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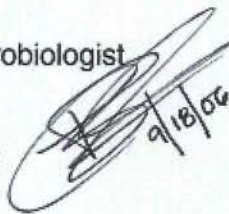
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

September 14, 2006

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 67619-8, CPPC Ultra Bleach 2;
DP Barcode: 330546

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

Thru: Michele Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Emily Mitchell PM 32/ Wanda Henson
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Clorox Professional Products Company
PO Box 493
Pleasanton, CA 94566-0803

Formulations from Label

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Sodium Hypochlorite.....	6.15%
<u>Inert Ingredients</u>	<u>93.85%</u>
Total	100.00%

I BACKGROUND

The product, CPPC Ultra Bleach 2 (EPA Reg. No. 67619-8), is a registered disinfectant (bactericide, fungicide, tuberculocide, virucide), mildewcide, and sanitizer for use on hard, non-porous surfaces in household, institutional, commercial, food processing, animal care, and hospital or medical environments. The applicant requested to amend the registration of this product to add claims for effectiveness against Hepatitis B virus. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated June 12, 2006), two studies (MRID Nos. 468594-01 and 468594-02), Statements of No Data Confidentiality Claims for both studies, and the proposed label.

Note: The laboratory reports describe studies conducted for the product, F2001.0126. The applicant's letter to EPA (dated June 12, 2006) states that the tested product, F2001.0126, is the product, 67619-8 Basic CSF (i.e., CPPC Ultra Bleach 2), which is the subject of this efficacy report.

II USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces such as appliance exteriors, bathtubs, bed frames, cabinets, cat litter boxes, changing tables, clothes hampers, combs and brushes, counter tops, diaper pails, door knobs, faucets, floors, furniture, garbage cans, garbage disposals, light switch panels, kennels, patio furniture, recycling bins, showers, sinks, telephones, toilets, toys, urinals, and walls. The proposed label indicates that the product may be used on hard, non-porous surfaces including: enamel-painted woodwork, glass, glazed ceramic, glazed porcelain, glazed tile, linoleum, plastic laminate, and vinyl. Directions on the proposed label provided the following information regarding preparation and use of the product as virucide: Prepare a use solution by adding 2/3 cup of the product to 1 gallon of water (a 1:24 dilution). Wash, wipe, or rinse items with water. Apply use solution. Let stand for 5 minutes. Rinse thoroughly and allow to air dry.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an

appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Virucides – Novel Virus Protocol Standards

To ensure that a virus protocol has been adequately validated, data should be provided from at least 2 independent laboratories for each product tested (i.e., 2 product lots per laboratory).

IV SYNOPSIS OF SUBMITTED EFFICACY STUDIES

1. MRID 468594-01 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus – Confirmatory Assay" for F2001.0126, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – April 5, 2006. Project Number A03571.

This study, under the direction of Study Director Mary J. Miller, was conducted against the Duck Hepatitis B virus (Strain DHBV16; obtained from Hepadnavirus Testing, Palo Alto, CA) using primary duck hepatocytes (cultures prepared by Valley Research Institute using ducklings received from Metzger Farms) as the host system. One lot (Lot No. A8500514) of the product, F2001.0126, was tested according to ATS Labs Protocol No. CX14112205.DHBV.5 (copy not provided). A use solution was prepared by adding 1.0 ml of the product to 24.0 ml of 100 ppm AOAC synthetic hard water (titrated at 100 ppm; a 1:25 dilution). The stock virus cultures contained 100% duck serum as the organic soil load. Two glass carriers were tested for the single product lot against the target virus. Films of virus were prepared by spreading 0.2 ml of stock virus on the bottoms of separate sterile, glass Petri dishes. The virus films were air-dried for 30 minutes at 20.0°C at 60% relative humidity. Each virus film was exposed to 2.0 ml of the use solution for 5 minutes at 20.0°C. After the contact period, the virus-disinfectant mixture was scraped from the surface of the dish with a cell scraper. Each sample was loaded onto pre-spun Sephadex columns and passed through the column using the syringe plunger. Ten-fold serial dilutions were prepared, using Leibovitz L-15 medium supplemented with 0.1% glucose, 10 µM dexamethasone, 10 µg/ml insulin, 20 mM HEPES, 10 µg/ml gentamicin, and 100 units/ml penicillin. Primary duck hepatocytes were inoculated in quadruplicate with 1.0 ml of each dilution and fed with 2.0 ml of the test medium. The inoculum was allowed to adsorb overnight at 36-38°C in a humidified atmosphere of 5-7% CO₂. Post-adsorption, 3.0 ml of the test medium was added to each cell culture well. The cultures were incubated for 9 days at 36-38°C in a humidified atmosphere of 5-7% CO₂. The plates were assayed by an indirect immunofluorescence assay. The log₁₀ reduction in infectivity was calculated using the EPA-approved method for calculating the Most Probable Number (MPN). Controls included those for input virus titer, dried virus titer, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

2. MRID 468594-02 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus" for F2001.0126, by Karen M. Ramm. Study conducted at ATS Labs. Study completion date – April 5, 2006. Project Number A03570.

