September 14, 2005

Jane M. Reise Regulatory Assistant International Dioxide, Inc. 554 Ten Rod Road North Kingstown, RI 02852

Subject:

Cryocide

EPA Registration No. 9150-11 Application Date: August 9, 2005 Receipt Date: August 18, 2005

Dear Ms. Reise:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

clarification of Directions For Use

General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable and a copy has been inserted in your file for future reference.

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

Sincerely,

Wanda Y. Henson Product Reviewer (32) Regulatory Management Branch II Antimicrobials Division (7510C)

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CONCURRENCES											
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					Emiy Mitchell					X None	Restricted	
4. Company/Product (Cryocide (R)	Name:	\$			PMF							
5. Name and Address	of Apr	plicant <i>Unclude ZIP Ce</i>	ode)	- 1	6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)							
	International Dioxcide Inc.				(b)(i), my product is similar or identical in composition and labeling							
554 Ten Rod Roa North Kingstown,	-	952		!	to: EPA Reg. No.							
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Check if this is a new address					Product Name							
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Resubmission i X Notification - E Explanation: Use at Correction of acid used 152.46, and no other of S.C. Sec. 1001 to willford Notice 98-10 and 40 C 14 of FIFRA."	in resp ixplain distion d to act thanges ully ma	below. nel page(s) if necesser tive the Cryocide produ s have been made to to take any false statement	ry. (For section uct. "This not!) the labeling or at to EPA. I furt	tfication is co the confider ther understa n of FIFRA a	onsistent w ntial staten and that if	Agency lett "Me Too" / Other - Exp Ith the provisionent of formuthis notification subject to	ter det Applica slain be slons o ula of ti ion is n	elow. of PR Notice this product,	98-10 a I unders	stand that it is ne terms of P	s a violation of 18 t R	
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3. Location of Net Contents Information 4. Size(s) F 8.4 lb.				£ 3					ibel Dira	ctions		
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Name				Title					1	····	clude Ares Code)	
Jane M. Reise									294 680	-		
<u> </u>	hat any	ments i have made on y knowlinglly false or i lew.		d all ettachr						Rece	Application lived Stamped)	
2. Signature				3. Title								
Janem Reise				REGULATORY ASSISTANT								
4. Typed Name	6. Date					\neg						
Jane M. Reise				August 9, 2005								

PRECAUTIONARY STATEMENTS: Hazards to Human & Domestic Animals CAUTION: Causes moderate eye initiation. Avoid contact with skin eyes or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and west clothing before rause

ENVIRONMENTAL HAZARDS: This posticide is toxic to fish and equatic organisms. Do not discharge effluent containing this product into takes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutarit 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, containts-capture spillage and dispose of in accordance with the Pesticide Disposal Instructions Ested 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 rines (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 amoke.

CRYOCIDE® 20 is a disinfectant, fungicide, virucide, bactericide, mildewcide and mildewstat. It also provides exceptional cleaning and deodortzing. CRYOCIDE® 20 provides broadspectrum efficiency and economy for commercial institutional, industrial and agricultural dentectos

CRYOCIDE® 20% ability to OXIDIZE MALODORS offers a definite plus to its deinfecting

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, meet-pecking plants, fish processing plants, duries, industrial processing plants, poultry hatcheries, agricultural storage facilities (including containers, trailers, rail cars and vessels) and arring transport vehicles and equipment.

CRYOCIDE® 20 can also be used in numeries, greenhouses, landscapes and improscapes.

CRYOCIDE® 20 is for use on hard, non-porous surfaces such as appliances, basins, bethroom fodures, bethutes, cabinets, cages chains, countentops, examining links, floors, sinks, tables, tollets, urinets and wells and other hard, non-porous surfaces made of fibergless formics, glass, ceramic, metal, plastic and steel.

Directions for Use

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

Preparation of Use-Solution

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

Virucidal (against animal viruses): Put 1 part of CRYOCIDE® 20 into a clean pair and add 4 parts of a 10% acid activator solution. The acid activator can be either citric, phosphoric. hydrochoric, plycolc or an equivalent acid, Allow the acid scivated CRYOCIDE* 20 solution by mach in the dark for 15-30 minutes. Then diute the activated solution with 5 rarts water. repare in a well-ventilated area.

Tuberculocidal (against Mycobacterium bovis, BCG): Put undivised CRYOCID: 20 into a clean pair and add a 10% acid activator solution until the pH reaches 3.0± 0.06. The acid activator can be either citic, 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 motel and mildows: Dikto 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 milders: Dikts 1 part of CRYDCIDE® 20 into a clean pail and add 7 parts water to make your working solution

<u>Application Instructions</u>
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-clearing is recommended.

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

For sprayer applications, use a course 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 startlant/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 stanizzation 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 intrimete 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 contect.



