UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 20, 2019

Daniel Paznek
Operations Manager ClorDiSys Solutions, Inc.
ClorDiSys Solutions, Inc.
P.O. Box 549
Lebanon, NJ 08833

Subject: PRIA Label Amendment – Addition of Sterilization Application
Product Name: CSI CD CARTRIDGE
EPA Registration Number: 80802-1
Application Date: December 19, 2018
Decision Number: 557558

Dear Mr. Paznek:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

with FIFRA section 6. If you have any questions, please contact Melanie Bolden by phone at (703) 347-0165, or via email at Bolden.Melanie@epa.gov.

Sincerely,

Demson Fuller, Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

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

Net Weight: 3lb. 14 oz.

ACCEPTED

11/20/2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 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 cartridge in the trash. Return used cartridge 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 to be used on porous and non-porous surfaces when used with sterility instructions. 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 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.

To control odor causing microorganisms, generate 20 ppm of chlorine dioxide gas within the confined treatment space or closed duct system for at least 5 hours. A minimum initial relative humidity of 65% or greater and a minimum temperature of 52 degrees should be maintained during treatment. Follow instructions below to control odor causing microorganisms.

For Sterility: This product is for use in ClorDiSys Solutions, Inc. application systems ONLY and must be used by trained personnel. For proper generation and application of chlorine dioxide from automated systems, you must follow the instructions in the ClorDiSys Systems Operations Guides (8).

Package Insert for CD Cartridge
EPA Registration 80802-1

Table of Contents

1. Personal Protective Equipment

Full face protective respirator using 3M 6003 or equivalent cartridges for acid vapor, chlorine and chlorine-dioxide-gas, when concentrations are at or below 5ppm. Use NIOSH/MSHA-approved TC-13F-314 Low Pressure Self Contained SCBA Respirator or equivalent for gas concentrations above 5.0 ppm

Follow manufacturer's instruction for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Rinse thoroughly and discard clothing and other absorbent materials that have been drenched or heavily contaminated with the product's concentrate.

THIS PRODUCT IS DANGEROUS WHEN GENERATED

Chlorine dioxide (CD) gas is a strong oxidizing agent. Chlorine dioxide is irritating to the respiratory tract. The symptoms of chlorine intoxication depend on its concentration and on the exposure time; they include lacrimation, headache, vomiting, severe cough, asthmatic bronchitis, dyspnea and even death. DO NOT INHALE CHLORINE DIOXIDE. Exposure to high concentrations of chlorine dioxide can cause death. Do not allow unprotected workers to be exposed to chlorine dioxide gas.

2. Fumigation Management Plan (FMP)

The ClorDiSys Solutions Inc. trained applicator is responsible for working with the owners and/or responsible employees of the site to be fumigated to develop a Fumigation Management Plan (FMP) for each site that will be treated with CD Gas. A FMP is not required for sealed enclosures smaller than 40 cubic feet since reentry by applicators or other individuals is not possible. All other applicable precautions should be adhered to. The applicator is responsible for all tasks of the fumigation process unless otherwise noted in the FMP and must be on site for the entire fumigation treatment process. The FMP must address characterization of the site, and include appropriate monitoring and notification requirements, consistent with, but not limited to, the following:

2.1. Monitoring and Notification requirements

1. Inspect the structure and or area to determine its suitability for fumigation.
2. When sealing is required, consult previous records for any changes to the structure, seal leaks, and monitor any occupied adjacent rooms and/or buildings to ensure safety
3. Prior to each fumigation, review any existing FMP, SDS, Equipment Manual and other relevant safety procedures with company officials and appropriate employees.
4. Consult with company officials in the development of procedures and appropriate safety measures for nearby workers who will be in and around the area during application and aeration.
5. Consult with company officials to develop an appropriate monitoring plan that will confirm that nearby workers and bystanders are not exposed to levels above the allowed limits during application, fumigation and aeration. This plan must also demonstrate that nearby residents will not be exposed to concentrations above the allowable limits.
6. Consult with owners and or responsible employees at the site who will be responsible for development of procedures for local authorities to notify nearby residents in the event of an emergency.
7. Confirm the placement of placards to secure entrance into any area under fumigation.
8. Confirm the required safety equipment is in place and the necessary manpower is available to complete fumigation.

These factors must be considered in putting a FMP together. It is important to note that some plans will be more comprehensive than others. All plans should reflect the experience and expertise of the applicator and circumstances at and around the structure and/or area.

In addition to the plan, the applicator must read the entire label and equipment manual and follow all directions carefully. If the applicator has any questions about the development of an FMP, contact ClorDiSys Solutions, Inc for further assistance.

2.2. GUIDANCE FOR PREPARATION OF A FUMIGATION MANAGEMENT PLAN

A Fumigation Management Plan (FMP) is an organized, written description of the required steps involved to help ensure a legal and effective fumigation. It will also assist you and others in complying with pesticide product label requirements.

The guidance that follows is designed to help assist you in addressing all the necessary factors involved in preparing for and fumigating a structure and/or area.

