



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

April 18, 2017

Dr. Melba Morrow  
Authorized Representative for IsoKlean, LLC  
toXel  
Toxicology & Regulatory Affairs  
7140 Heritage Village Plaza  
Gainesville, VA 20155

Subject: Notification per PRN 98-10 – Labeling Revisions  
Product Name: ISO-10  
EPA Registration Number: 92031-1  
Application Date: March 21, 2017  
Decision Number: 527512

Dear Dr. Morrow:

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 Karen M. Leavy at (703)-308-6237 or via email at [Leavy.Karen@epa.gov](mailto:Leavy.Karen@epa.gov).

Sincerely,

A handwritten signature in black ink that reads "Karen M. Leavy Esq,". The signature is written in a cursive style with a large initial 'K' and a trailing flourish.

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

# NOTIFICATION

92031-1

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:

04/18/2017

{MASTER LABEL}  
{All text in brackets [xxx] is optional & may or may not be included on a printed label.}  
{All text in braces {xxx} is administrative communication & will not appear on a printed label.}



### Disinfectant for Hospital, Institutional and Industrial Use

Iso-10 is a hospital grade disinfectant used to provide effective cleaning, deodorization, and disinfection of non-food contact surfaces. Continued use of the Iso-10 product will assist in controlling surface bacteria in hospitals, nursing homes, medical facilities, hotels and other commercial applications. This product, when used as directed, is formulated to disinfect the following hard non-porous non-food contact surfaces, inanimate environmental surfaces; floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, vanity tops, shower stalls, bathtubs, and cabinets. This product meets AOAC Use-Dilution Test Standards for hospital grade disinfectants.

ACTIVE INGREDIENTS	
N-Alkyl (C14-95%, C12-3%, C16-2%) dimethyl benzyl ammonium chloride	78.05%
Trichloromelamine	15.53%
Alkyl (60%C14, 30%C16, 5%C12, 5%C18) dimethyl benzyl ammonium chloride	1.22%
Alkyl (68%C12, 32%C14) dimethyl ethylbenzyl ammonium chloride	3.98%
INERT INGREDIENTS	100.00%
Total	100.00%

### KEEP OUT OF REACH OF CHILDREN

### DANGER

See [back] [side] [panel[s]] [outer carton label] [and][or] [leaflet] for additional [precautionary statements] [First Aid] [storage and disposal] [and] [directions for use].

### FIRST AID

Have the product container or label with you when calling a 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 eye. Call a poison control center or doctor for treatment advice.  
**If on skin or clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.  
**If swallowed:** 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:** 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.  
**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. See SDS for additional precautionary statements.

### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER. CORROSIVE.** May cause irreversible eye damage and skin burns. May be fatal if inhaled, swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Do not breathe dust. Remove contaminated clothing and wash before reuse. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Wear appropriate Personal Protection Equipment (PPE) including respiratory protection i.e. N100 mask, safety glasses or face shield, protective clothing, and rubber gloves, in accordance with OSHA/institutional standards.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.  
**DISINFECTION** - To disinfect inanimate, hard, non-porous, non-food contact surfaces, fill a clean container with 1/2 gallon of tap water. Open Iso-10 pouch and empty entire pouch contents (all 3 packets - total weight 4.1 grams) into the container. If 3 packets are not present, discard contents and open a new pouch. Shake in a sealed container vigorously for 30 seconds, add remaining 1/2 gallon of tap water to container and shake for an additional 30 seconds. Pre clean the entire surface to be treated. Apply solution with a mop, cloth, sponge, hand pump trigger sprayer or low volume sprayer. Wet all surfaces thoroughly. Allow to remain wet for 10 minutes. Shake before each use. 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) contact 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. **STABILITY OF USE-DILUTION:** For best results, use the solution the day it is mixed. If the diluted product becomes visibly dirty or contaminated, it must be discarded and fresh product prepared. Always use clean, properly labeled containers when diluting this product. **BACTERICIDAL ACTIVITY** - Iso-10 exhibits effective disinfectant activity against the organisms: Pseudomonas aeruginosa (ATCC 15442) and Staphylococcus aureus (ATCC 6538), meeting all requirements as a hospital grade disinfectant. **CONTACT TIME:** Allow surface to remain wet for 10 minutes. **FOR GENERAL CLEANING** - Apply diluted solution to soiled area with a mop, cloth, sponge, hand pump trigger sprayer or low pressure volume sprayer. Thoroughly wet soiled surface. Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product. **DEODORIZATION** - To deodorize a room, apply this product with a mop, cloth, sponge, hand pump trigger sprayer or low volume sprayer as indicated under the heading **DISINFECTION**.

### STORAGE AND DISPOSAL

#### DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

**PESTICIDE STORAGE** - Store in a dry place no higher in temperature than 90 F° Do not use or store near heat or open flame. Do not mix with oxidizers, soap, or other anionic materials.  
**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 label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. This product is for indoor use only.  
**CONTAINER HANDLING** - Non refillable container. Do not reuse or refill this container. Completely empty pouch into application equipment by shaking and tapping sides and bottom. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed of in accordance with local, state and federal regulations. When completely empty, offer for recycling if available or dispose of empty bag in a sanitary landfill. Offer outer box for recycling or dispose of empty box in trash. If the box is contaminated, dispose of in the manner required for the pouch.  
**REUSABLE DILUTION CONTAINER** - A container, such as a clean spray bottle, can be reused once empty. First prepare an appropriate use-solution from pouch per directions. Remove cap/spray nozzle from empty container. Fill empty container with newly prepared use-solution. Replace cap/spray nozzle. Follow directions for use.

Sold by: IsoKlean LLC  
2939 Pacific Drive  
Norcross, GA 30071  
Tel: 770-810-2009  
FAX: 770-452-1213  
www.isoklean.com



EPA REG No 92031  
EPA EST No 71441-OH-001

Net Content: 2.3 oz (16 - 0.144 oz pouches)

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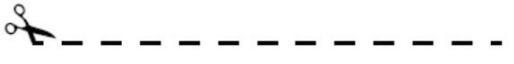
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{MASTER LABEL}  
{All text in brackets [xxx] is optional & may or may not be included on a printed label.}  
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{optional marketing claims and graphics}



WINDOWS FAUCETS VANITIES FLOORS



Hospital Disinfectant + Cleaner

Great for surface cleaning

16 pouches per box

3 packets per pouch

3 packets

Patent Pending

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