UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 24, 2006

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 67619-8
CPPC Ultra Bleach 2
DP Barcode: D323286
Case No:

To: Emily Mitchell PM 32 / Delores Williams, Team Reviewer
Regulatory Management Branch II
Antimicrobials Division (7510C)

From: Robert A. Turpin, Jr., Scientist R.T.
Chemistry/Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

1/24/06

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Clorox Professional Products Co.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Sodium hypochlorite	6.15
Other Ingredient(s):	93.85
Total:	100%

BACKGROUND: The registrant has submitted two acute toxicity studies to support the registration of its product, CPPC Ultra Bleach 2. Included are studies of acute inhalation toxicity and dermal sensitization.

RECOMMENDATIONS (PSB findings):

The acute toxicity profile for Reg. No. 67619-8 is currently:

acute oral toxicity		
acute dermal toxicity		
acute inhalation toxicity	IV	Acceptable
primary eye irritation		
primary skin irritation		
dermal sensitization	Non-sensitizer	Acceptable

LABELING:

N/A

DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

Product Manager: Emily Mitchell
MRID No.: 466723-01

Reviewer: R. Turpin
Study Completion Date: 10/11/05
Report No.: 17777

Testing Laboratory: Product Safety Laboratories
Author: Daniel J. Merkel
Quality Assurance (40 CFR §160.12): Statement provided

Test Material: Ultra Clorox Brand 6.15% Bleach, Formula No. F2005.0078
Concentration: 4.36 mg/L

Species: Rat
Weight: Males - 222-268 grams; Females - 175-187 grams
Age: Young adults (8-9 weeks)
Source: Ace Animals, Inc.

Summary:

1. **LC_{50} (mg/L):** **Males** = >2.18 mg/L
   Females = >2.18 mg/L
   Combined = >2.18 mg/L
2. **The estimated LC_{50} is** >2.18 mg/L
3. **MMAD**: (2.18 mg/L): 2.4 μm
4. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-3): None reported.

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.18 mg/L	0/5	0/5	0/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	particles <
2.18 mg/L	2.3 µm	1.82 µm	89.3
2.08 mg/l	2.5 µm	1.81µm	86.7

Chamber Environment	
Chamber Volume	6.7
Airflow	25.7
Temperature	19-20 ° C
Relative Humidity	61-67

Clinical Observations: **Exposure level 1 (2.18 mg/L)**: All animals survived exposure to the test atmosphere and gained body weight over the 14-day observation period. Following exposure to the test atmosphere, most rats had facial staining and one animal appeared hypoactive. All affected animals recovered from the above symptoms by Day 12 and appeared active and healthy for the remainder of the study.

Gross Necropsy Findings: No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: Emily Mitchell
MRID No.: 466723-02

Reviewer: R. Turpin
Study Completion Date: 9/16/2005
Report No.: PSB00067

Testing Laboratory: Charles River Laboratories
Author: Jason W. Smedley

Quality Assurance (40 CFR §160.12): Statements provided.

Test Material: Ultra Clorox Brand 6.15% Bleach / Sample #2005-020
Positive Control Material: α-Hexylcinnamaldehyde (HCA)

Species: Guinea pig
Weight: Females - 326-357 grams; Males - 303-377 grams **Age**: 6 weeks
Source: Hilltop Lab Animals, Inc.

Method: Modified Buehler Design

Summary:

1. **This Product is not a dermal sensitizer.**

2. **Classification**: Acceptable

Procedure (Deviation From §81-6):

- The laboratory reported that the animal room relative humidity range (44 - 76%) exceeded the preferred range (30-70%) during the study but that this occurrence was considered not to have an adverse impact on the outcome of the study.
- The laboratory reported that the data supporting the characterization and stability of the positive control substance was not performed in according to Good Laboratory Practice regulations

Procedure:

Preliminary Irritation: On the day prior to each dose administration, the guinea pigs had the hair removed with a small animal clipper. Care was taken to avoid abrading the skin. A 0.3 mL dose of the test article was placed on a 25 mm Hilltop chamber backed by adhesive tape (occlusive patch). The chambers were then applied to the clipped surface as quickly as possible. Following chamber application, the trunk of the animal was wrapped with elastic wrap which was secured with adhesive tape to prevent removal of the chamber and the animal was returned to its cage.

Induction Phase: On the day prior to the first induction dose administration (day 1), all test and control animals were weighed and the hair was removed from the left side of the test animals. On the day following clipping (day 0), chambers were applied as follows:

Group	Material	Induction No.	Test Concentration (%)[a]	Site No.	# of Animals	
					Male	Female
Test	Ultra Clorox® Brand 6.15%	1	80	1	10	10
		2	80	1		
		3	80	1[b]		

[a]The vehicle utilized was distilled water.
[b]Test site was adjusted but remained at Site 1.

The induction procedure was repeated on study day 7 and on study day 14 so that a total of three consecutive induction exposures were made to the test animals.

Challenge Phase: On the day prior to challenge dose administration, the test and challenge control animals were weighed and the hair was removed from the right side of the animals. One the day following clipping (day 28), chambers were applied as follows:

Group	Material	Concentration (%)[a]	Test Site No.	# of Animals	
				Male	Female
Test	Ultra Clorox® Brand 6.15% Bleach	40	2	10	10
Challenge Control	Ultra Clorox® Brand 6.15% Bleach	40	2	5	5

[a]The vehicle utilized was distilled water.

Approximately six hours after chamber application, the binding materials were removed. The test sites were wiped with gauze moistened in deionized water, followed by dry gauze to remove test article residue. The animals were then returned to their cages.

The test sites were graded for irritation at approximately 24 and 48 hours following chamber application (Induction) or chamber removal (Challenge) using the Dermal Grading System presented below. Any unusual observations and mortality were recorded. The animals were observed for general health/mortality twice daily, once in the morning and once in the afternoon.

Results:

Based on the results of this study, the laboratory states that the test substance is not considered to be a contact sensitizer.

Sensitization Response Indices (Erythema)				
	Incidence of Positive Response[1]		Severity[2]	
	Hours		Hours	
	24	48	24	48
Test Animals - Induction 1	3 / 20	3 / 20	0.15	0.15
Test Animals - Induction 2	9 / 20	10 / 20	0.55	0.60

Test Animals - Induction 3	8 / 20	12 / 20	0.55	0.85
Test Animals - Challenge	2 / 20	1 / 20	0.1	0.05
Naive Control Animals - Rechallenge	0 / 10	0 / 10	0	0

[1] Animals with scores greater than 0.5

[2] Sum of the erythema scores divided by the number of animals evaluated.

Scoring System for Severity of the Sensitization Response

0 = no reaction
± = very faint erythema, usually non-confluent*
1 = faint erythema, usually confluent
2 = moderate erythema
3 = severe erythema with or without edema

*Very faint erythema is not considered a positive reaction.

ACUTE TOX ONE-LINER

1. PC CODE: 014703

2. CURRENT DATE: 1/20/06

3. TEST MATERIAL: Ultra Clorox Brand 6.15% Bleach Formula No. F2005.0078

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
acute oral toxicity /		LD_{50} (mg/kg)		
acute dermal toxicity /		LD_{50} (mg/kg)		
acute inhalation toxicity / Rat /Product Safety Lab /17777 /10-11-05	466723-01	LC_{50} (mg/L) = >2.18 mg/L	IV	A
primary eye irritation /				
primary skin irritation /				
dermal sensitization / Guinea pig / Charles River Labs / PSB00067	466723-02	Non-sensitizer	---	A

A = Acceptable
U = Unacceptable
S = Supplementary
V = self-Validated