This guidance is intended to help you plan any fumigation that you might perform PRIOR TO ACTUAL TREATMENT. It is meant to be somewhat prescriptive, yet flexible enough to allow the experience and expertise of the fumigator to make changes based on circumstances that may exist in the field. By following a step-by-step procedure, yet allowing for flexibility, an effective fumigation can be performed.

Before any fumigation begins, carefully read and review the label and the Equipment Manual. This information must also be given to the appropriate company officials (supervisors, foreman, safety officer, etc.) in charge of the structure and/or area. Preparation is the key to any successful fumigation. If the type of fumigation that you are to perform is not listed in this Guidance Document you will want to construct a similar set of procedures. Finally, before any fumigation begins you must be familiar with and comply with all applicable state and local laws. The success of the fumigation is not only dependent on your ability to do your job but also upon carefully following all rules, regulations, and procedures required by governmental agencies.

2.3. A CHECKLIST GUIDE FOR A FUMIGATION MANAGEMENT PLAN

This checklist is provided to help you take into account factors that must be addressed prior to performing all fumigations. It emphasizes safety steps to protect people and property. The checklist is general in nature and cannot be expected to apply to all types of fumigation situations. It is to be used as a guide to prepare the required plan. Each item must be considered, however, it is understood that each fumigation is different and not all items will be necessary for each fumigation structure and/or area.

2.3.1. PLANNING AND PREPARATION

2.3.1.1. Determine the purpose of the fumigation.

- Sterilization of room or other enclosures.
- Sterilization of emergency vehicles.

2.3.1.2. Determine the type of fumigation, for example:

- Pharmaceutical Operations, clean rooms, medical device sterilization manufacturing
- Laboratories, animal research facilities,
- Patient rooms, hotel rooms, offices, recreational facilities.
- Cruise ship rooms, In addition to the Equipment Manual, read the US Coast Guard Regulations 46CFR 147A.
- Manufacturing or production facilities

2.3.1.3. Evaluate the structure or area to be fumigated, and develop a site-specific plan that includes the following points, as applicable:

- The general structure layout, construction (materials, design, age, maintenance, of the structure, fire or combustibility hazards, connecting structures and escape routes, above and below ground, and other unique hazards or structure characteristics. Meet with the owner/operator/person in charge. Draw or have a drawing or sketch of structure to be fumigated, delineating features, hazards, and other structural issues.
- The need for buffer zones in rooms adjacent to the treated enclosure to limit access to only trained applicators. This would include adjacent rooms that could be occupied when using CD gas in areas such as hotel rooms, patient rooms or offices. Additional consideration should also be given to adjacent rooms above or below the enclosure if the structure does not consist of solid construction (i.e. Floors/walls adjacent to the enclosure) that would preclude exposure if the treated enclosure was not properly sealed.
- The number and identification of persons who routinely enter the area to be fumigated (i.e., Employees, visitors, customers, etc.).
- Accessibility of utility service connections.
- Nearest telephone or other means of communication, and mark the location of these items on the drawing/sketch.
- Emergency shut-off stations for electricity water and gas.
- Current emergency telephone numbers of local Health, Fire, Police, Hospital and Physician responders.

- Name and phone number (both day and night) of appropriate company officials.
- Checkmark and prepare the points of fumigation application.
- Review labeling and Equipment Manual.
- Exposure time considerations.
    - Fumigant to be used.
    - Minimum fumigation period, as defined and described by the label use directions.
    - Down time required to be available.
    - Aeration requirements.
- Determination of dosage.
    - Cubic footage or other appropriate space/location calculations.
    - Structure sealing capability and methods.
    - Label directions.
    - Past history of fumigation of structure
    - Exposure time.

2.3.2. PERSONNEL

- Confirm that all personnel in and around the area to be fumigated have been notified prior to application of the fumigant. Consider using a checklist that each employee initials indicating they have been notified.
- Instruct all fumigation personnel about the hazards that may be encountered; and about the selection of personal protection devices, including detection equipment.
- Confirm that all personnel are aware of and know how to proceed in case of an emergency situation.
- Instruct all personnel on how to report any accident and/or incidents related to fumigant exposure. Provide a telephone number for emergency response reporting.
- Instruct all personnel to report to proper authorities any theft of fumigant and/or equipment related to Fumigation.
- Establish a meeting area for all personnel in case of emergency.
- Confirm that all applicators have been trained in the use of CD gas and are in good standing including the required refresher training.
- Develop a Worker Health and Safety Plan as required by OSHA for applicators. The owner/operators of the facility being treated should have a Worker Health and Safety Plan as required by OSHA developed for their employees located within close proximity of the application process.

2.3.3. MONITORING

Perimeter Safety - Monitoring of CD Gas concentrations must be conducted immediately adjacent to the fumigated space to prevent excessive exposure and to determine where exposure may occur. When monitoring for leaks, ensure there is no CD Gas present above the 0.1 ppm levels where people are located. Subsequent leak monitoring is not routinely required. However spot checks must be made, especially if conditions significantly change. Monitoring must be conducted during aeration and corrective action taken if gas levels exceed the allowed levels in an area where bystanders and/or nearby residents may be exposed.

