

9150-11

4-30-2003

1/5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

April 30, 2003

Ana Rodriguez-Koster
Lewis & Harrison, LLC
122 C Street NW
Suite 740
Washington, DC 20001

Subject: International Dioxide, Inc.
Cryocide-20
EPA Registration No. 9150-11
Application Dated: February 24, 2003
Receipt Date: February 24, 2003

Dear Ms. Rodriguez-Koster:

This amendment responds to the Agency deficiency letter dated January 30, 2003 in which the Agency required that certain label changes be provided.

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is accepted with comments.

- Added animal confinement facilities and animal transport vehicles and equipment.
- Changed "chrome" to metal under hard non-porous surfaces.
- Added "General Disinfection" header.
- Corrected typographical errors.
- Added "Foot Bath" directions for use.

Comments

1. The heading for the "Hazards to Humans and Domestic Animals" statement must appear in bold letters.
2. The heading "General Disinfection" must appear in bold letters.
3. The heading "Directions for Use" must appear in bold letters and a larger type size.
4. The complete heading "Special Instructions for Cleaning and Decontamination Against HIV On Surfaces/Objects Soiled With Blood/Body Fluids" must appear in bold lettering.

CONCURRENCES							
SYMBOL	75						
SURNAME	M						
DATE	4-30-03						

5. Correct the empirical formula to read H_2SO_4 under the "Hospital Disinfection" directions for use.

General Comments

When you submit all future label amendments, please be certain to include use direction headings on the same page as the use directions.

A stamped copy of the accepted labeling is enclosed. Submit a copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

If you have any questions or comments concerning this letter, please contact Wanda Mitchell at (703) 308-6345.

Sincerely,



Robert S. Brennis
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

PRECAUTIONARY STATEMENTS: Hazards to Human & Domestic Animals - CAUTION Causes moderate eye irritation. Avoid contact with skin eyes or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Avoid contamination of food.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public 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.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal. **PESTICIDE STORAGE:** Store in the original container in a dry, temperature controlled area. Do not store in a manner where cross-contamination with other pesticides, fertilizers, food or feed could occur. If spilled during storage or handling, contain/re-capture spillage and dispose of in accordance with the Pesticide Disposal Instructions listed below. **PESTICIDE DISPOSAL:** Wastes resulting from the use of this product are toxic and may be disposed of on site or at an approved waste disposal facility. **CONTAINER DISPOSAL:** Do not reuse empty container. 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.

CRYOCIDE-20 provides broad-spectrum efficiency and economy for commercial, institutional, industrial and agricultural disinfection. CRYOCIDE-20's ability to OXIDIZE MALODORS offers a definite plus to its disinfecting activity.

SUGGESTED USES: For use on non-food, hard surfaces such as glass, plastic, metal, floors, examining tables and toilets in - Hospitals Nursing Homes - Institutions - Meat Packing Plants - Fish Processing Plants - Poultry Hatcheries - Industrial Processing Plants - Dairies - Food Processing Plants - Animal Confinement Facilities - Animal Transport Vehicles and Equipment

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

HOSPITAL DISINFECTANT

CRYOCIDE-20 is effective for disinfection of hard non-porous surfaces, at room temperature (20° -25°) in the presence of moderate amounts of organic soil. Remove gross filth and heavy soil prior to application. For disinfection against Tuberculosis Bacteria - Activate full strength CRYOCIDE 20 by reducing it's pH to 3.0 ±0.05 with 1.0 normal HCl or H2SO4 and allowing to stand for at least 15 minutes. Then using this resulting solution, proceed as directed under "General Disinfection".

GENERAL DISINFECTION: For general disinfection, apply CRYOCIDE-20 full strength to surface, wetting thoroughly with sponge, mop, spray, or by immersion in solution, and allow to remain wet for 10 minutes, and wipe dry. Although CRYOCIDE-20 destroys HSV-1 and 2(Herpes virus) and HIV-1 (AIDS virus) within 30 seconds of contact (see Special Instructions below) this contact time will not control other common types of viruses and bacteria

NOTICE: Seller expressly warrants that the product conforms to its chemical description. There are no warranties associated with the sale of the product either express or implied including but not limited to the warranties of fitness for a particular purpose or use

2/18/03

CRYOCIDE-20

· BACTERICIDAL · FUNGICIDAL(Pathogenic)
· PSEUDOMONICIDAL · VIRUCIDAL* · TUBERCULOCIDAL
· ODOR COUNTERACTANT

-Human Immunodeficiency Virus Type 1 (HIV-1)(AIDS Virus)
-Herpes Simplex Virus Type 1 and 2 - Influenza A2 (Hong Kong-68) Virus On Inanimate Environmental Surfaces

ACTIVE INGREDIENTS:

Chlorine Dioxide..... 0.72%
Didecyl Dimethyl
Ammonium Chloride..... 0.40%
INERT INGREDIENTS:.... 98.88%
TOTAL: 100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

First Aid 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 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 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 by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
For 24 hour emergency information on this product, call Chemtrec at 1-800-424-9300 (US, Canada, Puerto Rico, Virgin Islands) 1-703-527-3887 (All Other Areas)
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

See additional precautionary statements on side panels.

