



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 25, 2017

Melba S. Morrow, DVM
Authorized Representative for IsoKlean, LLC
IsoKlean, LLC
2939 Pacific Drive
Norcross, GA 30071

Subject: Label Amendment – To update label language
Product Name: ISO-10
EPA Registration Number: 92031-1
Application Date: July 26, 2017
Decision Number: 531991

Dear Ms. Morrow:

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.

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 Emilia Oiguenblik by phone at

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703 347 0199, or via email at Oiguenblik.emilia@epa.gov or Eric Miederhoff by phone at 703 347 8028, or via email at Miederhoff.eric@epa.gov.

Sincerely,



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

Enclosure: Stamped label

{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.}

ACCEPTED

09/25/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 92031-1



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 | 1.22% |
| INERT INGREDIENTS..... | 3.98% |
| 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. Causes 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 ½ 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 ½ 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 92031-1
EPA EST No 71441-OH-001

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

{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