Efficacy - CD gas readings should be taken from within the fumigated structure to ensure proper concentrations. This can be safely achieved outside the structure through the use of a remote sensor reading. All reading of CD gas concentration may be documented.

2.3.4. NOTIFICATION

- Confirm that all appropriate local authorities (fire departments, police departments, etc.) have been notified as per label instructions, local ordinances if applicable, or instructions of the client.
- Develop an "Emergency Response Plan" which contains explicit instructions, names, and telephone numbers so as to be able to notify local authorities if CD gas levels are exceeded in an area that could be dangerous to bystanders and/or domestic animals.

- In the event of a breach or leak of the enclosure where levels of CD gas are above 0.1 ppm in adjacent areas to the enclosure and people in the space cannot be relocated, abort the application process and initiate the aeration process in the sealed enclosure. Ensure that the adjacent areas where levels have exceeded 0.1 ppm are evacuated by general personnel and that proper respiratory protection is utilized by applicators that enter the area. Continue monitoring the area until levels are below 0.1 ppm CD gas. The treated enclosure and adjacent areas must remain unoccupied until CD gas levels are at or below 0.1 ppm. Early reentry into the sealed treated enclosure at use concentration levels in the case of an emergency requires wearing a Self-Contained Breathing Apparatus (SCBA) operated in pressure-demand mode, to protect from the inhalation hazard.

2.3.5. SEALING PROCEDURES

- Sealing must be adequate to prevent any leaks. Care should be taken to ensure that sealing materials will remain intact until the fumigation is complete. If possible verify effectiveness of the sealing process by conducting a smoke stick test to ensure there are no leaks where openings have been sealed in the enclosure.
- If the structure and/or area has been fumigated before, review the previous FMP for previous sealing information.
- Make sure that construction/remodeling has not changed the building in a manner that will affect the fumigation.
- Warning placards must be placed on every possible entrance to the fumigation site.

2.3.6. APPLICATION PROCEDURES & FUMIGATION PERIOD

- Plan carefully and apply all fumigants in accordance with the label requirements.
- When entering into the area under fumigation always work with two or more people under the direct supervision of a trained applicator wearing appropriate respirators.
- Apply fumigant from outside the fumigation space.
- Provide watchmen when a fumigation site cannot otherwise be made secure from entry by unauthorized persons.
- When entering structures always follow OSHA rules for confined spaces.
- The applicator should verify compatibility of item surfaces to be treated prior to the application process.

2.3.7. POST-APPLICATION OPERATIONS

- Provide watchmen when you cannot secure the fumigation site from entry by unauthorized persons during the aeration process.
- Ventilate and aerate in accordance with structural limitations.
- Turn on ventilating or aerating fans where appropriate.
- Use a suitable CD gas detector before reentry to determine fumigant concentration.
- Remove warning placards when aeration is complete.
- Inform business/client that employees/other persons may return to work or otherwise be allowed to reenter the aerated structure.

2.3.8. CRITERIA FOR SUCCESSFUL FUMIGATION:

- All CD gas fumigation process conditions (CD gas concentration and initial relative humidity) are achieved during the fumigation cycle.
- All BIs that are properly recovered (no breach of aseptic technique) are negative for growth*.
- Positive control BI's demonstrate growth following incubation*.
- Negative control BI's exhibit no growth following incubation*.

* [not applicable to areas not requiring validation]

3. Training and Certification of Applicators

Prior to use, applicators must be adequately trained and certified by ClorDiSys Solutions, Inc on the hazards and label directions for CSI CD Cartridge / CD Gas, on the use and operation of the CD gas generation equipment, CD gas monitoring procedures and when appropriate, validation procedures.

4. Preparation of Enclosures

- Cleaning: Remove gross filth and visible soil prior to application. Wash soiled surfaces with a compatible detergent using a cloth, sponge or appropriate cleaning device to ensure visible soils are removed. Rinse with potable water and allow to air dry.
- The CD gas generation equipment: Position or connect the CD gas generator equipment for optimum CD gas distribution into the treatment enclosure. See Equipment User's Manual for proper equipment preparation and setup.
- Sealing: Seal the treatment enclosure adequately to assure that CD gas levels outside the enclosure are kept at acceptable levels [< 0.1 ppm timed weighted average for eight hours (TWA)] and ensure sufficient concentration of CD gas sterilant in the treatment enclosure.
    - Close and seal windows and doors. Sealing techniques can vary, but most often includes polyethylene sheeting and adhesive tape.
    - Turn off lights and cover any sunlight from entering the space.
    - Turn off all ventilation systems including HVAC and seal any supply or return vents/ductwork.
    - Monitor areas immediately adjacent to the fumigated space to ensure levels are below TWA for CD gas.
- Securing Enclosure:
    - Assure all personnel have vacated the treatment enclosure prior to CD gas application. Remove all plants, animals, beverages and food.
    - Applicators must not reenter the treated enclosure until exposure levels of CD gas are at/or below 0.1 ppm.
- Placarding of Treatment Enclosure: The applicator must placard or post all entrances to the treatment enclosure and designated buffer zones with signs in English bearing:
    - The signal word "DANGER/PELIGRO" in red.
    - "Area under treatment, "DO NOT ENTER/NO ENTER."
    - The statement "This sign may only be removed after the treatment enclosure has been aerated to CD gas levels less than or equal to 0.1 ppm".
    - Identification of CD gas as hazard associated with the treatment process.
    - Contact information for the applicator.

