturated with this product until surface is completely wet. Let stand for five *or* [5] minutes. Wipe with a clean damp cloth or paper towel or allow to air dry.

To Disinfect Non Critical Pre Cleaned Instruments - Instruments must be thoroughly pre cleaned to remove excess organic debris, rinsed, and rough dried. (Clean and rinse lumens of hollow instruments before filling with this product or before immersion.)

Immersion method: using a soaking tray, immerse instruments into this product and let stand for five *or* [5] minutes.

To kill Clostridium difficile**or* C difficile**or* C diff* (spores) let stand for five *or*[5] minutes. Wipe with a clean damp cloth or paper towel and allow to air dry.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre clean or decontaminate critical or semi critical medical devices prior to sterilization or high level disinfection.

SANITIZATION OF NONPOROUS FOOD CONTACT SURFACES

Rinse Method: Prepare a sanitizing solution by thoroughly mixing 1 part of this product with 32 parts of water to provide approximately 200 ppm available chlorine by weight. Clean equipment surfaces using the cleaning directions [above *or* below]. Prior to use, rinse all surfaces thoroughly with the sanitizing solution, maintaining contact with the sanitizer for at least 2 minutes. Do not rinse equipment with water after treatment and do not soak equipment overnight.

Immersion Method: Prepare a sanitizing solution by thoroughly mixing 1 part of this product with 32 parts of water to provide approximately 200 ppm available chlorine by weight. Clean equipment surfaces using the cleaning directions [above *or* below]. Prior to use, immerse equipment in the sanitizing solution for at least 2 minutes and allow the sanitizer to drain. Do not rinse equipment with water after treatment.

*Follow [the] Special Instructions for Cleaning Prior to Disinfection [listed on label].

CLEANING DIRECTIONS

Dilute PCS 7000 through the PCS NPH dispenser *[may substitute other brand name dispenser]* that is pre-calibrated to dilute with 32 parts water or dilute with 32 parts water when dispenser is not available. Use to clean frequently used surfaces or to pre-clean prior to disinfection. Apply to surface, then wipe dry with a microfiber cloth or other clean dry absorbent cloth.

Rinse with potable water surfaces that come in contact with food and surfaces or objects that come in contact with children at the mouthing stage of development. For all other surfaces, no rinsing is required.

STORAGE AND DISPOSAL

Do not contaminate food or feed by storage, disposal or cleaning of equipment. **Storage:** Store in a cool dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water. **Product Disposal:** Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer. **Container Handling:**Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill the container ¹/₄ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip and dispose of rinsate in a sanitary sewer. Repeat procedure two more times. Offer container for recycling if available or reconditioning if appropriate or place in trash.

[batch code]