

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 2, 2018

Ms. Cinda Bell Regulatory Agent for, IndusCo., Ltd. 2319 Joe Brown Drive Greensboro, NC 27405

Subject: PRIA Label Amendment – To add Pseudomonas aeruginosa claims

Product Name: EnviroSystems ProShield 3651 D

EPA Registration Number: 53053-27 Application Date February 8, 2018

Decision Number: 538238

Dear Ms. Bell:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is 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.

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.

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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,

E. Midelloff

Eric Miederhoff

Product Manager 31

Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure

### EnviroSystems® ProShield® 3651 D DISINFECTANT and ANTIMICROBIAL AGENT A Silicone Quaternary Ammonium Salt

#### **Active Ingredients:**

3-(trimethoxysilyl)propyldimethyl octadecyl ammonium chloride	35.60%
n-alkyl (60%C14, 40%C12, 10%C16) dimethyl benzyl ammonium chloride	6.40%
Octyl decyl dimethyl ammonium chloride	4.80%
Dioctyl dimethyl ammonium chloride	1.92%
Didecyl dimethyl ammonium chloride	2.88%
Other Ingredients:	48.40%
Total	100.00%

Contains over 6% Methanol

# KEEP OUT OF REACH OF CHILDREN DANGER ♣POISON

NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 fluid oz.; 1, 5, 55, 150, or 300 gal

Lot No.:

EPA Reg. No.: 53053-27 EPA Est. No.: 53053-NC-01

#### FIRST AID

Have the product container or label with you when calling the poison control center or doctor, or going for treatment.

#### 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.
- Call a poison control center or doctor for treatment advice.

#### IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further 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 to an unconscious person.
- Methanol may cause blindness

ACCEPTED

07/02/2018

53053-27

#### 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.

#### NOTE TO PHYSICIAN

Probably mucosal damage may contraindicate the use of gastric lavage.

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER!** Corrosive: Methanol may cause blindness. Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wear protective eyewear (goggles or face shield) and gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

#### PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame. De-activation of EnviroSystems® ProShield® 3651 D can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of EnviroSystems® ProShield® 3651 D.

#### **ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish, aquatic invertebrates, oysters, and shrimp. 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.

Deactivation may be required during clean up if a spill occurs. Deactivation of EnviroSystems® ProShield® 3651 D can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of EnviroSystems® ProShield® 3651 D.

#### **DIRECTIONS FOR USE**

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

Allow treated areas and surfaces to dry before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

For use in homes, offices, institutions (schools, universities, daycare centers, churches, correctional facilities), medical related facilities (laundries, clinics, dental offices, health care facilities, hospitals, medical offices, nursing homes), public facilities (airports, transportation terminals, bars, convenience stores, athletic facilities, locker rooms, barber shops, salons, hotels, public restrooms, playgrounds), transportation (airplanes, ambulances, boats, buses, campers, cars, emergency vehicles, ships, taxis, trains, trucks) and animal facilities (animal laboratories, farms, kennels, pet shops, zoos). This product may not be used on food contact surfaces.

EnviroSystems® ProShield® 3651 D controls odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* (spray application only).

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 can be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.] (OR)

[This product is not for use on medical device surfaces to the proposed, product labeling.]

#### **Application Instructions:**

Dilute 2.0 fl. oz. in one gallon of water (1 gallon of EnviroSystems® ProShield® 3651 D per 64 gallons of water)

For spray application, dilute EnviroSystems® ProShield® 3651 D in water and mix well. Using a trigger pump sprayer, spray the entire surface area 4"- 6" from the surface making sure the surface is completely covered. The surface should remain visibly wet for 10 minutes then wipe surface dry.

For mop and bucket application, dilute EnviroSystems® ProShield® 3651 D in a bucket and mix well. Mop area thoroughly.

For soaking application, dilute EnviroSystems® ProShield® 3651 D in a container and mix well. Soak item for 10 minutes then wipe dry.

Laundry Bacteriostat: (Not for use in the state of California) Soiled and contaminated fabrics are of major housekeeping concern in hospitals, institutions, hotels, restaurants and schools. EnviroSystems® ProShield® 3651 D provides cleaning properties against odor-causing bacteria for laundered items such as diapers, hospital and institutional linens, and athletic clothing. Use 0.6 ounces EnviroSystems® ProShield® 3651 D per 100 pounds of dry fabric. Dilute the product in one to two gallons of water and add to the wash wheel in the final rinse. Retreat fabric after each washing. Dry fabric prior to use.