All entrances to the treatment enclosure must be placarded. Placards must be placed in advance of the treatment in order to keep unauthorized persons from entering the treated enclosure. Placards are removed after the treatment enclosure contains concentrations of CD gas at/or below 0.1 ppm.

5. Directions for Use for Mold and Mildew Odor Control

FOR USE ONLY BY PROFESSIONAL CLORDISYS SOLUTIONS PERSONNEL OR PERSONS TRAINED BY CLORDISYS PERSONNEL. IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

THE PERSONS APPLYING THIS PRODUCT ARE RESONSIBLE FOR FOLLOWING THESE DIRECTIONS UNDER BOTH STATE AND FEDERAL LAWS.

FOR MOLD AND MILDEW ODOR CONTROL IN WOOD, WALLBOARD, CONCRETE, MASONRY (CINDER) BLOCK AND OTHER CONSTRUCTION MATERIALS IN BUILDINGS - REMEDIAL TREATMENTS OF CONFINED SPACES, FLOORS & WALLS AND THEIR CONTENTS, INCLUDING DUCT WORK AND HVAC SYSTEMS.

For mold and mildew odor control, before applying the chlorine dioxide gas fumigation, visible mold growth must be removed and conditions favorable to mold growth must be identified and corrected.

ClorDiSys Solution chlorine dioxide mold and mold odor control fumigation process is designed for use on all kinds of surfaces including:

- Painted Wallboard
- Structural members and supports
- Ceilings and above ceiling spaces
- Basements and crawl spaces
- Cabinet and countertops
- Case goods and other furnishings
- Floor surfaces
- Air Ducts and HVAC Equipment
- Sheet metal (unlined)
- Air supply and return ducts and plenums fabricated with plywood, OSB or other wood like materials
- Flexible air ducts fabricated of metal, fabric or plastic
- Air distribution components such as air handlers, mixing boxes, transfer boxes, transitions, turning vanes, dampers, fans and fan housings and associated components
- Condensate drain pans

It is also used as one component of a comprehensive mold remediation or water damage restoration program. The purpose of such a program is to minimize damage from growth of mold and other potential contaminates and limit re-growth. This product is only to be used in those cases where visible microbial growth has been detected or conditions are likely to immediately result in such growth, and then only as a part of a program that removes that growth and identifies and corrects the conditions that led to that growth.

If you need help understanding any part of these instructions or have additional questions after reading these instructions, DO NOT APPLY THIS PRODUCT until you have received the answers to all of your questions.

5.1. Visible Growth of Mold and Mildew

All buildings must be comprehensively inspected for visible growth as part of the remediation plan. If it is ascertained that the only contamination within a building consists of visible growth of less than 30 sq. ft., then use of this product is not necessary. Contaminated areas larger than 30 square feet require special procedures and individuals trained in remediation. Guidelines for remediation of large areas of contamination must be addressed within the comprehensive remediation plan prepared prior to fumigation. Persons responsible for fumigation must coordinate with all participants to ensure remediation guidelines are followed. This includes general contractors, indoor air quality consultants, certified industrial hygienists, building engineers and associated architects. Mold contaminated objects that are of significant value such as rare books may be cleaned then decontaminated rather than bagged and discarded.

5.1.1. Pre-Cleaning

Removal of any trash and/or debris from the treatment space must be conducted prior to treatment. Significant accumulations of soils, lint and dust within the treatment space, including ducts and HVAC systems, must be removed and thoroughly cleaned prior to treatment. Cleaning of these affected areas must be carried out using one of the following or another preferred professional method. Prior to treating the area with chlorine dioxide gas, clean the affected area using one of the following or another preferred professional method.

5.1.1.1. Wood Surface- Cleanup Methods

- Method 1: Wet vacuum (in the case of porous materials, some mold spores/fragments will remain in the material but will not grow if the material is completely dried).

- Method 2: Damp-wipe surfaces with plain water or use a wood floor cleaner; scrub as needed.
- Method 3: High-efficiency particulate air (HEPA) vacuum after the material has been thoroughly dried. (Dispose of the contents of the HEPA vacuum in a well-sealed plastic bag(s).
- Method 4: Discard/remove water-damaged materials and seal in plastic bags while inside of containment. Dispose of as normal waste. HEPA vacuum area after it is dried.

