

71654-22

1-23-2008

1/6

FILE COPY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

January 23, 2008

Thomas C. McEntee
E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: Time Limited Amendment (1 Year to date of letter)
Cryocide Disinfectant Spray
EPA Registration No. 71654-22
Application Date: August 23, 2007
Receipt Date: August 27, 2007

Dear Mr. McEntee:

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

Conditions

Regarding the submitted data:

The proposed label claims that the product, Cryocide®, **kills mold (A. niger)** on hard, non-porous environmental surfaces at full strength and room temperature with a contact time of 10 minutes. These claims are not supported by the submitted data.

As DIS/TSS-6 states, if the product is intended for use as a **spray**, the AOAC Germicidal Spray Products Test (modified to conform with appropriate elements in the AOAC Fungicidal Test) must be employed. The Agency has agreed to allow this claim based on receipt of acceptable data by May 31, 2008.

van 3/13

Regarding the proposed labeling:

- i) Page 1 of the proposed label claims that the product "**Controls bacteria...growth.**" This statement is false and **must be removed.** The product was tested as a disinfectant with the standard 2 day incubation time. Controlling growth is a residual claim, for which the product has not been tested. The applicant may say "Kills bacteria" instead.
- ii) Page 1 of the label identifies the product as "**Fast Acting.**" These claims **must be removed.** The product harbors a 10 minute contact time, which is the maximum time allowed for disinfection label claims. Identifying the product as fast acting is false and misleading.

iii) The letter previously sent to the applicant (dated April 20, 2007), states:

"The company is not permitted to disinfect food contact surfaces and then instruct the user to rinse the treated surfaces with potable water. In order to have a food contact disinfection claim a different set of bacteria has to be tested, and all ingredients in the formulation must be cleared by our regulations for use on food contact surfaces. Rinsing the treated surface does not negate the need for the efficacy testing, nor renders the food contact surface safe from the pesticide residues."

This recommendation was not present in the previous efficacy review and is incorrect. Disinfectant (in contrast to sanitizer) products may be used to treat food-contact surfaces followed by a potable water rinse. There is no additional set of bacteria that needs to be tested for this claim. Therefore, the applicant's previous statement, "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," is acceptable.

iv) As stated in the Labeling Guidelines for pesticide use directions (Subdivision H, Subsection 101-1 (a)(8)(ii)(B)), the label must list the specific target microorganisms intended to be controlled by the product. Current labeling lists only *S. aureus* and *S. enterica*. **The label must also list *Trichophyton mentagrophytes*.** At such time that data is accepted for *A. niger*, this organism must be listed as well.

v) The applicant **must list ATCC numbers for all organisms** appearing on the product label (See ATCC Letter, soon to be posted online). The applicant may choose to list ATCC numbers for the tested organisms in one of the following locations:

- On the data matrix,
- On the master label (as optional text) with the listing of the organisms claimed, or
- As the final page of the master label (as optional text).

General Comments

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

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

Sincerely,

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

4/6

CRYOCIDE® Disinfectant Spray

- 32 OUNCE [OPT]
- 1 GALLON [OPT.]
- KILLS MOLD [OPT.]
- KILLS MOLD & MILDEW [OPT.]
- PRE-PAINT TREATMENT AND DISINFECTANT SPRAY [OPT]
- CONTROLS BACTERIA, MOLD & MILDEW GROWTH [OPT]
- FRESH SCENT [OPT.]
- POWERFUL NON-BLEACH FORMULA [OPT]
- USE AROUND BATH AND SHOWER STALL TO KILL BACTERIA AND FUNGI [OPT]
- TREAT THEN PAINT [OPT]
- CLEAN THEN PAINT [OPT]
- DISINFECT THEN PAINT [OPT]
- PRE-PAINT CLEANER AND DISINFECTANT [OPT]
- PRE-PAINT FUNGICIDE AND DISINFECTANT [OPT]
- FUNGICIDE AND DISINFECTANT [OPT.]
- FUNGICIDE, DISINFECTANT AND DEODORIZER [OPT.]
- INHIBITS MOLD & MILDEW PRIOR TO PAINTING [OPT.]
- PRE-PAINT CLEANER, DISINFECTANT AND DEODORIZER [OPT.]
- CLEANS, DISINFECTS AND DEODORIZES [OPT.]
- PRE-PAINT FUNGICIDE, DISINFECTANT AND DEODORIZER [OPT.]
- KILLS BACTERIA AND FUNGI IN BATHROOMS [OPT]
- KILLS BACTERIA, FUNGI, AND ODORS IN BATHROOMS [OPT]
- KILLS BACTERIA IN BATHROOMS [OPT]
- KILLS BACTERIA AND ODORS IN BATHROOMS [OPT]
- BACK PANEL: KILLS *Staphylococcus aureus* (STAPH) AND *Salmonella enterica* (SALMONELLA)[OPT]
- CONTROLS & PREVENTS MOLD AND MILDEW GROWTH [OPT.]

