UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

March 5, 2007

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 75757-E, CDG Solution 3000;
DP Barcode: 336587

From: Tajah L. Blackburn, Ph.D., Microbiologist
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Applicant: CDG Research Corporation
759 Roble Road
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Formulations from Label

Active Ingredient(s)	% by wt.
Chlorine dioxide	0.3%
Inert Ingredients	99.7%
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. An

internal meeting with the applicant resulted in the submission of efficacy studies to support registration of the product.

The current data package includes EPA Form 8570-35 (two copies), three efficacy studies, Statement of No Data Confidentiality Claims for all three studies, and the letter from the applicant's representative (dated February 2, 2007). All studies were conducted under GLP.

II USE DIRECTIONS

Per the submitted label, the product, CDG Solution 3000, is intended for the purification of water which has previously treated in accordance with Safe Drinking water Act (SDWA), such as that provided by municipal water treatment facilities. Intended applications include: Treatment of Potable Water and Cooling water in hospital/healthcare facilities, nursing homes, hotels, commercial office buildings, government buildings, residential buildings, and ships; treatment of industrial process water, food processing water and livestock drinking water. The product also claims to control of biological slime in human and animal potable water systems, process water systems, and cooling towers. Directions on the proposed label and dosing equipment manual provided the following information regarding preparation and use of the product as described:

Treatment of Potable water for Human Consumption: Add CDG solution 3000 to water at a dose up to 2.0 ppm (2.0 mg/L) chlorine dioxide (a dilution ratio of 1:1500). Under USEPA regulations, drinking water intended for human consumption may not contain more than 0.8 ppm (0.8 mg/L) residual chlorine dioxide or more than 1.0 ppm (1.o mg/liter) chlorite ion.

Treatment of Water for Animal Consumption: Add CDG Solution 3000 to the water at dose of 5.0 ppm (5.0 mg/L) chlorine dioxide (a dilution ratio of 1:600).

Treatment of Cooling Water Systems to Control Biological Slime: Add CDG Solution 3000 to the water at a dose of 50 ppm (50 mg/L) chlorine dioxide (a dilution of 1:60), and circulate or let stand overnight. Drain and rinse with clean water before re-use. To prevent slime growth after initial treatment, add CDG Solution 3000 to the water supply at a dose of 5.0 ppm (5.0 mg/liter) chlorine dioxide (a dilution ratio of 1:600).

Note: A copy of the operation manual was submitted for Agency review. The registrant stated that the operation manual is machine specific, and may vary accordingly.

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	%
Klebsiella terrigena (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**
Giardia muris or *Giardia lamblia****	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 10^7/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. Since this included the treatment of potable water, Giardia cysts data was not required.

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

Due to the limited application of this product, the applicant tested the representative Test Water #1, defined by following characteristics:

(a) Free of any chlorine or other disinfectant residuals;
(b) pH—6.5-8.5;
(c) Total Organic carbon (TOC)—0.1-5.0 mg/L
(d) Turbidity—0.1-5 NTU
(e) Temperature 20°C ± 5°C; and
(f) Total Dissolved Solids (TDS)—50-500 mg/L

Per Dr. Joseph Jacangelo (Director at the Center for Water and Health at Bloomberg School of Public Health, Johns Hopkins University), "most treated municipal waters ("tap water") used by hospitals fall in the range of the water quality parameters specified....For example, the Baltimore City municipal water used by the Johns Hopkins medical complex falls within the parameters....Conducting microbial inactivation within the range of water quality of Test Water #1 will provide a general appropriateness for the efficacy studies you plan."

IV SYNOPSIS OF SUBMITTED EFFICACY STUDIES

1. MRID No. 470479-03 "Product Antimicrobial Efficacy Study for CDG Research Corporation, CDG Solution 3000" against *Legionella pneumophilia* by Richard Danielson, PhD. Study Completed on January 25, 2007. Study was conducted at BioVir Laboratories. Laboratory Project ID# 062222.

The submitted study was conducted against *Legionella pneumophilia* (ATCC 33152) using the US EPA Guide Standard and Protocol for Testing Microbiological Water Purifiers (1987). The test water (dechlorinated Benicia tap water) as previously described was fed into holding tanks where general test water #1 (GTW) was made to specifications set forth in the "US EPA Guide Standard and Protocol for Testing Microbiological Water Purifiers". In a sterile 2 L beaker, 1.5 L of GTW was prepared. Organisms were added to achieve 10^7 CFU/ml, and mixed for 2 minutes. A sample of 10 ml was determined to be the time 0 for the GTW. Three amber glass jars were filled with 500 ml of the microbial suspension. One jar was placed into a water bath (20 ±0.5° C) water bath and allowed to equilibrate. Following equilibration, 250 µl of CDG Solution was added, to achieve a dose of ~ 1.5 mg/L of ClO_2 (as measured by HACH ClO_2 kit). After a contact time of 5 minutes, neutralizer was added to quench the ClO_2 exposure. In triplicate, 0.3 ml was inoculated onto BYCE-PAV to determine the presence or absence of L. *pneumophilia*. Plates were incubated for up to 72 hours at 37°C.

