

October 18, 2004

Eliot Harrison
Lewis & Harrison
122 C Street, NW
Suite 740
Washington, DC 20001

Subject: International Dioxide, Inc.
Cryocide 20
EPA Registration No. 9150-11
Application Date: July 15, 2004
Receipt Date: July 23, 2004

Dear Mr. Harrison:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

Conditions

Revise the directions for use under "Mold and Mildew Control" as follows.

1. Delete the instructions "If necessary, agitate the applied areas with a hard bristle brush or scrubbing machine or remove excess liquid with a clean cloth, mop or sponge otherwise allow to air dry" it is unclear. The first four use directions cover the pre-cleaning, concentration, method of application, and contact time.
2. Add "Repeat every 7 days or more frequently if growth reoccurs" under the "To Treat Surfaces Contaminated With Mold & Mildew" directions for use.

General Comments

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

CONCURRENCES

SYMBOL	7510C						
SURNAME	Mitchell						
DATE	10-18-04						

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

Sincerely,

*Emily H. Mitchell
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)*

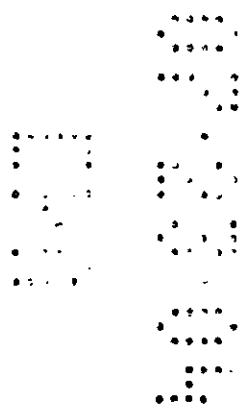
LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

July 15, 2004

Wanda Mitchell, Product Team (32)
Regulatory Management Branch #2
Antimicrobial Division (7510C)
Office of Pesticide Programs
Environmental Protection Agency
1921 Jefferson Davis Highway, Crystal Mall #2
Arlington, VA 22202




re: **Cyrocide® 20**
EPA Reg. No. 9150-11
Registrant: International Dioxide, Inc.
Label Amendment
Agency Letter of June 18, 2004

Dear Wanda:

On behalf of International Dioxide, Inc., I am responding to the Agency letter of June 18, 2004. Please note that a revised label (5 copies) that responds to the deficiencies noted in your letter is enclosed. The revised label only claims to control mold and mildew and specifies that the target surface is hard, non-porous surfaces.

If you have any questions about this response, please contact me at (202) 393-3903, ext. 14

Sincerely,


Eliot I. Harrison
Agent for International
Dioxide, Inc.

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.

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 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 is a disinfectant, fungicide, virucide, bactericide, mildewcide and mildewstat. It also provides exceptional cleaning and deodorizing. **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

CRYOCIDE® 20 has been designed for use in hospitals, medical and dental offices, nursing homes, industrial and institutional facilities, animal rearing and confinement facilities, animal research facilities and laboratories, meat-packing plants, fish processing plants, dairies, industrial processing plants, poultry hatcheries, agricultural storage facilities (including containers, trailers, rail cars and vessels) and animal transport vehicles and equipment.

CRYOCIDE® 20 can also be used in nurseries, greenhouses, landscapes and interiorscapes.

CRYOCIDE® 20 is for use on hard, non-porous surfaces such as appliances, basins, bathroom fixtures, bathtubs, cabinets, cages, chairs, countertops, examining tables, floors, sinks, tables, toilets, urinals and walls and other hard, non-porous surfaces made of fiberglass formica, glass, ceramic, metal, plastic and steel.

At full strength, **CRYOCIDE® 20** is an effective disinfectant against the following bacteria and viruses:

- Pseudomonas aeruginosa (Pseudomonas)
- Staphylococcus aureus (Staph)
- Salmonella choleraesuis (Salmonella)
- HIV-1 (AIDS virus)
- Herpes Simples Virus, Type 1 and 2
- Influenza A2 (Hong Kong-68)

A full strength activated solution of **CRYOCIDE® 20** is tuberculocidal against Mycobacterium bovis, BCG.

A 1:10 activated solution of **CRYOCIDE® 20** is effective against the following viruses:

- Canine parvovirus
- Minute virus of mice
- Rat coronavirus
- Mouse hepatitis virus

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

Controls Mold & Mildew

ACTIVE INGREDIENTS:

Chlorine Dioxide..... 0.72%

Didcyl 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

ACCEPTED
with COMMENTS
EPA Letter Dated

NET WT. 45 LBS.