This study, under the direction of Study Director Karen M. Ramm, was conducted against the Duck Hepatitis B virus (Strain DHBV16; obtained from Hepadnavirus Testing, Palo Alto, CA) using primary duck hepatocytes (cultures prepared by Valley Research Institute using ducklings received from Metzger Farms) as the host system. Two lots (Lot Nos. A8500514 and A8501309) of the product, F2001.0126, were tested according to ATS Labs Protocol No. CX14112205.DHBV.6 (copy not provided). A use solution was prepared by adding 1.0 ml of the product to 24.0 ml of 100 ppm AOAC synthetic hard water (titrated at 100 ppm; a 1:25 dilution). The stock virus cultures contained 100% duck serum as the organic soil load. Two glass carriers were tested for each product lot against the target virus. Films of virus were prepared by spreading 0.2 ml of stock virus on the bottoms of separate sterile, glass Petri dishes. The virus films were air-dried for 30 minutes at 20.0°C at 60% relative humidity. For each lot of product, separate dried virus films were exposed to 2.0 ml of the use solution for 5 minutes at 19.9-20.0°C. After the contact period, the virus-disinfectant mixture was scraped from the surface of the dish with a cell scraper. Each sample was loaded onto pre-spun Sephadex columns and passed through the column using the syringe plunger. Ten-fold serial dilutions were prepared, using Leibovitz L-15 medium supplemented with 0.1% glucose, 10 µM dexamethasone, 10 µg/ml insulin, 20 mM HEPES, 10 µg/ml gentamicin, and 100 units/ml penicillin. Primary duck hepatocytes were inoculated in quadruplicate with 1.0 ml of each dilution and fed with 2.0 ml of the test medium. The inoculum was allowed to adsorb overnight at 36-38°C in a humidified atmosphere of 5-7% CO₂. Post-adsorption, 3.0 ml of test medium was added to each cell culture well. The cultures were incubated for 9 days at 36-38°C in a humidified atmosphere of 5-7% CO₂. The plates were assayed by an indirect immuno-fluorescence assay. The log₁₀ reduction in infectivity was calculated using the EPA-approved method for calculating the Most Probable Number (MPN). Controls included those for input virus titer, dried virus titer, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

V RESULTS

MRID Number	Organism	Results			Dried Virus Control (log ₁₀ MPN)
			Lot No. A8500514	Lot No. A8501309	
468594-01	Duck Hepatitis B virus	10 ⁻² to 10 ⁻⁴ dilutions	Complete inactivation	---	4.55828 and 4.79357
		log ₁₀ MPN	#1.37983	---	
468594-02	Duck Hepatitis B virus	10 ⁻² to 10 ⁻⁴ dilutions	Complete inactivation	Complete inactivation	4.55828 and 5.05894
		log ₁₀ MPN	#1.37983	#1.37983	

VI CONCLUSIONS

1. The submitted efficacy data (MRID Nos. 468594-01 and -02) support the use of the product, CPPC Ultra Bleach 2 (also known as F2001.0126), as a disinfectant with virucidal activity against **Duck Hepatitis B virus (a surrogate for human Hepatitis B virus)** on **hard, non-porous surfaces** in the **presence of 100 ppm hard water** and a **100% organic soil load** for a **contact time of 5 minutes** at a **1:25 dilution**. Complete inactivation (no growth) was indicated in the 10⁻² through 10⁻⁴ dilutions. No cytotoxicity was observed. Recoverable virus titers of at least 10⁴ were observed. The studies were performed at the same laboratory but under the direction of different study directors. Both studies used two carriers per lot of product. The confirmatory study used one lot of product.

VII RECOMMENDATIONS

1. The proposed label claims are acceptable regarding the use of the product, CPPC Ultra Bleach 2, as a disinfectant against human Hepatitis B virus on hard, non-porous surfaces for a contact time of 5 minutes at a 2/3 cup product/gallon of water dilution. Data provided by the applicant support this claim.
2. The disinfection directions for fungi, viruses, and TB on page 4 of the proposed label must each include a statement such as the following: "Heavily soiled surfaces must be pre-cleaned prior to disinfection."

Note: This correction request was made on previous DER (dated 1/14/06).

3. "Special Instructions for Cleaning and Decontamination against HIV-1" should be extended to include HBV and HCV. Please revise the label as directed.