2. MRID No. 470479-01 "Product Antimicrobial Efficacy Study for CDG Research Corporation, CDG Solution 3000" against Poliovirus 1 (L Sc) and Rotavirus SA-11 by Richard Danielson, PhD. Study Completed on January 25, 2007. Study was conducted at BioVir Laboratories. Laboratory Project ID# 062222.

The submitted study was conducted against Poliovirus 1 (L Sc) (ATCC VR-59) and Rotavirus SA-11 (ATCC VR-2018) using Buffalo Green Monkey Kidney (BGMK)(BioVir Laboratories, Benicia, CA) cells using the US EPA Guide Standard and Protocol for Testing Microbiological Water Purifiers (1987). The test water (dechlorinated Benicia tap water) as previously described was fed into holding tanks where general test water #1 (GTW) was made to specifications set forth in the "US EPA Guide Standard and Protocol for Testing Microbiological Water Purifiers". In a sterile 2 L beaker, 1.5 L of GTW was prepared. Organisms were added to achieve 10^7 CFU/ml, and mixed for 2 minutes. A sample of 10 ml was determined to be the time 0 for the GTW. Three amber glass jars were filled with 500 ml of the microbial suspension. One jar was placed into a water bath (20 ±0.5° C) water bath and allowed to equilibrate. Following equilibration, 250 µl of CDG Solution was added, to achieve a dose of ~ 1.5 mg/L of ClO_2 (as measured by HACH ClO_2 kit). After a contact time of 5 minutes,

neutralizer was added to quench the ClO_2 exposure. Samples of 15 ml aliquots were diluted, and inoculated in the cell system of BGMK cells.

Note—The original EPA protocol written in 1987 suggests the use of a variety of African Green Monkey Kidney cells line known as MA-104 for the assay of the poilo- and rota-viruses used in this study were propagated and assayed using a BioVir cell line of the African Green Monkey Kidney variety (BV-BGMK). The BV-BGMK cell line produces ten times more virus (for spikes) than the suggested MA-104 cell line and therefore was used for this study.

3. MRID No. 470479-02 "Product Antimicrobial Efficacy Study for CDG Research Corporation, CDG Solution 3000" against *Klebsiella terrigena* by Richard Danielson, PhD. Study Completed on January 25, 2007. Study was conducted at BioVir Laboratories. Laboratory Project ID# 062222.

The submitted study was conducted against *Klebsiella terrigena* (ATCC 33257) using the US EPA Guide Standard and Protocol for Testing Microbiological Water Purifiers (1987) and the AOAC 991.47. The test water (dechlorinated Benicia tap water) as previously described was fed into holding tanks where general test water #1 (GTW) was made to specifications set forth in the "US EPA Guide Standard and Protocol for Testing Microbiological Water Purifiers". In a sterile 2 L beaker, 1.5 L of GTW was prepared. Organisms were added to achieve 10^7 CFU/ml, and mixed for 2 minutes. A sample of 10 ml was determined to be the time 0 for the GTW. Three amber glass jars were filled with 500 ml of the microbial suspension. One jar was placed into a water bath (20 ±0.5° C) water bath and allowed to equilibrate. Following equilibration, 250 µl of CDG Solution was added, to achieve a dose of ~ 1.5 mg/L of ClO_2 (as measured by HACH ClO_2 kit). After a contact time of 1 minute, neutralizer was added to quench the ClO_2 exposure. In triplicate, 100 ml samples were tested for the presence or absence of K. terrigena by the membrane filter technique on mFC agar and incubated for 24 hours at 35 ±5°C (corrected).

V RESULTS

Lot Number	*Legionella pneumophilia* (CFU/ml)	Log reduction
Untreated	3.00E + 07	
1	7.60E +03	3.60
2	5.10E + 03	3.77
3	5.40E + 03	3.74

Lot Number	Poliovirus + Rotavirus (PFU/ml)	Log reduction
Untreated	6.30E + 04	
1	1.00E + 01	5.80
2	2.10E + 00	4.48
3	<1	>5.80

Lot Number	*Klebsiella terrigena* (CFU/100 ml)	Log reduction
Untreated	3.70E +07	
1	<1	>7.57
2	<1	>7.57
3	24	6.19

VI CONCLUSIONS

1. The submitted efficacy studies support the use of the product, CDG Solution 3000, as a purifier for water previously treated in accordance with the Safe Drinking Water Act (SDWA), such as that provided by municipal water treatment facilities, for a 1-minute contact time. The water tested was analytically representative of the water conditions specified on the label.

VII RECOMMENDATIONS

1. The proposed label claims regarding the use of the product for treating potable water in cooling towers, process water systems, and for human/animal consumption are acceptable as documented. The dosing instructions are consist with the conditions in which the product was testing. A minimum contact time should be included on the proposed label consistent with the conditions in which acceptable efficacy data was generated.

2. The proposed label claims regarding the use of the product for controlling slime in cooling water systems and process water systems are acceptable. However, remove "biological" as a descriptor of slime.