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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 14, 2012

Paul Lorcheim
ClorDiSys Solutions, Inc.
5 Concord Road
Lebanon, NJ 08833

Subject: ClorDiSys Sterilization System CSI CD Cartridge
EPA Registration Number: 80802-1
Letter Date: October 14, 2011
EPA Receipt Date: November 16, 2011

Dear Mr. Lorcheim:

The label amendment, submitted in connection with registration under section of the federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed label amendment:

- Add potato storage areas to list of approved use sites on cartridge label
- Add Appendix K - illustrating which types of potato spoilage bacteria cartridge is effective against, and what concentration of chlorine dioxide gas to use - to Systems Operations Guides for ClorDiSys Sterilization Systems, which contain detailed use instructions and list of claims against specific potato spoilage organisms.

Should you have any questions or comments concerning this letter, please contact Eliza Blair via email at *blair.eliza@epa.gov* or by telephone at (703) 308-7279.

A stamped copy the label is enclosed for your record.

Sincerely,

Monisha Harris
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: Stamped Labeling

ClorDiSys Sterilization System
CSI CD Cartridge

FOR USE IN GENERATING CHLORINE DIOXIDE GAS

ACTIVE INGREDIENT:	
Sodium Chlorite	72.8%
OTHER INGREDIENTS:	27.2%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

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: 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 Swallowed: Call a 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 a 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 mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Hot Line Number: Have the product container or label with you when calling poison control center or doctor or when going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

EPA Registration No.: 80802-1
EPA Est. No.: 80802-NJ-001

LOT

EXP

Distributed by:

CSI ***ClorDiSys Solutions, Inc.***

P.O. Box 549
Lebanon, N.J. 08833

ACCEPTED
FEB 14 2012
Under the Federal Insecticide, Fungicide, and
for the
Registration Number
80802-1

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

DANGER. Corrosive. Causes eye and skin damage. May be fatal if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and use only Neoprene gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL OR CHEMICAL HAZARDS: This product contains a strong oxidizing agent. In the event the container is damaged, combustible material contaminated with the product's contents may burn rapidly. Do not expose to hot surfaces, sparks, or open flame.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic invertebrates, oysters, and shrimp.

STORAGE AND DISPOSAL: DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. Storage: Avoid exposure to high temperatures during storage. Store remote from other chemicals and combustible 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.

Container Disposal: Do not throw expended column in the trash. Return used column to an authorized disposal facility, as per manufacturer's instructions.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. People must vacate the chamber during the fumigation process until the fumigant is at or below the OSHA 0.1 ppm TWA level. This product contains a sodium chlorite mixture which, when contacted with chlorine, generates chlorine dioxide. CSI CD Cartridge is for use where sterility conditions are critical for optimal performance. Use CSI CD Cartridge to sterilize sealed spaces/enclosures, such as: sealed rooms, manufacturing and laboratory equipment and spaces, including Biological Safety Cabinets, incubators, fume hoods, HEPA housings, environmental surfaces, implements and components such as: manufacturing vessels, process tanks, piping, filters, portable vessels, beakers, test tubes, devices, and laboratory glassware; rooms; isolators and pharmaceutical isolators. Use CSI CD Cartridge to fumigate potatoes in potato storage facilities. This product is for use in ClorDiSys Solutions, Inc Sterilization Systems ONLY and must be used by trained personnel. For proper generation and application of chlorine dioxide, you must follow the instructions in the ClorDiSys Systems Operations Guides (4).

Net Weight 3lb. 14oz.

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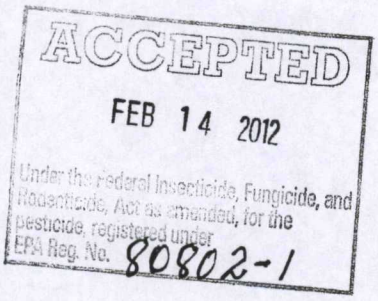
Appendix K. Specialized Applications

in this appendix . . .

- *Guidance and cycle development for specialized applications*



Background and Process Fundamentals

Chlorine dioxide (CD) is a greenish-yellow gas and is a single-electron-transfer oxidizing agent with a chlorine-like odor. CD has been recognized since the beginning of the century for its disinfecting properties; these properties have led to the widespread use of CD in the treatment of drinking water. Beyond this and numerous other aqueous applications, the sporicidal properties of *gaseous* CD were demonstrated in 1986. Subsequent to these initial studies, it has been shown that gaseous CD is a rapid and effective sterilant active against bacteria, yeasts, molds, and viruses. The rapid sterilizing activity of CD is present at ambient temperature and at relatively low gas concentrations. Chlorine dioxide has also been found to be extremely effective against tuber causing diseases leading to potato spoilage in storage areas.

Guidance on Development of Sterilization Processes

Tubers:

To control the spread of late blight, soft rot, pink rot, black scurf and other tuber disease causing organism on potatoes in potato storage areas:

Chlorine dioxide gas for use on tubers going into storage should be utilized at the optimal concentration level of 200-400 ppm. The gas can be injected directly into the potato storage area or into the plenum as part of the air stream feeding the storage area.