5.1.1.2. Wallboard (drywall and gypsum board) Cleanup Methods

- Method 1: HEPA vacuum after the material has been thoroughly dried. Dispose of the contents of the HEPA vacuum in a well-sealed plastic bag(s).
- Method 2: Discard/remove water-damaged materials and seal in plastic bags while inside of containment. Dispose of as normal waster. HEPA vacuum area after it is dried.

5.1.1.3. Other Construction Materials (concrete or cinder block) Cleanup Methods

- Method 1: Wet vacuum (in the case of porous materials, some mold spores/fragments will remain in the material but will not grow if the material is completely dried).
- Method 2: High-efficiency particulate air (HEPA) vacuum after the material has been thoroughly dried. Dispose of the contents of the HEPA vacuum in a well-sealed plastic bag(s).

Prior to chlorine dioxide gas treatment, thoroughly clean all surface to remove loose existing dirt. Limited or Full personal protective equipment is required during cleanup. Limited personal protective equipment includes: gloves, N-95 respirator or half-face respirator with HEPA filter. Full personal protective equipment includes: gloves, disposable full body clothing, headgear, foot coverings, and full-face respirator with HEPA filter.

Use professional judgment, consider potential for remediator exposure and size of contaminated area.

5.2. Preparation of Enclosed Area

A careful analysis of the treatment area including the ductwork system must be made prior to any treatment and the most appropriate strategy for application is to be made at that time. Prior to any gas release, the treatment space and its ventilation system must be sealed airtight. All doors, windows, outside vents and other openings must be sealed utilizing sealing materials such as tape and plastic. Special attention should be paid to wall openings, between rooms in the overhead spaces, and to ventilation and piping runs. Any ductwork that leads beyond the designated containment space must be isolated and sealed tight. Any negative air machines that exhaust air from the containment space must be shut off and sealed.

5.2.1. Cleaning: Remove gross filth and visible soil prior to application. Wash soiled surfaces with a compatible detergent using a cloth, sponge or appropriate cleaning device to ensure visible soils are removed.

5.2.2. Sealing: Seal the treatment enclosure adequately to assure that chlorine dioxide levels outside the enclosure are kept at acceptable levels [< 0.1PPM time weighted average for eight hours (TWA)].

5.2.2.1. Close and seal windows and doors. Sealing techniques can vary, but most often includes polyethylene sheeting and adhesive tape. A smoke test may be used to verify effectiveness of the sealing process.

5.2.2.2. Turn off all ventilation systems including HVAC and seal any supply or return vents/ductwork. If duct work is included and prior to gas injection, the air handler fan only must be turned on to circulate the gas through the duct system during the entire treatment period and during the subsequent chlorine dioxide dissipation period.

5.2.2.3. Monitor areas immediately adjacent to the fumigated space to ensure levels are below TWA for chlorine dioxide.

5.2.3. Securing Enclosure:

5.2.3.1. Assure all personnel have vacated the treatment enclosure prior to chlorine dioxide application. Remove all plants, animals, beverages and food.

5.2.3.2. Applicators must not reenter the treated enclosure until exposure levels of chlorine dioxide are at/or below 0.1PPM.

5.2.4. Placarding and Site Security

Appropriate placards, with contact information for the applicator, are to be placed in and around the treatment space in advance of the treatment in order to keep unauthorized persons from entering the treated enclosure. Placards are removed after the treatment enclosure contains concentrations of chlorine dioxide at/or below 0.1PPM.

5.2.5. Gas Monitoring. Periodically, during the treatment, the perimeter of the treatment space must be monitored for gas intrusion from the treatment space using a handheld chlorine dioxide monitor. The level of chlorine dioxide gas must be measured at or below 0.1 PPM by the metering devices.

5.3. Process Directions to Control Odor Causing Microorganisms

The chlorine dioxide gas fumigation process is described below.

5.3.1. Gas Levels for Antimicrobial Activity/Rate of Application for Control Odor causing microorganisms

Chlorine dioxide Gas: To control odor causing microorganisms, chlorine dioxide gas levels of 20 PPM should be generated within the confined treatment space or closed system for at least 5 hours. The relative humidity should be raised to 65% or greater. A minimum temperature of 52 degrees should be maintained during treatment.

5.3.2. Target Area Setup

5.3.2.1. Fans should be placed in rooms (typically 1 per room) to distribute the gas.

5.3.2.2. Starting RH should be a minimum of 65% in all areas

5.3.2.3. Temperature should be greater than of 52 Deg F.

5.3.3. Gas Generation

5.3.3.1. Using the chlorine dioxide gas generator, generate 20 PPM. Using CSI CD Cartridge and the Manual Generator, flow gas at 20 LPM (17-22LPM) and a maximum pressure of 25PSI (20-30 PSI) for 48 seconds for every 1000ft^3 of room volume. For large spaces multiple generators may be required to ensure gas distribution throughout the total area. For example: 1 injection point per floor. Room volume is calculated by multiplying the room length * width * height.

For example for 2500 ft^3, flow gas for 120 seconds (120 seconds = 48 seconds * (2500 ft^3 /1000 ft^3))

Carpets, furnishings, drapes, etc., may represent additional demand of the gas.

