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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 9, 2007

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 83046-R/ Hydrogen Peroxide 7.5 RTU
DP Barcode: D332773

To: Marshall Swindell/Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
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Through: Karen Hicks, Team Leader
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Antimicrobials Division (7510P)

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Product Science Branch
Antimicrobials Division (7510P)

Applicant: Mason Chemical Company

FORMULATION FROM LABEL:

Active Ingredient(s):		% by wt.
Hydrogen Peroxide		7.5
Other Ingredient(s):		92.5
	Total:	100.0

1) BACKGROUND: L3 Communications has submitted an acute toxicity package in support of the registration of this fungicide. The package includes a label, a Confidential Statement of Formula, and studies that have been submitted to and identified by the Agency as MRID's 46711303 (eye irritation), 46711305 (acute oral toxicity), 46711306 (acute dermal toxicity), 46711307 (skin sensitization), 46711308 (acute inhalation toxicity), and 46742701 (skin irritation).

2) RECOMMENDATIONS: PSB findings are:

a) The studies for acute dermal toxicity, acute inhalation, eye irritation, and skin irritation are acceptable.

b) The study for acute oral toxicity is acceptable; however, the Agency prefers the use of the Up-and-Down Method, the Fixed Dose Method, or the Acute Toxic Class Method.

c) The study for skin sensitization is acceptable; however, the Agency prefers the use of the Local Lymph Node Assay.

The acute toxicity profile for File Symbol 83046-R is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	46711305	IV	Acceptable
Acute Dermal Toxicity	46711306	III	Acceptable
Acute Inhalation Toxicity	46711308	IV	Acceptable
Primary Eye Irritation	46711303	I	Acceptable
Primary Skin Irritation	46742701	IV	Acceptable
Dermal Sensitization	46711307	Non-sensitizer	Acceptable

1) LABELING:

a) The Signal Word is "DANGER" based upon the results of the primary eye irritation.
b) The precautionary statements must read, "Causes irreversible eye damage. Do not get in eyes or on clothing. Wear long-sleeved shirt and long pants, socks, shoes, chemical-resistant gloves, and goggles, face shield, or shielded safety glasses. . Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the restroom. Remove and wash contaminated clothing before reuse."

c) The first aid statements must read:

IF ON SKIN

-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.

IF IN EYES

-Hold eye open and rinse gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.

-Call a poison control center or doctor for treatment advice.

d) Based on the eye irritation study, this product meets the qualifications for a Restricted-Use Pesticide as stated in 40 CFR 152.170. This product also meets the qualifications for Child-Resistant Packaging as stated in 40 CFR 157.22.

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

Product Manager: Marshall Swindell
MRID No.: 46711305

Reviewer: Chris Jiang
Study Completion Date: Oct. 19, 2005
Report No.: 05-072-3

Testing Laboratory: Tox Monitor Laboratories, Inc.
Author: Michael Kukulinski

Quality Assurance (40 CFR §160.12): A statement of GLP compliance was included.

Test Material: BIT Decon Solution, lot 10Mar05-A, clear liquid
Dosage: 5000 mg/kg

Species: Five male and five female Sprague-Dawley rats
Age: Young adult (6 to 10 weeks)
Weight: ♀: 206 to 212 g; ♂: 202 to 206 g
Source: Harlan Sprague Dawley, Indianapolis, Indiana

Conclusions:

1. LD_{50} (mg/kg): **Males** > 5000 mg/kg
Females > 5000 mg/kg
Combined > 5000 mg/kg

2. The estimated LD_{50} is greater than 5000 mg/kg.

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

Procedure (Deviations from 81-1): No deviations occurred during the study.

Results:

Reported Mortality

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	**Females**	**Combined**
5000	0/5	0/5	0/10

Observations: Clinical observations included piloerection.

Gross Necropsy Findings: Gross necropsies were unremarkable.

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

Product Manager: Marshall Swindell
MRID No.: 46711306

Reviewer: Chris Jiang
Study Completion Date: Oct. 18, 2005
Report No.: 05-072-4

Testing Laboratory: Tox Monitor Laboratories, Inc.
Author: Michael Kukulinski

Quality Assurance (40 CFR §160.12): A statement of GLP compliance was included.

Test Material: BIT Decon Solution, lot 10Mar05-A, clear liquid
Dosage: 2000 mg/kg

Species: Ten male and female New Zealand Albino rabbits
Weight: ♀: 2.01 to 2.22 kg; ♂: 2.56 to 2.67 kg
Age: Twelve weeks
Source: Kuiper Rabbitry, Gary, IN

Conclusions:

1. **LD_{50} (mg/kg):** **Males** > 2000 mg/kg
   Females > 2000 mg/kg
   Combined > 2000 mg/kg
2. **The estimated LD_{50} is greater than 2000 mg/kg**.
3. **Tox. Category**: III **Classification**: Acceptable

Procedure (Deviations from 81-2): No deviations occurred during the study.

Results:

Reported Mortality

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	**Females**	**Combined**
2000	0/5	0/5	0/10

Observations: Clinical observations included erythema and edema at the application site.

Gross Necropsy Findings: Gross necropsies were unremarkable.

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

Product Manager: Marshall Swindell
MRID No.: 46711308

Reviewer: Chris Jiang
Study Completion Date: Oct. 21, 2005
Report No.: 05-072-6

Testing Laboratory: Tox Monitor Laboratories, Inc.
Author: Michael Kukulinski

Quality Assurance (40 CFR §160.12): A statement of GLP compliance was included.

