

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 20, 2017

Melba Morrow, DMV Agent for DRS Laboratories, Inc. toXcel LLC. 7140 Heritage Village Plaza Gainsville, VA 20155

Subject: PRIA Label Amendment – Add use to sterilize/decontaminate confined areas

Product Name: Technical Sodium Chlorite

EPA Registration Number: 90094-1 Application Date: Aug 02, 2017 Decision Number: 532079

Dear Ms. Morrow:

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.

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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 Ben Chambliss by phone at (703) 308-8174, or via email at chambliss.ben@epa.gov.

Sincerely,

Warda AC

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

Office of Pesticide Programs

Enclosure: Stamped Label

Technical Sodium Chlorite

{Alternate trade name - CD Generation Part "A"}

[FOR USE TO GENERATE CHLORINE DIOXIDE GAS] [FOR WATER TREATMENT]

ACTIVE INGREDIENT: Sodium Chlorite80% OTHER INGREDIENTS:20% TOTAL......100%

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 or clothing	 Brush off excess chemical. 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	 Have person drink a glass of water immediately if able to swallow. Call a poison control center, or doctor immediately for treatment advice. 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 inhaled	 Move person to fresh air and monitor for respiratory distress. If cough or difficulty in breathing develops, consult a physician immediately. 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 treatment advice. 		
	cal Emergency call CHEMTREC (24 hours): 800-424-9300 (Within USA & Canada) +1 703-527-3887 (Outside USA & Canada) uct 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.

EPA REG. NO.: 90094-1 EPA EST. NO.: 90094-PA-001

NET. CONTENTS: X oz. or lbs. (Y g or kg) Lot. No. {as indicated on the container}

Manufactured by: DRS Laboratories, Inc. P.O. Box 20247

Lehigh Valley, PA 18002 Phone: 1-888-377-1533 www.drslaboratories.com

ACCEPTED

12/20/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under 90094-1 Page 1

EPA Reg. No.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

DANGER - Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Irritating to nose and throat. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles or safety glasses). Wear protective clothing and neoprene gloves when handling this product. Avoid breathing dust or fumes. Wash thoroughly with soap and water after handling and before eating, drinking, and chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse to avoid fire.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the 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.

PHYSICAL AND CHEMICAL HAZARDS

Danger: strong oxidizing agent. Mix only into water. Contamination may start a chemical reaction with generation of heat, liberation of hazardous gases (chlorine dioxide is a poisonous, explosive gas), and possible fire and explosion. Do not contaminate with moisture, garbage, dirt, organic matter, household products, chemicals, soap products, paint products, solvents, acids, vinegar, beverages, oils, pine oil, dirty rags, or any other foreign matter. Do not use moist or damp utensils.

DIRECTIONS FOR USE

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

Use Restrictions: This product may not be used as a terminal high level disinfectant or sterilant for reprocessing of any critical or semi-critical medical devices in a healthcare setting. Not for use in residential applications.

<u>DIRECTIONS FOR USE TO GENERATE CHLORINE DIOXIDE GAS USED AS A [DECONTAMINANT] [STERILANT] [FUMIGANT]</u>:

CD Generation Part A, sodium chlorite, is for use with DRS Laboratories' CD gas generating equipment only. Under the appropriate conditions, the final generated product is chlorine dioxide (CD) gas, which is a strong oxidizer that effectively [decontaminates] [sterilizes] [fumigates] under prescribed conditions of use of DRS CD gas generating equipment. Read and follow this product's label and the appropriate DRS Equipment Instruction Manual for operating procedures of the DRS equipment.

This method of CD gas generation utilizes *CD Generation Part A* in cold tap water solution with addition of *CD Generation Part B*, a solid acid, to generate CD gas that will be used to [decontaminate] [sterilize] [fumigate] confined contaminated spaces.

Read and follow the appropriate DRS equipment Instruction Manual for complete instructions for:

- Methods of measuring CD gas at use concentrations and surrounding ambient concentrations,
- Cleaning, sealing, and use of this product in validated and non-validated applications, and
- Instructions on development of an appropriate decontamination, sterilization or fumigation plan.