5.3.4. Chlorine Dioxide Gas Dissipation/Aeration

For low concentrations, 20 PPM, chlorine dioxide gas rapidly breaks down within the sealed space and gas levels at and below Permissible Exposure levels (PEL) of 0.1 PPM are attained within approximately 6 to 12 hours. Do not reenter confined space without PPE until the chlorine dioxide gas is lower than 0.1PPM. If it is necessary for a worker to enter the space, he/she must use a full-face protective respirator using 3M 6003 or equivalent cartridges for acid vapor, chlorine and chlorine dioxide gas, or NIOSH/MSHA approval TC-13F-314 Low Pressure Self Contained (SCBA) Respirator, or equivalent, when gas concentrations are above 5PPM.

The HVAC systems can be returned to full operation as soon as the treatment is completed and all gas has cleared the spaces.

5.4. Post Treatment Activities

Chlorine dioxide gas leaves no visible residue on surfaces within the treatment space. All fumigation equipment will be removed from the spaces, placards removed and all sealing material removed to bring the space back into normal use.

6. Process Directions for Applications Requiring USER Validation With Biological Indicators

CSI CD Cartridge has been registered by ClorDiSys Solutions, Inc in accordance with Federal Regulations for the specific uses described in this package insert. CSI CD Cartridge Sterilant is used with enclosures that have been pre-cleaned of visible soils and any gross contamination. Uses other than as specified and described are not permitted: CSI CD Cartridge Sterilant may not be effective in sterilization without careful, thorough development and validation. The instructions that follow explain how to define appropriate use conditions and validate these conditions for use in a pre-cleaned sealed enclosure of a fixed size, location and materials of composition. This includes sealed enclosures in industrial, commercial and institutional settings (including production operations in pharmaceutical manufacturing, manufacturing clean rooms, production rooms and facilities, medical device sterilization as part of a manufacturing process, laboratories, animal research facilities, patient rooms, hotel rooms, offices, cruise ships, recreational facilities, transport vehicles, and emergency response vehicles). Process conditions must be properly validated prior to use to achieve the desired level of kill of the treated space.

6.1. Validation of Alternate Use Conditions:

CSI CD Cartridge Sterilant may be used in validated custom cycles for treatment of pre-cleaned, sealed enclosures and spaces when the space to be treated is of a fixed volume configuration and contains materials of composition that remain consistent in comparison to the chlorine dioxide gas validation run. The custom cycle developed for the treatment enclosure must be capable of consistently achieving the desired log reduction in the number of *Geobacillus stearothermophilus* ATCC 7953 spores or other spores inoculated on biological indicator substrates. CSI recommends spore strips wrapped in Tyvek envelops inoculated on paper carriers.

6.2. System Characterization:

Several factors need to be considered when validating an application such as the volumetric size, materials of construction and the physical nature of the contents In general, large enclosures will take longer to reach the target concentrations due to larger volumes. Chlorine dioxide gas is a surface sterilant; therefore the enclosure and its contents should be prepared to maximize surface areas. 65% RH can be used to soften the spore walls. Standard Operating Procedures (SOPs) or other documentation must be written to describe the physical preparation of an enclosure and its contents required to achieve reproducible results.

6.3. Biological Indicator Selection and Distribution:

The cycle effectiveness for applications must be validated using Biological Indicators (BI's). Bacillus endospores are the most resistant class of organisms to deactivation and thus provide suitable challenge organisms. Spore strips containing *Geobacillus stearothermophilus* spores or other spore strips can be used. *Geobacillus stearothermophilus* also has inherent practical operational advantages in that it is thermophilic with an optimum incubation temperature of 57°C, reducing the possibility of false positives due to the high incubation temperature. It is also a category 1 organism so is not harmful to humans and thus may be easily and safely handled. Use BI's with spore populations of 10^3 or 10^6 (depending upon user requirements) when validating enclosure application processes. Spores strips are commercially available from various manufacturers (Crosstex, Mesa Labs, 3M) and should be wrapped in Tyvek® and the endospores inoculated on paper carriers or stainless carriers depending on surface to be treated. For sterilization claim, both type of carriers must be used. Paper carriers provide consistent results compared to hard surfaces which promote spore clumping. Paper carriers also represent porous surfaces to be treated; which are typically more difficult to kill on than hard surfaces. Stainless steel carriers are used to represent hard non-porous surfaces to be treated. These can be prone to clumping issues an inconsistent results. Numerous BI locations are used when validating a new application. Biological indicators are often geometrically distributed, but should also be placed in areas considered to be most difficult. BI's should be placed throughout the target volume, typically placed in the corners of rooms. The number of biological indicators used to validate the process must at a minimum be based on the following: 1 BI per 100 ft^2 of floor space in the enclosure for each type of carrier.

