



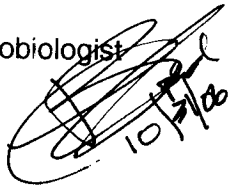
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

October 31, 2006

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 75757-E, CDG Solution;
DP Barcode: 331415

From: Tajah L. Blackburn, Ph.D., Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P) 

Thru: Michele Wingfield, Chief
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To: Emily Mitchell PM32/ Wanda Henson
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: CDG Research Corp.
140 Webster Street
Bethlehem, PA 18015

Formulations from Label

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Chlorine dioxide.....	0.3%
<u>Inert Ingredients</u>	<u>99.7%</u>
Total	100.0%

I BACKGROUND

The product, CDG Solution 3000 (EPA Establishment No. 75757-E) is a new product, employing chlorine gas to purify water for animal and human consumption. Per the label, this product is designed to purify potable water including hospital and cruise ship water systems, potable water for human consumption, and water for livestock.

Claims to control microbial slime in food-processing, industrial, pulp and papermaking process water, cooling water, and water storage and delivery systems are also present on the proposed label. No data was cited or referenced to support these additional sites. The registrant has submitted a list of citations to support historical data. Per the registrant, a revised matrix is enclosed, including all reference listed in PDMS supporting chlorine dioxide, and the label was amended to include only water purification. In a letter dated August 11, 2006, the registrant states that "this product is NOT like most chlorine dioxide products which actually contain sodium chlorite [sic] which is to be mixed with an 'activator' which then causes chlorine dioxide to be released. Rather this is a simple solution of highly pure, actual chlorine dioxide gas, in distilled water. The chlorine dioxide gas is generated via a gas generator system that uses dedicated cartridges containing a registered technical sodium chlorite [sic], through which the chlorine gas is passed. This system is already used commonly in water purification. The new product represents only an intermediate stage, effectively "splitting" the process of injecting chlorine dioxide gas into [sic] water into [sic] 2 parts—first a more concentrated 3000 ppm solution, that can then be further diluted as needed. This 2-part process facilitates use of the technology in sites where it is difficult or impossible to place the bulky gas-generating equipment, or where it is undesirable to have the risk of chlorine gas in pressurized containers on-site." The registrant believes that "the efficacy is already established...covered primarily by Formulator's exemption, and no added data are needed to simply 'split' the otherwise identical application of chlorine dioxide gas into 2 stages for the sake of accessibility to water supply systems."

The data package included two letters from the registrant (dated July 14, 2006 and August 11, 2006), Data Matrix (EPA Form 8570-35), numerous references, and the proposed label.

II USE DIRECTIONS

Per the submitted label, the product, CDG Solution 3000, may be used to disinfect and sterilize water systems (including Legionella) in hospitals, bottling plants, breweries, animal research, food processing plants, meat/fish processing plants, distilleries, irrigation water, institutional kitchens, dairy/poultry farms, and animal confinement. Directions on the proposed label provided the following information regarding preparation and use of the product as described:

To disinfect water for human consumption: Add CDG solution 3000 to drinking water supply to provide a 1 to 5 ppm dilution (1: 600 to 1:3000). Stop treatment of water at least one full day prior to vaccinations, and resume treatment 24 hours after vaccinations.

To Control Buildup of Biofilm, Slime and Slime-Forming Bacteria in Coolers, Pasteurizers, Transfer Lines and Similar Equipment: Clean equipment with detergent and rinse with potable water before treatment. Prepare a 20 ppm dilution of CDG 3000 in potable water (1:150). Fill equipment and lines with this dilute solution and leave overnight. Drain and allow to dry before next start up.

To Control Buildup of Biofilm, Slime and Slime-Forming Bacteria in Process Water for Vegetable Rinses and Associated Tanks, Flumes, and Lines: Clean equipment with detergent and rinse with potable water before treatment. Add CDG Solution 3000 to

rinse tanks or chill tanks to deliver and maintain 5 ppm dilution (1:600) in the water in the system. Test chlorine dioxide levels with a suitable monitor, and maintain at 5ppm.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Guide Standard and Protocol for testing Microbiological Purifiers

As set forth in EPA Enforcement Strategy and as supported by a Federal Trade Commission (FTC) decision (FTC v. Sibco Products Co., Inc., *et al.* November 22, 1965), a unit, in order to be called a microbiological water purifier, must remove, kill or inactivate all types of disease-causing microorganisms from the water, including bacteria, viruses, and protozoan cysts so as to render the processed water safe for drinking. In order to make the claim of "microbiological water purifier," units must be tested and demonstrated to meet the microbiological reduction requirements of Table 1 according to the test procedures (identified as Section 3) described in the Challenge Test Water/Halogen Disinfection (specific for the type of unit involved).