Distributed by:
INTERNATIONAL DIOXIDE INC.

554 Ten Rod Road
No. Kingstown, RI 02852

OCT 18 2004

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

Directions for Use

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Preparation of Use-Solution

Disinfection: Use undiluted (neat)

Virucidal (against HIV-1, Herpes Simplex and Influenza): Use undiluted (neat)

Virucidal (against animal viruses): Put 1 part of CRYOCIDE® 20 into a clean pail and add 4 parts of an acid activator. The acid activator can be either citric, phosphoric, hydrochloric, glycolic or an equivalent acid. Allow the acid activated CRYOCIDE® 20 solution to react in the dark for 15-30 minutes. Then dilute the activated solution with 5 parts water. Prepare in a well-ventilated area.

Tuberculocidal (against Mycobacterium bovis, BCG): Put undiluted CRYOCIDE® 20 into a clean pail and add an acid activator until the pH reaches 3.0± 0.05. The acid activator can be either citric, phosphoric, hydrochloric, glycolic or an equivalent acid. Allow the acid activated CRYOCIDE® 20 solution to react in the dark for 15-30 minutes.

For controlling mold and mildew: Dilute 1 part of CRYOCIDE® 20 into a clean pail and add 4 parts water to make up your working solution

For preventive maintenance against mold and mildews: Dilute 1 part of CRYOCIDE® 20 into a clean pail and add 7 parts water to make your working solution

Application Instructions

Hospitals, Medical and Dental Offices, Nursing Homes

Apply undiluted CRYOCIDE® 20 to hard, non-porous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge or sprayer, or by immersion. Treated surfaces must remain wet for 10 minutes. Wipe dry with a cloth, sponge or mop or allow to air dry. For heavily soiled surfaces, a pre-cleaning is recommended.

Rinse all surfaces that come in contact with foods such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes.

For sprayer applications, use a coarse spray device. Spray 6-8 inches from the surface rub with a brush, sponge or cloth. Do not breathe spray.

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.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING AGAINST HIV OR SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS that involve healthcare settings or other 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 or rubber 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 Material: Any blood or other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

Poultry Houses and Animal (poultry, beef, swine) Confinement / Research / Laboratory Facilities

Use CRYOCIDE® 20 to treat incubators, floors, walls, ceilings, stainless steel cold rooms, bench tops, hoods, cages, and equipment. For disinfection, use undiluted CRYOCIDE® 20 and apply as indicated above. For controlling animal viruses and tuberculosis bacteria, use a 1:10 solution of activated CRYOCIDE® 20 as described above.

Prior to treatment, remove all animal and feed from premises, animal transport vehicles, enclosures, coops and crates. Remove all bedding, litter, droppings and manure from floors, walls, and surfaces of facilities occupied and traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Do not house animals or employ equipment until treatment has been absorbed set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waters, and other equipment which dispenses food or water with soap or detergent and rinse with potable water before reuse.

Animal Transport Vehicles and equipment

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. 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 Storage Facilities (Containers, Trailers, Rail Cars and Vessels)

Use CRYOCIDE® 20 to control spoilage microorganisms in agricultural storage facilities and containers, trailers, rail cars and vessels. Prior to application of CRYOCIDE® 20, sweep and wash 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 dilution water. Foam the diluted product on the interior and exterior of the trailer, rail car or vessel. Allow at least a 10 minute contact time. A potable water rinse is required for any food-contact surface that is treated.

MOLD AND MILDEW CONTROL (For Hospitals, Institutions, and Home)

CRYOCIDE® 20 controls mold and mildew on hard non-porous surfaces. CRYOCIDE® 20 rapidly and thoroughly so it is an ideal product for controlling molds in a single treatment. The efficacy and fast mode of action makes CRYOCIDE® 20 the perfect product for effective single operation mold and mildew control.