For DRS's Mini-CD system (MCS), the following procedures will ensure that the conditions of NSF/ANSI Standard 49 and EPA validation criteria for decontamination, sterilization or fumigation of all types and components of the biological safety cabinets (BSC's) are met or exceeded:

- 1. Relative humidity should be monitored and maintained within a range of 60% to 85% RH throughout the decontamination, sterilization or fumigation process and temperature range should be 59-104°F (15-40°C).
- 2. Generation rate and times shall be at the specified as per volume of the BSC under decontamination, sterilization or fumigation. Determine and annotate the overall volume contained by the BSC enclosure. Multiply the BSC volume by 0.13 g/ft³ (4.7 g/m³) to determine the mass of CIO₂ required to be generated. Divide the mass of CIO₂ value by 0.167 for volumes <25 ft³ or by 0.245 for volumes >25 ft³, which is the grams of CIO₂ yielded per gram of CD Generation Part "A", in order to determine the grams of this product required for the decontamination, sterilization or fumigation.
- 3. The direction of the decontaminant sterilant or fumigant injection in conjunction with the sealing parameters shall be in the same direction of the airflows within an operating BSC. To ensure even distribution of the decontamination chemical and ensure that no potentially contaminated air from within the BSC will be pulled into the decontaminating device before it appropriate contact time; it will only be recirculated via the exhaust HEPA filter, as to rely on for personal and surrounding environmental protection.
- 4. Circulation or internal distribution rates and times shall be specified in order to ensure a uniform concentration of the decontaminant, sterilant or fumigant throughout the BSC. Periodically operate the BSC's internal blower to assist circulation. The MCS generation provides a means to assist circulation of the decontaminating, sterilization or fumigation agent in the event of a non-operating BSC to ensure a uniform concentration.
- 5. Exposure times shall include start and end of the exposure period.
- 6. Final concentration shall be provided within the BSC, by which the chemical concentration within the BSC was monitored throughout the decontamination validation process.
- 7. Neutralization or aeration, scrubbing /venting rates and times provided to remove or render harmless the decontaminant used.

Alternatively, you may use the following table to determine the number of pre-weighed (20 gram) packets of *CD Generation Part "A"* required in the MCS.

Volume	BSC Size	CD Generation
ft ³ (m ³)	Width - ft ³ (m ³)	Chemicals (packets)*
0 (0.0) to 25 (0.7)	0-2 ft. (0.00-0.60)	1 each of A & B
25 (0.7) to 60 (1.7)	3-4 ft. (0.91-1.22)	2 each of A & B
60 (1.7) to 90 (2.5)	5-6 ft. (1.52-1.83)	3 each of A & B
90 (2.5) to 120 (3.4)	n/a – special situation	4 each of A & B

*NOTE: To be used in 500 ml of cold tap water

Only personnel trained to use our DRS CD gas generators may use this product with the mandatory use of the safety equipment specified in the relevant DRS Instruction Manual. All personnel directly involved in the [decontamination] [sterilization] [fumigation] procedure must be familiar with the guidance pertaining to use of CD gas for laboratory and laboratory equipment decontamination in "Biosafety in Microbiological and Biomedical Laboratories" (U.S. DHHS, PHS, CDC, NIH, current edition) and in "NSF/ANSI Standard 49, Annex G" (current edition).

Inoperable internal BSC blowers: if the internal motor blower is inoperable and BSC cannot assist in recirculation of the RH and CD gas, (this is worst case scenario, if there is a BSC blower failure, no air recirculation by the BSC's internal blower or safety components shut down the internal blowers, the circulation of the RH and CD gas will need additional assistance) the MCS CD Generation pump must perform this function to circulate the CD gas through the HEPA filters. The MCS CD Generation pump must then operate for the full 90 to 150 minutes of CD generation and contact time. In addition to

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circulating the CD the humidification may take up to an additional 30 - 45 minutes without the internal recirculation fan operating. Follow all other aforementioned procedures as normal.

Approved Uses: *CD Generation Part "A"* is accepted for use to generate CD gas used to [decontaminate] [sterilize] [fumigate] non-porous and porous (HEPA filters) surfaces in sealed enclosures, confined spaces, rooms or areas, structures, buildings, or vehicles located in government, industrial, manufacturing, fermentation, commercial and institutional microbiological laboratory settings, including human and animal research facilities and areas, cleanrooms; animal isolation rooms, necropsy suites, pass throughs, airlocks, and decontamination chambers; biological safety cabinets, glove boxes, isolators, incubators, animal cages and devices, laboratory equipment, supply and exhaust filter systems, and HEPA filtered devices.

