



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

92031-1

Date of Issuance:

2/1/17

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Iso-10

Name and Address of Registrant (include ZIP Code):

Melba Morrow
IsoKlean, LLC
2939 Pacific Drive
Norcross, Ga 30071

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

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

Date:

2/1/17

2. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
 - a. ADBAC-GDCI-069184-30910
 - b. ADBAC-GDCI-069104-30881
 - c. ADBAC-GDCI-069154-30906
 - d. Trichloromelamine-GDCI-077101-27850

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

- d. Be aware that proposed data requirements have been identified in a Work Plan for Trichloromelamine. For more information on these proposed data requirements, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>
- e. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
- f. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 92031-1.”
- g. Submit one copy of the final printed label for the record before you release the product for shipment.

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 fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 12/01/2016

If you have any questions, please contact Karen M. Leavy by phone at (703)-308-6237, or via email at Leavy.Karen@epa.gov.

Enclosure

{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

02/01/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 92031-1

Iso-10

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

(1) N-Alkyl (C14-95%, C12-3%, C16-2%) dimethyl benzyl ammonium chloride	78.05%
(2) Trichloromelamine.....	15.53%
(3) 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. 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 breath 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 foil 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 foil 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 foil packet 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 packet.

REUSABLE DILUTION CONTAINER - A container, such as a clean spray bottle, can be reused once empty. First prepare an appropriate use-solution from foil 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-XX
EPA EST No 71441-OH-001

Net Content: 16/64 foil packets per box.