- READY-TO-USE [OPT.]
- FAST ACTING [OPT.]
- FAST ACTING FORMULA [OPT.]
- BACTERICIDAL [OPT.]
- FUNGICIDAL(PATHOGENIC) [OPT.]
- DISINFECTANT [OPT]
- FUNGICIDE (PATHOGENIC) [OPT]
- BACTERICIDE [OPT]
- MILDEWCIDE [OPT]
- MILDEWSTAT [OPT]
- ELIMINATES ODORS [OPT]
- KILLS BACTERIA AND ELIMINATES ODORS [OPT]
- KILLS STAPH AND SALMONELLA [OPT.]
- ODOR COUNTERACTANT [OPT]
- ODOR ELIMINATOR [OPT.]
- ELIMINATES ODORS [OPT.]
- ECONOMICAL ONE STEP DISINFECTANT [OPT.]
- KILLS STAPH [OPT]
- BROAD SPECTRUM DISINFECTANT [OPT]
- CONTROLS MOLD & MILDEW [OPT]

ACCEPTED
with COMMENTS
EPA Letter Dated:

JAN 23 2008

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

71654-22

5/6

ACTIVE INGREDIENTS:
 Chlorine Dioxide..... 0.18%
 Didecyl Dimethyl Ammonium Chloride..... 0.10%
OTHER INGREDIENTS:..... 99.72%
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- 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- 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)

Medical Emergency 1-800-441-3637 (outside U.S. 1 302-774-1139)

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 [back] panels.
 EPA Reg. No. 71654-22 EPA Est. XXXXX-YY-Z

Manufactured For: E.I. duPont de Nemours and Company, P.O. Box 80402, Wilmington, DE 19880-0402

Cryocide® is a registered trademark of International Dioxide Inc., a DuPont Company © 2006. E.I. du Pont de Nemours and Company. All rights reserved.

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.

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/recapture 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 this container. Place in trash or offer for recycling if available.

6/6
CRYOCIDE® Disinfectant Spray kills Mold & Mildew on hard, non-porous surfaces. [OPT.]

CRYOCIDE® Disinfectant Spray inhibits and prevents mold and mildew growth prior to painting and kills bacteria throughout the house on hard, non-porous surfaces. CRYOCIDE® Disinfectant effectively cleans, disinfects and deodorizes bathroom countertops, tubs, tile, around toilet areas, hampers and diaper pails as well as in kitchens, basements, attics and storage areas to control, inhibit and prevent the growth of mold and mildew and eliminate their odors. [Opt.]

CRYOCIDE® Disinfectant Spray effectively cleans, disinfects and controls mold & mildew on surfaces prior to painting and kills bacteria throughout the house on hard, non-porous surfaces. Use around bath and shower stalls, around sinks, counters and toilet areas as well as in kitchens, basements, attics and damp storage areas to control and prevent the growth of mold and mildew and eliminate their odors. [Opt]

CRYOCIDE® Disinfectant Spray is a disinfectant, fungicide, bactericide, mildewcide and mildewstat. It also provides exceptional cleaning and deodorizing [Opt.] **CRYOCIDE® Disinfectant Spray** provides broad-spectrum efficiency and economy for commercial, institutional, industrial, and residential disinfection. [Opt.] **CRYOCIDE® Disinfectant Spray: Its ability to OXIDIZE MALODORS** offers a definite plus to its Disinfectant activity. [Opt.] **CRYOCIDE® Disinfectant Spray** has been designed for use in industrial and commercial facilities, and homes. [Opt.]

CRYOCIDE® Disinfectant Spray [optional] is for Disinfectant hard, non-porous surfaces such as appliances, basins, bathroom fixtures, bathtubs, cabinets, cages, chairs, countertops, floors, sinks, tables, toilets, urinals and walls and other hard, non-porous surfaces made of fiberglass, Formica®, glass, ceramic, metal, plastic, painted surfaces and steel. [Opt.]

DIRECTIONS FOR USE

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

Containers larger than 32 Fl. Oz.: Application Instructions

For General Disinfection Applications in Commercial, Industrial, Schools, Apartments and Homes:

Apply product to hard, non-porous surfaces with a commercial low pressure sprayer, wet mop, sponge, wipe or other suitable application device, thoroughly wetting surfaces. [32 Fl. Oz. Size or smaller: **Application Instructions, Shake container well.** Apply thoroughly and evenly, 6-8 inches away from surface, using the SPRAY nozzle position for large areas or STREAM for a concentrated jet on hard to reach areas. OPT.] 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.

MOLD & MILDEW

MOLD AND MILDEW CONTROL AND DEODORIZATION (For Schools, hotels, correctional facilities, apartments and Homes)

CRYOCIDE® Disinfectant Spray controls, inhibits and prevents mold and mildew on hard non-porous surfaces. CRYOCIDE® Disinfectant Spray works thoroughly so it is an ideal product for controlling and preventing mold in a single treatment. The efficacy makes **CRYOCIDE® Disinfectant Spray** the perfect product for effective single operation for mold and mildew control and prevention.

1. Remove all heavy build-up of gross filth and loose debris from areas to be treated.

2. Apply the product onto the surface; spray 6 – 8 inches from the surface.

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 approved respirator is advised

3. Make sure the treated area is thoroughly wet for at least 10 minutes and allow to air dry

4. Repeat every 7 days or more frequently if growth reoccurs.

To Control, Inhibit and Prevent the Growth of Mold & Mildew: Spray 6-8 inches away from a dry, pre-cleaned surface until thoroughly wet. The treated area must remain wet for at least 10 minutes. Allow to air dry. Repeat as needed.

To Deodorize: Spray surfaces as needed to eliminate odors retained on hard surfaces.