DRS's Chlorine Dioxide gas generation system is unaffected by the size or location of the ultimate destination for the CD gas. The CD gas is intended for use to [decontaminate] [sterilize] [fumigate] enclosures up to 120 cubic feet (validated) or greater (non-validated). Uses other than those specified in the appropriate DRS equipment Instruction Manual are not permitted and may not be effective. Review and follow all DRS equipment Instruction Manual instructions and precautions on how to properly utilize this product.

It is strongly recommended that at least *Bacillus atrophaeus* biological indicator (BI) strips be used to confirm each decontamination, sterilization or fumigation has been successful. If one or more of the *Bacillus atrophaeus* BI strips show growth in appropriate media after the decontamination, sterilization or fumigation treatment, the treatment has failed and should be repeated. Do not use this product to treat enclosures over 90 cubic feet (validated use area) without development of an appropriate decontamination, sterilization or fumigation plan that includes validation with BI's. Read and follow the appropriate DRS Instructions for instructions regarding development of an appropriate plan.

WATER TREATMENT APPLICATIONS:

Directions for controlling the Growth of Algae in Recirculating Cooling Water Towers

1) Clean badly fouled systems before starting treatment. 2) When algae are visible, add an initial dosage of 5.3 fl. oz. (3.4 oz. by wt.) of Sodium Chlorite per 1,000 gals. of water in the system. Repeat if necessary until control is evident. 3) Where algae control is evident, use a subsequent dose of 2.6 fl. oz. (1.7 oz. by wt.) of Sodium Chlorite solution per 1,000 gals. of water in the system twice a week or as needed to maintain control. 4) Add Sodium Chlorite directly to the cooling tower drip pan (cold water basin) near the inlet to the recirculating pump.

Directions for Use in the Mechanical or Electrolytic Generation of Chlorine Dioxide as a Disinfectant, or for Microorganism or Mollusk Control, and as a Chemical Oxidant in Aquatic Systems

Feed requirements: Feed rates of Sodium Chlorite Technical will depend on the severity of contamination and the degree of control desired. The exact dosage will depend on the size of the system and residual necessary for effective control. Depending on the generator type, Sodium Chlorite Technical is typically diluted at the point of use to prepare a 25% active aqueous solution for use in chlorine dioxide generators.

Some examples of industrial applications of chlorine dioxide include:

- Potable water disinfection and removal of sulfide.
- Control of bacterial slime, algae and mollusks in industrial recirculating and one-pass cooling systems.
- Biocontrol in food processing flumes, water-using equipment, cooling water, and recycled waters.

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- Disinfection of sewage and plant wastes.
- Destruction of phenolics, simple cyanides and sulfides by chemical oxidation.
- Bacterial slime control in white water paper mill systems.
- Bacterial control in oil well and petroleum systems.

Method of feed: Large amounts of chlorine dioxide can be generated by several common methods, including:

- 1. The chlorine method which utilizes a Sodium Chlorite solution and chlorine gas, or
- 2. The hypochlorite method which utilizes a Sodium Chlorite solution, a hypochlorite solution, and an acid.

[Your DRS Laboratories representative can guide you in the most appropriate selection, installation, and operation of feed systems for your specific needs and situation.] Before using this product, consult the SDS and instructions specific to the chlorine dioxide generation/feed equipment to confirm that it is both appropriate for the intended use and compatible with this product. User is responsible for compliance with applicable Federal, state and local laws regarding the proper use and disposal of the chlorine dioxide generates.

Potable Water Treatment

Chlorine dioxide (ClO₂) is used as both an oxidant and a disinfectant in drinking water treatment. The required dosages will vary with source water conditions and the degree of contamination present. For most municipal and public potable water systems, a chlorine dioxide residual concentration of up to 2 ppm is sufficient to provide adequate disinfection. Residual disinfectant byproducts must be monitored as required by the National Primary Drinking Water Regulations (40 CFR Part 141) and state drinking water standards.

Industrial Cooling Water Treatment

For control of bacterial slime and algae in industrial recirculating and one-pass cooling systems, the required dosages will vary depending on the exact application and the degree of contamination present. The required chlorine dioxide residual concentrations range between 0.1 and 5.0 ppm. Chlorine dioxide may be applied either continuously or intermittently. The typical chlorine dioxide residual concentration range is 0.1 - 1.0 ppm for continuous doses, and 0.1 - 5.0 ppm for intermittent doses. The minimum acceptable residual concentration of chlorine dioxide is 0.1 ppm for a minimum one minute contact time.