Table 1. Microbiological Reduction Requirements

Organism	Influent Challenge*	Min. Required Reduction	
		Log	%
<i>Klebsiella terrigena</i> (ATCC-33257)	10 ⁷ /100 ml	6	99.9999
Poliovirus ¹ (ATCC VR-59)	1 x 10 ⁷ /L	4	99.99**
Rotavirus (Wa or SA-11) (ATCC VR-899/VR-2018)	1 x 10 ⁷ /L	4	99.99**
<i>Giardia muris</i> or <i>Giardia lamblia</i> ***	10 ⁶ /L	3	99.9

* The influent challenges may constitute greater concentrations than would be anticipated in source waters, but these are necessary to properly test, analyze and quantitatively determine the indicated log reductions.

** Virus types are to be mixed in roughly equal 1 x 10⁷/L concentrations and a joint 4 log reduction will be acceptable.

*** It should be noted that new data and information with respect to cysts may in the future necessitate a review of the organism choice and of the challenge and reduction requirements.

Challenged Test Water/Halogen Disinfectant

This water is intended for the stressed challenge phase of testing where units involve halogen disinfectants, and shall have the following specific characteristics:

- (a) Free chlorine or other disinfectant residual;
- (b) pH 9.0 ± 0.2;
- (c) Total Organic Carbon (TOC) not less than 10 mg/L;
- (d) Turbidity not less than 30 NTU;
- (e) Temperature 4°C ± 1° C;
- (f) Total Dissolved Solids (TDS) 1,500 mg/L ± 150 mg/L

IV SUBMITTED REFERENCES

- (1) MRID No. 469102-01, "Additional Data Supporting Efficacy of Chlorine Dioxide Alternative Disinfectants and Oxidants Guidance Manual" Completion date—September 2004.
- (2) MRID No. 468898-05, US EPA, 2003. Verification of Chlorine Dioxide Gas Technologies for Decontaminating Indoor Surfaces Contaminated with Biological or Chemical Agents.
- (3) MRID No. 468898-05, CN Haas, Drexel University. 2001. "Decontamination Using Chlorine Dioxide."
- (4) MRID No. 468898-05, A. Srinivasan *et al.*, Johns Hopkins Hospital, 2003. A 17-Month Evaluation of a Chlorine Dioxide Water Treatment System to Control Legionella Species in a Hospital Water Supply.
- (5) MRID No. 468898-05, MK Ijaz *et al.*, MicroBioTest Laboratories. [J]Hohns Hopkins School of Public Health and University of Ottawa CREM, 1999. Bactericidal, Cysticidal, Oocysticidal, and Virucidal Effects of Chlorine Dioxide in Contaminated Water.
- (6) MRID No. 468898-05, NZ Eleraky *et al.*, University of Tennessee, 2002. Virucidal Efficacy of 4 New Disinfectants.
- (7) MRID No. 468898-05, J Winiacka-Krusnell *et al.* Karolinska Institute, 1998. Cysticidal Effect of Chlorine Dioxide on *Giardia intestinalis* cysts.
- (8) MRID No. 468898-05, DG Korich *et al.*, University of Arizona, 1990. Effects of Ozone, Chlorine Dioxide, Chlorine, and Monochloramine on *Cryptosporidium parvum* Oocysts Viability.
- (9) MRID No. 468898-05, Y Gao *et al.* University of Pittsburgh, 2000. Monochloroamine and Chlorine Dioxide as Alternative Disinfection Methods for Legionella Control: Results of Pilot Studies in Model Plumbing System.

VI CONCLUSION

1. The requirements for registration were outlined in a pre-meeting with the Agency on July 27, 2006. The details and outcome of this meeting were not disclosed in the current data package, nor were they cited in the product jacket. The current submission includes numerous references, with no actual product data for water purification, the subject of this registration. The submitted references alone are not sufficient to support registration. In the absence of actual pre-meeting determinations, the PM can provide additional assistance to address the deficiencies associated with the data package. Furthermore, the performance standard and test methodology are explained in Section III. AGENCY STANDARDS FOR PROPOSED CLAIMS.

2. The proposed claims for “Slime Control in Cooling Towers and Industrial Process Water,” are considered non-public health claims. Although efficacy data submission is not required by the Agency, data must still be generated and maintained.

VII RECOMMENDATIONS

1. Please remove any and all references to “biofilm” from the proposed label. Biofilm claims are public-health, and require prior submission and acceptance of a protocol.
2. In the section entitled, Gas Phase Decontamination of Enclosures, change “buy” to “by”.
3. According to the registrant’s letter (dated August 11, 2006), this submission was “reduce[d] to the first, most basic need/market for the product, which is water purification,” however the label reflects other uses. Please submit a revised label addressing only the areas and uses for which the product is applicable.