6.4. Process Development:

Typically, the initial step in validating the chlorine dioxide gas process is to determine the effectiveness of the process against *Geobacillus stearothermophilus* BI's of a known population. This is achieved by injecting the sterilant and exposing at varying dosages in order to determine the level of surviving organisms remaining on the BI at each exposure time. This information can be utilized to determine the cycle parameters to achieve the desired level of BI kill. Humidity is a factor with spore log reductions. Relative humidity (RH) conditions the spores to allow the sterilant to inactivate the spore.

Example dosage calculations: Dosage is measured in PPM-Hours which is a certain concentration (PPM) for a certain amount of time. A concentration of 1mg/L is 362PPM. As an example, this concentration of 1.0 mg/L for 2 hours equals 720PPM-Hours (362 * 2 = 724PPM-Hours) or this concentration for 3 hours equals 1,086 ppm-hrs (362 * 3 = 1,086 PPM-Hours). Lower concentrations can be used, but the exposure time has to be extended (for example 0.5mg/L [181 PPM] would be held for approximately 4 hours to achieve 720PPM-Hours). Conversely higher concentrations can be

used and exposure times are shortened (for example 5.0mg/L [1810PPM] would be held for approximately 30 minutes to attain a dosage of 720 PPM-hours).

The following steps are required in developing a validated application process:

6.4.1. Pre-Condition: During Pre-condition, Relative Humidity is raised until the target RH is reached (75%).

6.4.2. Condition: During Condition, RH is allowed to penetrate the spores and hydrate them properly. A 5 minute condition time should be used. For small volumes (<200 ft^3) longer condition times may be necessary.

6.4.3. Charge: During Charge, the chlorine dioxide gas is generated and introduced into the chamber to achieve a set concentration of gas.

6.4.4. Exposure: During Exposure, the concentration of chlorine dioxide gas is monitored. This measurement allows the calculation of PPM-Hours. Using the PPM-Hours calculation examples above, the exposure is held until the correct dosage is reached.

6.4.5. Aeration: During aeration, the chlorine dioxide gas is removed from the chamber. This is accomplished by allowing clean air into the chamber and the removal of chlorine dioxide from the chamber. It typically takes 12-15 air exchanges to remove the gas.

Upon completion of aeration, you MUST ensure, via low level safety sensor (ATI C16 Portasense) or other acceptable methods, that the chamber environment is free from or at safe levels (less than 0.1PPM) of chlorine dioxide before ending the cycle.

Once acceptable cycle parameters have been determined, three decontamination cycle replicates must be conducted to verify the performance of the process. After successful validation of the process, the applicator must use these validated cycle conditions and contact time for future treatments.

6.5. Criteria for Successful Fumigation:

- All chlorine dioxide gas fumigation process conditions (chlorine dioxide gas dosage and relative humidity)
- All BI's that are properly recovered (no breach of aseptic technique) are negative for growth.
- Positive control BI's demonstrate growth following incubation.
- Negative control BI's exhibit no growth following incubation.

6.6. Reentry Instructions:

6.6.1. Early reentry in the case of an emergency requires wearing a Self-Contained Breathing Apparatus (SCBA) operated in pressure-demand mode, to protect from the inhalation hazard. When entering into the area under fumigation always work with two or more people under the direct supervision of a trained applicator wearing appropriate respirators.

6.6.2. Reentry to the sealed enclosure by a trained and certified applicator is allowed with a self-contained breathing apparatus at chlorine dioxide gas concentrations over 5 ppm to allow for windows to be opened and to augment the aeration process if deemed appropriate at the specific location by the trained and certified applicator. Reentry to the sealed enclosure by a trained and certified applicator is allowed with a respirator appropriately rated for chlorine dioxide at chlorine dioxide gas concentrations under 5 ppm. Otherwise, do not reenter the treated enclosure until exposure levels of chlorine dioxide are at or below 0.1 PPM.

6.7. Releasing Treated Sealed Enclosure for Return to Service:

6.7.1. Once CD gas levels are determined to be at or below 0.1 ppm, applicators may re-enter the treated enclosure and remove any sealing materials and disconnect/remove CD gas generator equipment from the treated sealed enclosure.

6.7.2. Turn on ventilation systems including HVAC.

6.7.3. Remove placards and release the treated enclosure for normal operation and use after the levels of CD gas are determined to be at or below 0.1 ppm.

6.7.4. Release the treated enclosure for general public use after CD gas levels are determined to be at or below 0.1 ppm.

7. Process Directions for Applications up to 3,019 ft^3 Not Requiring User Validation of Use Conditions (ie. Pre-validated cycles)

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 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.

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 (8).

CD gas sterilant may also be applied to sealed pre-cleaned enclosures without prior validation when the area is treated on a non-routine basis or enclosures being treated vary in configuration, materials of composition and content of items located in the treatment enclosure. The use of the CD gas process in these conditions requires the applicator to apply a fixed CD gas concentration over a set contact time. In addition the enclosure must be humidified and conditioned as part of the application process and aerated after sterilization. CD gas sterilant may be applied at a set concentration and contact time to sealed enclosures of up to 3,019 ft^3 in sealed enclosures in industrial, commercial and institutional settings (including production operations in pharmaceutical manufacturing, manufacturing clean rooms, production rooms, medical device sterilization as part of a manufacturing process, laboratories, animal research facilities, patient rooms, hotel rooms, offices, cruise ships, recreational facilities and emergency response vehicles).