To Treat Surfaces Contaminated With Mold & Mildew

1. Remove all heavy build-up of growth filth and loose debris from areas to be treated.
2. Mix 1 part of the concentrate Cryocide 20 with 4 parts water.
3. Apply the product onto the surface with a commercial low-pressure sprayer 6 – 8 inches from the surface or utilizing a wet mop, sponge, wipe or other suitable applying device.
 Note: Where mist or vapors may be generated, proper ventilation must be provided in accordance with good ventilation practices. In the absence of proper environmental controls, a NIOSH/MSHA jointly approved respirator is advised
4. Make sure the treated area is thoroughly wet for at least 10 minutes and allow to air dry
5. If necessary, agitate the applied areas with a hard bristle brush or scrubbing machine or remove excess liquid with a clean cloth, mop or sponge otherwise allow to air dry.
6. Repeat application if needed.

For Preventative Maintenance Against Mold & Mildew

1. The treated area should be pre-cleaned of growth filth and loose debris prior to treatment.
2. Mix 1 part of the concentrate Cryocide 20 with 7 parts of water.
3. Apply the product onto the application point with a commercial low-pressure sprayer, wet mop, sponge, wipe or other suitable applying device.
 Note: Where mist or vapors may be generated, proper ventilation must be provided in accordance with good ventilation practices. In the absence of proper environmental controls, a NIOSH/MSHA jointly approved respirator is advised
4. Make sure the treated area is thoroughly wet for at least 10 minutes and allow to air dry
5. If necessary, agitate the applied areas with a hard bristle brush or scrubbing machine or remove excess liquid with a clean cloth, mop or sponge otherwise allow to air dry.
6. Repeat application at weekly intervals or when growth appears

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

This 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.

Horticulture Uses

CRYOCIDE® 20 is a general antimicrobial and algicide that has been designed for non-foliar use in the Nursery, Greenhouse, Landscape & Interiorscape areas of ornamental horticulture. It will control a variety of fungal, bacterial and viral plant pathogens, bacterial and fungal leaf rots, slime forming fungi, odor causing bacteria and algae. CRYOCIDE® 20 may be used as part of an overall program of microbe and algae control on a variety of surfaces and in water management equipment and devices.

Work Area and Benches:

CRYOCIDE® 20 has been designed to control cross-contamination that may occur between plants or production surfaces. Apply CRYOCIDE® 20 routinely before each work period and again after each plant cycle is completed. Remove all debris and litter from surfaces prior to application of CRYOCIDE® 20. Then mix 9 fl. oz. of CRYOCIDE® 20 per gallon of water and apply the use-solution to hard surfaces and watering devices by thoroughly wetting surfaces with cloth, mop, sponge or sprayer. Do not apply directly to plant material. Treated surfaces must remain wet for 10 minutes. Allow to air dry. For sprayer applications, use a coarse sprayer. CRYOCIDE® 20 is effective in reducing the transfer of fungal and bacterial pathogens that cause plant diseases such as root rots, crown rots, botrytis, and downy mildews.

Pots and Flats:

Apply CRYOCIDE® 20 to used planting devices such as pots and flats. Prior to application, remove all loose soil and plant residue. Then soak the pots and flats in a solution containing 18 fl. oz. of CRYOCIDE® 20 per gallon of water for 10-15 minutes. Remove from solution and allow to air dry before use.

Cutting Tools:

Use CRYOCIDE® 20 to control plant pathogens on cutting tools. Soak or dip cutting tools in a use-solution of 9 fl. oz. of CRYOCIDE® 20 per gallon of water. Allow cutting tools to remain wet for best results. At end of work period, dry and oil tools, or follow other specific instructions provided by tool manufacturer.

Recirculating Water Systems:

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.

Bulb Dip:

Prepare a solution using 9-18 fl oz of CRYOCIDE® 20 per 1 gallon of water. Soak cleaned bulbs for approximately 10 minutes, remove and allow to drip dry before storage. Treatment acts as a surface disinfectant for a variety of fungal and bacterial pathogens but will not control systemic pathogen events.

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:

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.