Mollusk Control in Water Systems

Chlorine dioxide generated from sodium chlorite may be used for mollusk control in commercial and industrial recirculating and one-pass cooling water systems. The required dosages will vary with the system type, system conditions, the degree of water contamination present, and the desired level of control. Depending on the extent of the infestation, sodium chlorite may be applied either continuously or intermittently through a chlorine dioxide generating system to achieve the necessary chlorine dioxide residual concentration.

Veliger Control: Maintain a continuous chlorine dioxide residual of 0.1 - 0.5 ppm.

<u>Intermittent Dose</u>: Apply chlorine dioxide to obtain a chlorine dioxide residual concentration of 0.2 - 25 ppm. Repeat as necessary to maintain control.

Continuous Dose: Maintain a chlorine dioxide residual concentration of up to 2 ppm.

Food Plant Process Water Treatment

Chlorine dioxide generated from sodium chlorite is effective for use in controlling non-public health/nonpathogenic microbiological growth in flume water and other food processing water systems such as chill water systems and hydrocoolers. The required dosages will vary with process conditions and the degree of contamination present. Depending on the requirements of the specific water system, sodium chlorite should be applied continuously or intermittently through a chlorine dioxide generating

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system to achieve a chlorine dioxide residual concentration between 0.25 and 5.0 ppm. Water containing up to 3 ppm residual chlorine dioxide may be used for washing fruits and vegetables that are not raw agricultural commodities in accordance with 21CFR§173.300. Treatment of the fruits and vegetables with chlorine dioxide must be followed by a potable water rinse, or by blanching, cooking or canning.

Wastewater Treatment

Chlorine dioxide (ClO₂) is effective as both a disinfectant and an oxidant in wastewater treatment. The required dosages will vary with water conditions and the degree of contamination present. For most municipal and other wastewater systems, a chlorine dioxide residual concentration of up to 5 ppm is sufficient to provide adequate disinfection. For sulfide odor control, between pH 5-9, a minimum of 5.2 ppm (wt) of chlorine dioxide should be applied to oxidize 1 ppm of sulfide (measured as sulfide ion). For phenol destruction, at pH less than 8, 1.5 ppm chlorine dioxide will oxidize 1 ppm phenol; at pH greater than 10, 3.3 ppm chlorine dioxide will oxidize 1 ppm phenol.

Bacterial Slime Control in Paper Mills

Chlorine dioxide generated from sodium chlorite is effective for use in controlling non-public health/non-pathogenic microbiological growth in white water paper mill systems. The required dosages will vary with the degree of microbiological and process contamination present. Depending on the specific requirements of the system, sodium chlorite should be applied continuously or intermittently through a chlorine dioxide generating system to achieve a chlorine dioxide residual concentration between 0.1 and 5.0 ppm. Intermittent treatments should be repeated as often as necessary to maintain control.

Bacterial Control in Oil Wells and Petroleum Systems

Chlorine dioxide is effective in the remediation of bacterial and sulfide contamination commonly found in oilfield production, injection and disposal fluids. The required dosages will vary with process conditions. Sodium chlorite may be applied either continuously or intermittently through a chlorine dioxide generating system to oil well production water as it is separated from the oil, and before it is re-injected into the well.

For continuous feeds, chlorine dioxide may be applied at dosages slightly higher than sulfide's oxidative demand as determined by a demand study. For intermittent treatment, chlorine dioxide should be applied at a shock dosage of 200-3000 ppm.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not contaminate water, food or feed by storage or disposal. Keep product in original sealed pouches when not in use. Store in a cool, dry, well-ventilated area away from heat or open flame. Avoid exposure to high temperatures during storage. Store remote from other chemicals, combustible materials and in area inaccessible to children.

EMERGENCY HANDLING: In case of contamination or decomposition, do not reseal pouches. If possible, isolate pouch in open and well-ventilated area. Flood with large volumes of water. If fire occurs, extinguish fire by applying large quantities of water. Any unopened pouches near the fire should be cooled by spraying with water.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Do not reuse or refill pouch. Place empty pouch into separate plastic bag, tie off and then discard in trash. 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.