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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Friday, March 11, 2005

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 1448-UGG / Busan 1215
DP Barcode: D313227

To: Velma Noble, PM 31/ Drusilla Copeland
Regulatory Management Branch
Antimicrobials Division (7510C)

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

3/15/05

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

Applicant: Buckman Laboratories, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Ammonia	7.59
Other Ingredient(s):	92.41
Total:	100.00%

1) BACKGROUND: Buckman Laboratories, Inc., has submitted a complete "six-pack" of acute toxicity / irritation studies to support the registration of their product, "Busan 1215". The studies were conducted by Product Safety Laboratories, Inc. The MRID Numbers are 464351-08 through 464351-13.

2) RECOMMENDATIONS: PSB findings are:

a) Each of the six submitted studies is acceptable.

The acute toxicity profile for File Symbol 1448-UGG is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	464351-08	IV	Acceptable
Acute Dermal Toxicity	464351-09	IV	Acceptable
Acute Inhalation Toxicity	464351-10	IV	Acceptable
Primary Eye Irritation	464351-11	IV	Acceptable
Primary Skin Irritation	464351-12	IV	Acceptable
Dermal Sensitization	464351-13	Nonsensitizer	Acceptable

3) LABELING:

a) The signal word is "Caution".
b) Due to the acute toxicity profile (all category IV and nonsensitizer), no precautionary labeling is required.

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

Product Manager: 31
MRID No.: 464351-08

Reviewer: I. Blackwell
Study Completion Date: 10/7/2004
Lab Study No.: 15282

Testing Laboratory: Product Safety Laboratories, Inc.
Authors: Daniel J. Merkel, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Busan 1215; "clear liquid"
Method: Up and Down Procedure

Species: Sprague-Dawley-derived albino rat
Age: 9-10 weeks
Weight: 180-214 g
Sex: 6 females
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 of body weight.**
3. **Toxicity Category**: IV **Classification**: Acceptable

Procedure (Deviations from §81-1): None

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
175	---	0/1	---
550	---	0/1	---
1,750	---	0/1	---
5,000	---	0/3	---

Observations: No abnormalities noted.

Gross Necropsy: No gross abnormalities observed.

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

Product Manager: 31
MRID No.: 464351-09

Reviewer: Ian Blackwell
Study Completion Date: 10/7/4
Lab Study No.: 15283

Testing Laboratory: Product Safety Laboratories, Inc.
Author: Daniel J. Merkel, B.S.
Quality Assurance (40 CFR §160.12): Included

Test Material: Busan 1215; "clear liquid"

Species: Sprague-Dawley derived albino rat
Weight: males = 292-308g; females = 209-216g **Age**: 9-10 weeks
Source: Ace Animals, Inc.

Summary:

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

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

3. **Toxicity 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: No abnormalities were observed.

Gross Necropsy Findings: No gross abnormalities were observed.

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

Product Manager: 31
MRID No.: 464351-10

Reviewer: I. Blackwell
Study Completion Date: 10/7/4
Lab Study No.: 15284

Testing Laboratory: Product Safety Laboratories, Inc.
Author: Daniel J. Merkel, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Busan 1215; "clear liquid"
Concentration: Gravimetric-2.08 mg/L; Nominal -157.09 mg/L (nose-only exposure)

Species: Sprague-Dawley derived albino rat
Weight: males = 241-256g; females= 186-214g
Age: 8-9 weeks
Source: Ace Animals, Inc.

Summary:

1. **LC_{50} (mg/L):** **Males** > 2.08 mg/L
   Females > 2.08 mg/L
   Combined > 2.08 mg/L

2. **The estimated LC_{50} is greater than 2.08 mg/L of air.**

3. **MMAD**: 3.05 μm

4. **Toxicity Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-3): None

Results:

Reported Mortality

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

Chamber Atmosphere			
Dose Level	MMAD	GSD	particles < 4.7 μm
2.08 mg/L	3.05 μm	2.405 μm	66.95%

Chamber Environment	
Chamber Volume	6.7 liters
Airflow	25.4 – 25.8 lpm
Temperature	20-21° C
Relative Humidity	55-57%

Clinical Observations: No abnormalities observed.

Gross Necropsy Findings: No gross abnormalities observed.

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

Product Manager: 31
MRID No.: 464351-11

Reviewer: Ian Blackwell
Study Completion Date: 10/7/4
Lab Study No.: 15285

Testing Laboratory: Product Safety Laboratories, Inc.
Author(s): Daniel J. Merkel, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Busan 1215; "clear liquid"
Dosage: 0.1 mL
Species: New Zealand albino rabbit
Sex: 3 females
Weight: Not reported **Age**: Young adult
Source: Robinson Services, Inc.

Summary:

1. **Toxicity Category**: IV

2. **Classification**: Acceptable

Procedure (Deviations From §81-4): None

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	---	---	---	---
Iritis	0/3	0/3	0/3	0/3	---	---	---	---
Conjunctivae								
Redness	3/3	0/3	0/3	0/3	---	---	---	---
Chemosis	0/3	0/3	0/3	0/3	---	---	---	---
Discharge	0/3	0/3	0/3	0/3	---	---	---	---

- - - = no observations at this point

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

Product Manager: 31
MRID No.: 464351-12

Reviewer: Ian Blackwell
Study Completion Date: 10/7/4
Lab Study No.: 15286

Testing Laboratory: Product Safety Laboratories, Inc.
Author: Daniel J. Merkel, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Busan 1215; "clear liquid"
Dosage: 0.5 mL
Species: New Zealand albino rabbit
Age: young adult
Sex: 3 males **Weight**: not reported
Source: Robinson Services, Inc.

Summary:

1. **Toxicity Category**: IV

2. **Classification**: Acceptable

Procedure (Deviations From §81-5): None.

Results: One and twenty-four hours after exposure, 3/3 test animals had very slight erythema with no edema. No other irritation was reported.

Special Comments: None.

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

Product Manager: 31
MRID No.: 464351-13

Reviewer: Ian Blackwell
Study Completion Date: 10/7/4
Lab Study No.: 15287

Testing Laboratory: Product Safety Laboratories, Inc.
Author: Daniel J. Merkel, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Busan 1215; "clear liquid"
Positive Control Material: α – Hexylcinnamaldehyde (HCA)

Species: Hartley albino guinea pig
Weight: 324-386 g **Age**: young adult
Source: Elm Hill Breeding Labs

Method: Buehler Method

Summary:

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

2. **Classification**: Acceptable

Procedure (Deviation From §81-6): None

Procedure:
Induction: Once each week for three weeks, 0.4 mL of the neat test material was applied. After the six-hour exposure, the test material was removed and the test sites were cleaned. Twenty-seven days after the first induction dose, 0.4 mL of neat test material was applied as a challenge dose. The sites were evaluated 24 and 48 hours after treatment.

Results: Twenty-four hours after induction treatment #1, 8/20 test material-induced animals displayed very faint, usually non-confluent erythema. Twenty-four hours after induction treatment #3, 4/20 test material-induced animals displayed very faint, usually non-confluent erythema.

Twenty-four hours after challenge, 7/20 test material-induced animals displayed very faint, usually non-confluent erythema. At this same point in

the study, 6/10 naïve control animals displayed very faint, usually non-confluent erythema.

Positive control study: Twenty-four hours after induction treatment #1, 6/10 animals displayed faint, usually confluent erythema, and 3/10 displayed faint, confluent erythema. Twenty-four hours after challenge, 7/10 positive control animals displayed faint, usually confluent erythema, and 3/10 displayed faint, confluent erythema. Only 2/5 naïve positive control animals displayed very faint, non-confluent erythema.