EPA Reg. No. 9150-11 EPA Est. 9150-RI-1

NET WT; 45 LBS.

Distributed by:

INTERNATIONAL DIOXCIDE INC.

554; Ten Rpd Road
No. Kingstown, RI 02852

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS that involve health care settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids and in which the surfaces/objects soiled with blood or body fluids can be associated with the transmission of HIV-1: CRYOCIDE-20 destroys HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood or other body fluids in 30 seconds contact. **PERSONAL PROTECTION:** The worker should wear disposable latex gloves, gown, mask and eye protection to prevent contamination from soiled items. **CLEANING PROCEDURE:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of CRYOCIDE-20. **CONTACT TIME:** Allow CRYOCIDE-20 to contact treated items for 30 seconds. This time will not control other common types of viruses and bacteria. **DISPOSAL OF INFECTIOUS MATERIALS:** Any blood and other body fluids should be autoclaved and disposed of according to federal, state & local regulations for infectious waste disposal.

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 may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

TO DISINFECT POULTRY HOUSES AND ANIMAL (poultry, swine, beef) CONFINEMENT FACILITIES

Remove all poultry, animals and feed from the premises. Remove all gross soil litter, manure, droppings from animals and poultry from floors, walls and surfaces of barns, pens, stalls, chutes, hatchers and other facilities and fixtures occupied or traversed by animals and poultry. Empty all troughs, racks and other feeding and watering appliances.

Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with Cryocide-20 at full strength for a period of 10 minutes.

Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing litter and manure in Cryocide-20 disinfectant at full strength. Allow to remain in contact for 10 minutes.

Ventilate buildings, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.

Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waters with soap or detergent, rinse with potable water before reuse.

ACCEPTED
with COMMENTS
EPA Letter # 9150-11-001

APR 30 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 9150-11

3/5

Animal Transport Vehicles: Use Cryocide-20 to control animal pathogens on vehicles and equipment that are used to transport live animals (poultry, swine, beef). Prior to application of Cryocide-20, remove all animals from the vehicle and then clean the vehicle with water to remove debris and dirt. Then apply one quart of Cryocide-20 through a foaming wand that delivers 4-6 gallons per minute (gpm) dilution water to the interior and exterior of the vehicle, transport cages, crates and other related equipment. Allow at least 10 minutes of contact time. Allow to air dry.

Shoe Bath: To prevent tracking of animal pathogens into animal areas, shoe baths containing one inch of freshly made solution (1-2 ounces of Cryocide-20 per gallon of water) should be placed at all entrances to buildings. Scrape waterproof work boots and then place in the shoe bath for at least 60 seconds. Change the shoe bath solution daily or when solution appears soiled.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling, and with the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

Personal Protective Equipment (PPE):

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: long-sleeved shirt, long pants, and shoes with socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box only apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agriculture pesticides (40 CFR part 170). The WPS applies when this product is used on farms, forests, nurseries, or greenhouses.

Keep children and pets out of treated areas until sprays have dried.

Personal Protective Equipment (PPE):

Long-sleeved shirt, long pants, and shoes with socks.

TO CONTROL THE BACTERIAL, FUNGAL AND VIRAL PLANT PATHOGENS AND ALGAE IN HORTICULTURAL APPLICATIONS:

Cryocide 20 has been shown to be effective for the curative and preventative management of algae, and bacterial, fungal and viral plant pathogens in Nurseries, Greenhouses, Landscapes & Interiorscapes. Follow specific direction for use sites indicated below.

Greenhouse Glass:

Mix 4-9 fl oz Cryocide 20 per 1 gallon of water and apply as a wet down spray to glass surfaces. Use with proper ventilation and allow application to dry. After 24 hours, wash of dead algae with water for improved light penetration. Reapply as needed. Avoid overspray, do not apply directly to plant material.

Walkways and under bench areas:

Mix 4-9 fl oz Cryocide 20 per 1 gallon of water and apply as a wet down spray to floor and under bench surfaces. For best results, do not rinse. Use with proper ventilation and allow application to dry. Reapply as needed. Avoid overspray, do not apply directly to plant material. Floor grown plants/flats may be returned after surface has dried. May be used in conjunction with other management techniques for the control of fungus gnats and shore fly larvae.

Evaporative Coolers:

Add 4-9 fl oz of Cryocide 20 for each 10 gallons of water volume contained in the system and allow to circulate throughout cooling pads and catch basins. For best results, repeat addition as needed or on a routine schedule every 14 days.

Retention basins and ponds:

4/5

Cryocide 20 can be used for the control of algae in irrigation water recapture systems and retention ponds. Add Cryocide 20 at a concentration of 2-5 ppm (4-9 fl oz per 100 gallons) for the control and prevention of water borne fungal and bacterial pathogens. Repeat application weekly for best results. Do not use where fish are present.

Decorative pools, fountains, and water displays:

For initial dosage when algae is present, apply 9-18 fl oz of Cryocide 20 per 100 gallons of water volume to achieve a 5-10 ppm solution. For maintenance, add no more than ½ the initial dosage as need or on a routine schedule every 14 days. Do not use when fish are present. When unit is to remain empty or not in use for extended period, apply a wet down spray to the hard surface of the unit at a rate of ½ fl oz per gallon.

50-43-20

WD

5/5