



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 12, 2016

Susan Stracquatano
Agent for,
c/o nzymSys, Inc.
Delta Analytical Corporation
12510 Prosperity Drive, Suite 160
Silver Spring, MD 20904

Subject: PRIA Label and CSF Amendment – To add fungicidal claims to the product labeling, update the basic CSF with a new manufacturing site and new source for the active ingredient
Product Name: Oceanic Disinfectant Cleaner
EPA Registration Number: 85799-1
Application Date: October 5, 2015
Decision Number: 509834

Dear Ms. Stracquatano:

The amended label and CSF(s) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Please note that the record for this product currently contains the following CSF(s):

- Basic CSF dated 10/05/2015

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Karen M. Leavy by phone at 703-308-6237, or via email at Leavy.Karen@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "E. Miederhoff".

Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

OCEANIC Disinfectant Cleaner

Chlorine Free

Cleaner / Deodorizer / Disinfectant

Bactericidal / Fungicidal

Ready to use spray

ACCEPTED

02/12/2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 85799-1

Oceanic Disinfectant Cleaner is designed specifically as a general cleaner and disinfectant for use in homes, hospitals, nursing homes, patient rooms, shower rooms, locker rooms, restrooms, schools and facilities where housekeeping is of prime importance in controlling the hazard of cross contamination on contaminated surfaces.

Oceanic Disinfectant Cleaner is formulated to disinfect hard, non-porous, inanimate environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, chrome, brass, copper, laminated surfaces, baked enamel surfaces, bathrooms, shower stalls, bathtubs and cabinets.

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chlorides	0.1%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl	
ethylbenzyl ammonium chlorides	0.1%
OTHER INGREDIENTS	<u>99.8%</u>
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for additional precautionary statements.

EPA REG. NO. 85799-1

EPA EST. NO. 08405-MA-001

nzymSys, Inc.

131 Pitkin Street

East Hartford, CT 06108

Net Contents: [24 oz.] [1 Quart] [1 Gallon]

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.

FIRST AID	
IF IN EYES	Hold eyes open and rinse slowly and gently with water. Remove contact lenses, if present, after the first 5 minutes and continue to rinse for 10 – 15 minutes. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Contact the Poison Control Center at 1-800-222-1222 for 24 hour emergency medical treatment information.	

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner that is inconsistent with its labeling.
This product is not for use on medical devices and equipment.

DISINFECTION, DEODORIZING AND CLEANING

Remove gross filth or heavy soil prior to the application of this product. Hold sprayer 8 - 12 inches from surface to be treated. Spray area until it is covered with solution. Allow the surface to remain wet for 10 minutes. Wipe off or let dry.

STORAGE AND DISPOSAL

[Use the following for commercial and institutional use:]

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

Storage: Store in an area inaccessible to children. Store at room temperature. Wipe up spills with any absorbent material and dispose in trash. Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. Container Handling: Nonrefillable Container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

[Use the following for residential use:]

Storage: Store in an area inaccessible to children. Store at room temperature. Wipe off spills with any absorbent material and dispose in trash. Pesticide Disposal and Container Handling: Nonrefillable Container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

Oceanic Disinfectant Cleaner, [or This product,] when used as directed on hard, non-porous surfaces with a 10 minute contact time, is effective [*or is bactericidal*] in the presence of organic soil (5% blood serum) against *Staphylococcus aureus*, [ATCC 6538], *Salmonella enterica*, [ATCC 10708], *Pseudomonas aeruginosa*, [ATCC 15442] and [*is fungicidal against*] *Trichophyton mentagrophytes* [(Athlete's foot fungus)] [ATCC 9533].

[Batch code required]