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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Friday, October 15, 2010

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 5813-RNN
DP Barcode: D382375
Product Name: *PUMA*

From: Ian Blackwell, Biologist
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Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader
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To: Wanda Henson, Acting PM 32
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: The Clorox Company

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Sodium hypochlorite	8.25
Other Ingredient(s):	91.75
Total:	100.00

I BACKGROUND: The Clorox Company has submitted acute oral and dermal toxicity studies to support the data requirements of their product, "Puma". Eurofins|PSL conducted these studies. This data package also includes two acute toxicity waiver requests (MRID Numbers 482169-03 and -04).

1. Both documents request waivers – one for the primary eye irritation and the other for the primary skin irritation study.
2. Both waivers based their request upon the pH of the product being above 11.5.
3. According to the 6/9/2010 CTT Product Chemistry review of 5813-RNN, its pH is 12.066.

The Chemistry and Toxicology Team (CTT) conducted prior acute toxicity reviews of this product on 4/21/2010 and 7/6/2010. The results of the 7/6/2010 review were:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	00007274, 00007540	?	Data Gap
Acute Dermal Toxicity	00007277, 00007540	?	Data Gap
Acute Inhalation Toxicity	480175-02	IV	Acceptable
Primary Eye Irritation	00007274, 00007540	?	Data Gap
Primary Skin Irritation	00007277, 00007540	?	Data Gap
Dermal Sensitization	466732-02	Nonsensitizer	Cited

II RECOMMENDATIONS:

1. The acute oral and dermal toxicity studies are acceptable.

2. CTT waives the primary eye and skin irritation studies for 5813-RNN based upon the pH (12.066) of the product. This waiver is in accordance with the 40 CFR §158.500; but, requires that each study be assigned toxicity category I. Should the registrant feel that toxicity category I for primary eye and skin irritation is not indicative of the hazards posed by 5813-RNN, they may have primary eye and/or skin irritation studies conducted.

The acute toxicity profile for File Symbol 5813-RNN is currently:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	482169-01	IV	Acceptable
Acute Dermal Toxicity	482169-02	IV	Acceptable
Acute Inhalation Toxicity	480175-02	IV	Acceptable
Primary Eye Irritation	482169-03	I	Waived
Primary Skin Irritation	482169-04	I	Waived
Dermal Sensitization	466732-02	Nonsensitizer	Cited

III LABELING:

1. The Signal Word is "DANGER", based upon the acute toxicity categorization of the primary eye and skin irritation studies.

2. The Precautionary Statements must state:

   "Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear goggles, face shield or safety glasses. [Wear full-cover clothing and protective eyewear – or- Wear long-sleeved shirt, pants, and protective eyewear.] Wear chemical-resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse."

3. Statements for Contaminated Personal Protective Equipment (Label Review Manual, Chapter 10, 6, B):

   "Follow the manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

4. The First Aid statements must state:

   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:

- 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.

"Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage."

"Have product container or label with you when calling a Poison Control Center or doctor for treatment advice."

"For emergency information on [product, use, etc.], call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222."

5. This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary eye and skin irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards). **Please refer to the 40 CFR §152.170 for information on Restricted-Use products.**

6. Based upon data placing it in toxicity category I for primary eye and skin irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP *in addition to* Restricted-Use Classification. **Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions.** Thus, CTT recommends that this product be assigned Restricted-Use classification; if not, this product should at least be packaged in CRP.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

(Up and Down Procedure)

Testing Laboratory: Eurofins PSL

Product Manager: 32 **Reviewer**: I. Blackwell
MRID No.: 482169-01 **Study Completion Date**: 8/27/2010
Lab Study No.: 30477

Authors: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: PUMA Formula No. 2009.0092, Sample No. 2010-036.

Species: Sprague-Dawley derived albino rats
Weight: 165-176 grams **Age**: 9 weeks
Source: Ace Animals, Inc.

Conclusion:

1. LD_{50} (mg/kg): **Males=** Not tested
Females > 5,000 mg/kg
Combined= Not tested

2. The estimated LD_{50} is greater than 5,000 mg/kg b.w.
3. Tox. Category: IV **Classification**: Acceptable

Procedure (Deviations from §81-1): None

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000 mg/kg	---	0/3	---

Observations: Hypoactivity.

Gross Necropsy: No gross abnormalities were observed.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 32 **Reviewer**: I. Blackwell
MRID No.: 482169-02 **Study Completion Date**: 8/27/2010
Lab Study No.: 30478

Testing Laboratory: Eurofins PSL
Author: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: PUMA Formula No. 2009.0092; Sample No. 2010-036.

Species: Sprague-Dawley derived albino rat
Weight: Males= 296-312 g **Age**: 9-10 weeks
Females= 195-225 g
Source: Ace Animals, Inc.

Summary:

1. **LD_{50} (mg/kg)**: **Males** > 5,000 mg/kg
Females > 5,000 mg/kg
Combined > 5,000 mg/kg

2. **The estimated LD_{50} is greater than 5,000 mg/kg of b.w.**

3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-2): None

Results:

Reported Mortality

DOSAGE (mg/kg)	**(NUMBER DEATHS/NUMBER TESTED)**		
	Males	**Females**	**Combined**
5,000	0/5	0/5	0/10

Observations: Yellow staining at the test site, desquamation, erythema, hyperkeratosis, eschar.

Gross Necropsy Findings: No gross abnormalities were observed.