In these applications, the CD gas concentration should be monitored using a CD gas sensor to ensure an adequate concentration level is maintained during the STERILIZATION phase of the process. In addition, CD gas chemical indicators must be placed throughout the enclosure to be treated to verify distribution of CD gas throughout the enclosure. If more than one room of a consistent dimension is being treated, the applicator may use the same CD gas cycle settings as established in the initial room without use of a CD gas sensor to confirm the concentration of the treatment cycle. These operations should be carried out by ClorDiSys Solutions trained and certified applicators familiar with the set up and operation of CD gas application equipment.

7.1. Sterilization of Sealed, Dry Precleaned Enclosures:

Prepare the treatment enclosure as defined above (Preparation of Enclosures Section) including pre-cleaning and preparation of CD gas generator (refer to User's Manual for CD Gas Generating Unit), sealing the enclosure and placarding of the enclosure to be treated. Place CD gas monitor in a location most difficult for CD gas target concentration to be reached in the treatment enclosure. This is typically in a comer in the enclosure farthest away from the CD gas injection. All drawers, closets & cabinet doors, etc. must be opened to permit exposure to CD gas sterilant. Place chemical indicators throughout the enclosure to verify effective distribution of CD gas sterilant. The number of indicators placed throughout the enclosure must be based on the formula of one chemical indicator per 100 ft^2. The chemical indicators must be placed in room corners and in areas difficult for the CD gas sterilant to access such as closets, dressers, cabinets or other partially occluded areas. Place fans throughout the enclosure to facilitate effective distribution of the CD gas sterilant.

Program the CD gas generator to:

Cycle Step	Cycle 1	Cycle 2	Cycle 3
RH SP	75%	75%	75%
Condition Time	5 minutes	5 minutes	30 minutes
CD gas Concentration	0.3	1mg/L	5mg/L
Exposure time	1842 minutes	553 minutes	111 minutes
Aeration	site specific	site specific	site specific
PPM-Hours	3334	3334	3334

During the Charge/Exposure phase, monitor areas adjacent to the sealed enclosure with devices such as low level safety sensor (ATI C16 Portasense) or other acceptable methods to assure CD gas levels do not exceed 0.1 ppm. If this level is exceeded outside the treatment enclosure and people in the space cannot be relocated, abort the application process and initiate the aeration process in the sealed enclosure. Ensure that the adjacent areas where levels have exceeded 0.1 ppm are evacuated by general personnel and that proper respiratory protection is utilized by applicators that enter the area. Continue monitoring the area until levels are below 0.1 ppm CD gas. The treated enclosure and adjacent areas must remain unoccupied until CD gas

levels are at or below 0.1 ppm. Upon completion of the Charge/Exposure phase, begin the Aeration phase to reduce levels of CD gas to or below 0.1 ppm (TWA).

7.2. Monitoring of CD Gas Concentrations in the Sealed Enclosure and Reentry Instructions Following Aeration.

7.2.1. CD gas Monitoring: low level safety sensor (ATI C16 Portasense) or other acceptable methods are utilized by means of a minimally invasive technique for CD gas sampling to determine the CD gas concentration in the sealed enclosure during and after the aeration phase. After the CD gas concentration within the treated enclosure is at or below the OSHA Permissible Exposure Limit (PEL) of 0.1 ppm, the enclosure may be released to normal operations and general public use,

7.2.2. Criteria for Successful Fumigation:

- All chlorine dioxide gas fumigation process conditions (chlorine dioxide gas dosage and relative humidity)

7.3. Reentry Instructions:

7.3.1. Early reentry in the case of an emergency requires wearing a Self-Contained Breathing Apparatus (SCBA) operated in pressure-demand mode, to protect from the inhalation hazard. When entering into the area under fumigation always work with two or more people under the direct supervision of a trained applicator wearing appropriate respirators.

7.3.2. Reentry to the sealed enclosure by a trained and certified applicator is allowed with a self-contained breathing apparatus at chlorine dioxide gas concentrations up to 5 ppm to allow for windows to be opened and to augment the aeration process if deemed appropriate at the specific location by the trained and certified applicator. Otherwise, do not reenter the treated enclosure until exposure levels of chlorine dioxide are at or below 0.1 PPM.

7.4. Releasing Treated Sealed Enclosure for Return to Service:

7.4.1. Once CD gas levels are determined to be at or below 0.1 ppm, applicators may re-enter the treated enclosure and remove any sealing materials and disconnect/remove CD gas generator equipment from the treated sealed enclosure.

7.4.2. Turn on ventilation systems including HVAC.

7.4.3. Remove placards and release the treated enclosure for normal operation and use after the levels of CD gas are determined to be at or below 0.1 ppm.

7.4.4. Release the treated enclosure for general public use after CD gas levels are determined to be at or below 0.1 ppm.