Test Material: BIT Decon Solution, lot 10Mar05-A, clear liquid
Dosage: 2.77 mg/L

Species: Five male and five female Sprague-Dawley rats
Age: Young adult (6 to 10 weeks)
Weight: ♀: 204 to 215 g; ♂: 256 to 272 g
Source: Harlan Sprague Dawley, Indianapolis, Indiana

Summary:

1. **LC_{50} (mg/L):** **Males** > 2.77 mg/L
   Females > 2.77 mg/L
   Combined > 2.77 mg/L
2. **The estimated LC_{50} is greater than 2.77 mg/L.**
3. **MMAD**: 6.7 µm
4. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviations from 81-3): No deviations occurred during the study.

Results:

Reported Mortality

Dosage (mg/L)	Mortality (number tested/number deaths)		
	Males	Females	Combined
2.77	0/5	0/5	0/10

Chamber environment	
Chamber Volume	400 L
Airflow	83 lpm
Temperature	18.3 to 19.4 °C
Relative Humidity	39 to greater than 96 %

Clinical Observations: Clinical signs included oily/wet fur from the test spray.

Gross Necropsy Findings: Gross necropsies were unremarkable.

DATA REVIEW FOR EYE IRRITATION TESTING (81-4, 870.2400)

Product Manager: Marshall Swindell
MRID No.: 46711303

Reviewer: Chris Jiang
Study Completion Date: Oct. 25, 2005
Report No.: 05-072-1

Testing Laboratory: Tox Monitor Laboratories, Inc.
Author: Michael Kukulinski

Quality Assurance (40 CFR §160.12): A statement of GLP compliance was included.

Test Material: BIT Decon Solution, lot 10Mar05-A, clear liquid
Dosage: 0.1 mL

Species: Six female New Zealand White rabbits
Weight: 2.10 to 2.48 kg
Age: Eight to ten weeks
Source: Kuiper Rabbitry, Gary, IN

Summary:

1. **Toxicity Category**: I
2. **Classification**: Acceptable

Procedure (Deviations From §81-4): No deviations occurred during the study.

Results:

Observation	1 hr	24 hrs	48 Hrs	72 hrs	168 hrs	336 hrs	504 hrs
Corneal Opacity	-/6	5/6F	5/6F	4/6F	2/6F	2/6F	1/6F
Iritis	1/6	4/6	3/6	2/6	2/6	1/6	0/6
Redness	2/6	4/6	4/6	4/6	2/6	1/6	0/6
Chemosis	2/6	4/6	3/6	2/6	2/6	0/6	0/6

F-fluorescein dye retention associated with corneal opacity

DATA REVIEW FOR PRIMARY SKIN IRRITATION TESTING (81-5, 870.2500)

Product Manager: Marshall Swindell
MRID No.: 46742701

Reviewer: Chris Jiang
Study Completion Date: Oct. 7, 2005
Report No.: 05-072-2

Testing Laboratory: Tox Monitor Laboratories, Inc.
Author: Michael Kukulinski

Quality Assurance (40 CFR §160.12): A statement of GLP compliance was included.

Test Material: BIT Decon Solution, lot 10Mar05-A, clear liquid
Dosage: 0.5 mL

Species: Six female New Zealand White rabbits
Weight: 2.10 to 2.26 kg
Age: Eight to ten weeks
Source: Kuiper Rabbitry, Gary, IN

Summary:

1. **Toxicity Category**: IV
2. **Classification**: Acceptable

Procedure (Deviations From §81-5): No deviations occurred during the study.

Results

Animal Number	Draize score for erythema/edema after patch removal			
	4.5 hr	24 hr	48 hr	72 hr
715	1/1	1/0	0/0	0/0
716	1/1	1/1	1/0	0/0
717	1/1	1/1	1/0	0/0
718	1/1	1/0	0/0	0/0
724	1/1	1/0	1/0	0/0
725	1/1	1/0	0/0	0/0

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

Product Manager: Marshall Swindell
MRID No.: 46711307

Reviewer: Chris Jiang
Study Completion Date: Nov. 4, 2005
Report No.: 05-072-5

Testing Laboratory: Tox Monitor Laboratories, Inc.
Author: Michael Kukulinski

Quality Assurance (40 CFR §160.12): A statement of GLP compliance was included.

Test Material: BIT Decon Solution, lot 10Mar05-A, clear liquid
Positive Control Material: 1-Chloro-2,4-dinitrobenzene (DNCB)

Species: Male Hartley guinea pigs
Age: Young adult
Weight: 308 to 433 g
Source: Kuiper Rabbitry, Gary, Indiana

Method: Buehler

Summary:

1. **This Product is not a dermal sensitizer.**
2. **Classification**: Acceptable

Procedure (Deviation From 81-6): No deviations occurred during the study.

Procedure: After a preliminary study, the definitive study was undertaken. Once each week for three weeks, either 0.4 mL of the test material or deionized water was applied to the clipped left side of each animal using occlusive Hilltop chambers. After chamber application, the chambers were secured with Micropore tape and Kendall adhesive tape. After the exposure period, the tape and chambers were removed and the guinea pigs were scored at 24 and at 48 hours after each induction.
Two weeks after the third induction, all animals were challenged with 0.4 mL of the test material. The guinea pigs were scored at 24 and at 48 hours after challenge.
A historical positive control study was done using DNCB using similar induction and challenge procedures as described above.

Results: At 24 hours after the first induction, diffuse erythema was noted in 2/20 animals. No irritation was observed at 48 hours after the first induction. One animal displayed diffuse erythema at 24 hours after the second induction. No irritation was observed at 48 hours after the second induction. One animal displayed diffuse erythema at 24 hours after the third induction. 2/20 guinea pigs had diffuse erythema at 24 hours after challenge. No irritation was observed at 48 hours after challenge.

The positive controls showed appropriate results.