



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 13, 2022

Melba Morrow
Authorized Representative of IsoKlean, LLC (toXcel, LLC)
IsoKlean, LLC
2939 Pacific Drive
Norcross, GA 30071

Subject: PRIA Label Amendment – To add claims against emerging viral pathogens
Product Name: ISO-10
EPA Registration Number: 92031-1
Received Date: 9/30/2021
Action Case Number/Decision Number: 00327770

Dear Melba:

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. Pursuant to 40 CFR 156.10(a)(6), 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.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease

outbreak that meets all the following criteria:

- a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large non-enveloped, enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Norovirus (Feline Calicivirus) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

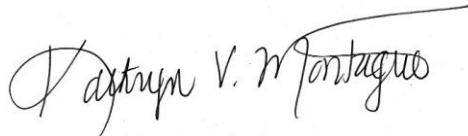
Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists 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, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is

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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 Assurance.

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 Hebert.John@epa.gov or Oiguenblik.Emilia@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Kathryn V. Montague". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Kathryn V. Montague
Senior Regulatory Advisor
Antimicrobials Division, 7510M
US EPA

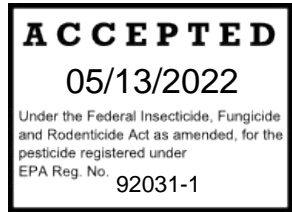
Enclosure: Stamped label



Disinfectant, Virucide and Fungicide for Hospital, Institutional and Industrial Use

Iso-10 is a hospital/healthcare broad spectrum disinfectant, virucide and fungicide 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 was tested using the AOAC use-dilution test method.

Table with 2 columns: Ingredient Name and Percentage. Includes Active Ingredients (N-Alkyl, Trichloromelamine, Alkyl) and Inert Ingredients, totaling 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]. {Note to Reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label, with the exception of small containers, which will include a reference statement for the first aid.}

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.
BACTERICIDAL ACTIVITY - Iso-10 exhibits effective disinfectant activity against the organisms: Pseudomonas aeruginosa (ATCC 15442) and Staphylococcus aureus (ATCC 6538). VIRUCIDAL ACTIVITY - Iso-10 exhibits effective virucidal activity against Feline Calicivirus (surrogate for Human Norovirus) meeting the requirements for a virucide. FUNGICIDAL ACTIVITY - Iso-10 exhibits effective fungicidal activity against Trichophyton interdigitale, ATCC9533 meeting the requirements for a fungicide.
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 visibly 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.
FOR GENERAL CLEANING - Apply diluted solution to soiled area. Follow directions as shown above. Thoroughly wet soiled surface. Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.
DEODORIZATION - follow directions for use as shown above.
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.

EMERGING VIRAL PATHOGEN CLAIM

Table with 2 columns: EMERGING VIRAL PATHOGEN CLAIM For an emerging viral pathogen that is a/an... and ...follow the directions for use for the following organisms on the label:
Enveloped virus: Norovirus (Feline calicivirus surrogate)
Large, non-enveloped virus: Norovirus (Feline calicivirus surrogate)

Emerging Pathogen Claims - This product meets the criteria for use against emerging enveloped viral pathogens and large, non-enveloped viral pathogens when used in accordance with the use directions for Norovirus.

The following statements shall be made only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.)

- [Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es) from table above] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.
[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es) from table above] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

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 4313-TX-1

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



WINDOWS



FAUCETS



VANITIES



FLOORS



Hospital Disinfectant + Cleaner

Great for surface cleaning

16 pouches per box

3 packets per pouch

Patented