·BACTERICIDAL · FUNGICIDAL(Pathogenic) · PSEUDOMONICIDAL · VIRUCIDAL" · TUBERCULÓCIDAL · 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 Dloxide..... Didecvi Dimethyl

0.72% 0.40%

Ammonium Chloride...... **INERT INGREDIENTS:...**

98.88%

TOTAL:

KEEP OUT OF REACH OF CHILDREN CAUTION

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

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with planty 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-tomouth, 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. 8.4 LBS.

Distributed by: INTERNATIONAL DIOXCIDE INC. 554 Ten Rod Road No. Kingstown, RI 02852

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Personal Protection: The worker should wear disposable latex gloves or nubber gloves, gown, mask and eye protection to prevent contamination from solled 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 firm will not control other common types of viruses and bectaria.

Disposal of infectious Mixterial: 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 Artimal (poultry, beef, swine) Confinement / Research / Laboratory

Facilities

Use CRYOCIDE® 20 to treat incubators, floors, walls, callings, stainless steel cold rooms, banch tops, hoods, cages, and equipment. For disinfection, use unditated 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 scap 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 scap or detergent and rinse with potable water before reuse.

Animal Transport Vehicles and equipment

Use CRYOCIDE® 20 to control aritimal pathogens on vehicles and equipment that are used to transport live enimals (poultry, swine, beef). Prior to application of CRYOCIDE® 20, remove all animale 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 4-8 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.

To prevent tracking of arrimal pathogens into animal areas, since beths containing one inch of treshly 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 50 seconds. Change the shoe bath solution daily or when solution appears solled. Agricultural Storage Facilities (Containers, Trailers, Rail Cars and Vessels)

Use CRYCCIDE® 20 to control spoilings microorganisms in agricultural storage facilities and containers, trailers, rail cars and vessels. Prior to application of CRYCCIDE® 20, sweep and wesh vehicle with water to remove debris and dirt. Then apply one quart of CRYOCIDE® 20 shrough 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 works 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

Remove all heavy build-up of growth fifth and loose debris from areas to be treated.

Mbx 1 part of the concentrate Cryocide 20 with 4 parts water.

Apply the product onto the surface with a commercial low-pressure sorayer 6 - 8 inches from the surface or utilizing a wet mop, sponge, wipe or other suitable applicating

Note: Where mist or vapore may be generated, proper ventilation must be provided in accordance with good ventilation practices. In the absence of proper environmental controls, a NIOSH/MSHA lointly approved respirator is advised Make sure the treated area is thoroughly wet for at least 10 minutes and allow to air dry

Repett every 7 days or more frequently if growth reoccurs. For Preventative Maintenance Against Hold & Mildew

The treated area should be pre-cleaned of growth fifth and loose debris prior to

Mix 1 part of the concentrate Cryocide 20 with 7 parts of water.

Apply the product onto the spotcation point with a commercial low-pressure sprayer, wet mop, sponge, wipe or other suitable applicating 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

Make sure the treated area is thoroughly wet for at least 10 minutes and allow to air dry If necessary, egitate the applied areas with a hard bristle brush or acrubbing mechine or

remove excess liquid with a clean cloth, mop or sponge otherwise allow to air dry.

Repeat application at weakly 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 posticides. It contains requirements for training, decontemination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label about personal protective equipment (PPE), and restrictedentry 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

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Personal Long-stee

Hortiouture CRYOCIDE in the Nurser control a veri forming fungi, program of equipment an

Work Area a or production each plant cy CRYOCIDE solution to he sponge or ap 10 minutes. effective in n auch as root (Pote and Fla

Apply CRYO remove all lo fl. oz. of CRY to air dry befo Cutting Tool

Use CRYOCI une equation o Allow cutting follow other s

Regiroudation and prevention best results.

Bulb Dip: Prepare a so bulbs for app control system

Greenhouse Mix 4-9 fl cz surfaces. Use deed algee wi not apply dire

Walkways ar Mbx 4-9 fl oz (under bench application to Floor grown p with other me

Evaporative : Add 4-9 fl cz and allow to addition as ne

Retention Be CRYOCIDE® retention ponfor the contr application we

Decorative P of water voter initial dossos present. When spray to the h



International Dioxcide, Inc. 554 Ten Rod Road North Kingstown, RI 02852 401-295-8800 Tel 401-295-7108 Fax

August 9, 2005

Document Processing Desk Ms. Emily Mitchell Antimicrobials Division (7510C) US Environmental Protection Agency Office of Pesticide Programs Ariel Rios Building 1200 Pennsylvania Avenue NW Washington, DC 20460

Reference: Cryocide® 20, EPA Registration No. 9150-11; NOTIFICATION

Dear Ms. Mitchell,

Please find the attached EPA Form 8570-1 and two copies of revised labeling submitted in support of notification of label change in accordance with PR Notice 98-10 II.M.3. for the subject product. Also attached is a one copy of the label highlighting the change in the directions.

The revised labeling incorporates, under "Preparation of Use-Solution" Tuberculocidal and Virucidal, a 10% acid activator solution.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Should you have any questions, feel free to call.

Sincerely,

Jane M. Reise Regulatory Assistant

International Dioxcide, Inc.

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