#### OPTIONAL LANGUAGE and MARKETING CLAIMS

EnviroSystems® ProShield® 3651 D is an effective disinfectant against Salmonella choleraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa.

EnviroSystems® ProShield® 3651 D is effective against odor causing bacteria, bacteria that cause staining and discoloration, fungi (mold and mildew), and algae.

EnviroSystems® ProShield® 3651 D may be used for treatment of the following hard nonporous surfaces to impart disinfection (*Salmonella choleraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa*), bacteriostatic/fungistatic/algaestatic, and deodorizing activity: Tubs, glazed tiles, vanity tops, shower stalls (areas), sinks, washable walls, vinyl wall paper for non-food contact, floors, window sills, cabinets, garbage cans, exterior surfaces of appliances and refrigerators.

MOLD, MILDEW, ODOR PROTECTOR, ODOR INHIBITOR

Concentrate (Concentrated)

**Bactericidal** 

Deodorizes (Deodorizer)

Disinfects (Disinfectant)

For Hospital, Institutional, Industrial and Home Use

A Disinfectant for use in Hospitals

Hospital Disinfectant

EnviroSystems® ProShield® 3651 D can be used

- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps.
- as a broad-spectrum disinfectant in Ultrasonic Baths (Ultrasonic cleaning units).
- for cleaning and disinfecting of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces. Will not cause swelling of transducer membrane or harm compressor plates.
- Veterinary Practices, Animal Care, Animal Laboratory and Farm Premise applications.
- for swine premise sanitation on/in hauling equipment, loading equipment, farrowing barns and areas, nursery, blocks, creep areas.
- for farm premise sanitations on floors, walls, forks, shovels, scrapers and other nonporous surfaces in barns, pens, stalls, and other facilities and fixtures occupied or traversed by animals.
- to clean and disinfect (manicure)(nail)(salon)(barber) tools and instruments: combs, brushes, scissors, blades, and manicure instruments.

- on (to clean and disinfect) nonporous athletic mates, wrestling mats, gymnastic mats, exercise equipment and training tables.
- on (to clean and disinfect) wrestling headgear, boxing headgear, protective headgear, athletic helmets, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, hearing protectors, and ear muffs. Rinse all equipment that comes in prolonged contact with skin with warm water and allow to air dry before reuse.

EnviroSystems® ProShield® 3651 D, an antimicrobial agent, disinfects hard, non-porous surfaces and kills *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* in hospitals and other medical facilities.

EnviroSystems® ProShield® 3651 D is an antimicrobial agent effective against odor causing bacteria and fungi (mold and mildew) that cause offensive odors on hard, non-porous surfaces.

EnviroSystems® ProShield® 3651 D is an antimicrobial agent effective against odor causing bacteria in the kitchen and bathroom.

EnviroSystems® ProShield® 3651 D is an antimicrobial agent effective in controlling mold and mildew, and inhibiting the growth of mold and mildew.

EnviroSystems® ProShield® 3651 D, an antimicrobial agent, disinfects hard, non-porous surfaces and kills *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*.

EnviroSystems® ProShield® 3651 D, an antimicrobial agent, can be used in and around bathtubs and showers stalls to prevent the growth of mold and mildew.

EnviroSystems® ProShield® 3651 D provides an invisible barrier to inhibit the growth of odor causing bacteria.

EnviroSystems® ProShield® 3651 D provides an invisible barrier to inhibit the growth of bacteria which cause staining and discoloration.

EnviroSystems® ProShield® 3651 D provides an invisible barrier to inhibit the growth of fungi (mold and mildew).

EnviroSystems® ProShield® 3651 D provides an invisible barrier to inhibit the growth of algae.

EnviroSystems® ProShield® 3651 D prevents deterioration caused by odor causing bacteria and fungi (mold and mildew).

EnviroSystems® ProShield® 3651 D resists development of odor causing bacteria.

EnviroSystems® ProShield® 3651 D resists development of stains and discoloration due to odor causing bacteria.

EnviroSystems® ProShield® 3651 D resists development of stains due to fungi (mold and mildew).

EnviroSystems® ProShield® 3651 D resists stains due to algae.

#### STORAGE AND DISPOSAL

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

**Pesticide Storage:** Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed.

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

Containers 1 gallon or less: Wastes resulting from the use of this product may be disposed of on site.

Container Disposal: (plastic) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. (metal) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. (glass) Triple rinse (or equivalent), then dispose of in a sanitary landfill or by approved State and local procedures.

Container 1 gallon or less: Securely wrap original container in several layers of newspaper and discard in trash.

#### IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

IndusCo, Ltd. warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this label when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

INDUSCO, LTD. SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

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