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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 1448-RNL (Busan 11-M3), 1448-RNA (Busan 11-M4)

FROM: William S. Woodrow WSW 12-11-89
Precautionary Review Section E 1/4/90
Registration Support Branch
Registration Division (H7505C)

TO: Susan Lewis (PM 21)
Fungicide-Herbicide Branch
Registration Division (H7505C)

APPLICANT: Buckman Laboratories, Inc.
1256 N. Mclean Blvd.
Memphis, TN 38108

FORMULATION FROM LABEL:

	11-M3	11-M4
Active Ingredient(s):	% by wt.	
Barium metaborate as $BaB_2O_4 \cdot H_2O$	52.0	50.0
Inert Ingredient(s):	48.0	50.0
Total	100.0%	

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BACKGROUND

Buckman Laboratories requested acute toxicity study waivers March 20, 1987, for their products Busan 11-M3, and Busan 11-M4. The waiver requests are based on the fact that Busan 11-M3, and 11-M4 are made by combining Busan 11-M1 (a fully registered Buckman product (EPA Reg No. 1448-17) with [redacted]

The acute toxicity data base for the registered (11-M1, [redacted] product follows;

Busan 11-M1 acute tox. data: EPA Reg. 1448-17

Acute oral LD_{50} = 850mg/kg (M), 530mg/kg (F)
Lab # 84674 Toxicity Category III

Acute dermal LD_{50} = >2.0g/kg. Lab # 709240
Acc. # 139216 Toxicity Category III

Acute inhalation LC_{50} = 3.54 mg/l. Acc # 252062
Toxicity category III

Primary eye irritation Lab. # 709240 Yellow corneal involvement by day 7, irritation absent by day 7 (washed with, unwashed same)
Toxicity category III

CERT INGREDIENT INFORMATION IS NOT INCLUDED

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II-M1 (continued)

Primary dermal irritation ACC# 139192 Lab# 709240
P.I. index = 0.00 Not a skin irritant
Toxicity category IV

Dermal sensitization MRID# 408984-01
Not a sensitizing agent

Two acute toxicity studies for the proposed Busan II-M3 product were submitted:
Acute oral toxicity MRID# 401518-02
Toxicity category III
See Mary L. Waller May 11, 1988 review (EPA No. 1448-RNL)
Primary eye irritation MRID# 401518-03
Lab.# BUC-AT-043. No corneal or iris involvement. Irritation absent by day 2.
Toxicity category III

RECOMMENDATIONS:

1) The Registrant requests for acute toxicity waivers for: Busan II-M3 (EPA 1448-RNL; Modified Barium Metaborate), and Busan-II-M3 (EPA 1448-RNA; Modified Barium Metaborate) are justified and should be granted

Recommendations (continued)

2) Justification for granting acute toxicity waivers for Busan 11-M3, and Busan 11-M4 are the fact that registered Busan 11-M1 is supported by studies all within Toxicity category III, except Category IV for dermal irritation, and that 11-M3 and 11-M4 are made largely from 11-M1 [redacted]

In addition, the two acute toxicity studies conducted with M-M3 also were classed in Toxicity category III, just as were comparable 11-M1 studies. Thus, it is quite probable that further acute toxicity testing of Busan 11-M3, or 11-M4 would result in Toxicity categories identical to comparable 11-M1 studies.

LABELING: (for both Busan 11-M3, and Busan 11-M4; 1448-RNL and 1448-RNA, respectively).

1) The CAUTION signal word is appropriate

Labeling (continued)

2) Under Precautionary Statements, change the first sentence to read "Harmful if swallowed, absorbed through skin, inhaled and causes eye injury." After wash thoroughly after handling., add "Remove contaminated clothing and wash before reuse."

3) Under Statement of Practical Treatment, add, "Get medical attention." to the first sentense, and also add "Get medical attention." to the last sentence (concerning inhalation).

ADDITIONAL RECOMMENDATION:

3) The skin irritation study was graded Core minimum data; the 48 hour irritation scoring results were omitted.

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

Product Manager: (21)
MRID No.: 139192
Testing Laboratory: Raltech Sci. Services
Author(s): not given
Species: Rabbit, NZ White
Age: not stated
Sex: 3M + 3F
Weight: 2.19 – 2.59 kg
Dosage: 0.5ml, undiluted
Test Material: Busan 11-M1
Quality Assurance (40 CFR §160.12): None

Reviewer: Woodrow M. Waller
Report Date: 9-20-89
Report No.: 709240

Date of study: 1-31-79

Summary:

The Primary Irritation Index: 0.02

Toxicity Category: IV

Classification: Case premium (exact contact time not stated) (48 hour scoring not done)

Procedure (Deviations From §81-5): 0.5ml undiluted test material to backs of 3M+3F rabbits. Presume a 6 hour skin contact. Animals dosed and scored for irritation according to the Draize system at 24 and 72 hours post treatment.

Results:

P.I. Index = 0.02

Busan 11-M1, is not a skin irritant - when applied to rabbits.

Special Comments:

1/6 rabbits exhibited a 1.0 score @ 24 hours - no other scores were recorded.

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DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: (21)
MRID No.: none
Testing Laboratory: Raltech Sci. Serv.
Author(s): not stated
Species: Rabbit, NZ White
Sex: 4M, 5F Weight: Not given
Source: Lesser's Rabbitry, WI.
Dosage: 0.1g (100 mg), undiluted
Test Material: 11-MT, undiluted liquid
Quality Assurance (40 CFR §160.12):

Reviewer: Woodrow M. Waller
Report Date: 12-11-89
Report No. 709240

Summary:

Tox. Category: III Classification: Guidelines

Procedure ~~(Deviation from §81-4).~~ 100mg placed in one eye of 9 rabbits. Eyes of three treated rabbits washed for 1 minute, 30 seconds after test material instillation - Remaining eyes unwashed. Irritation reactions scored according to Draize.

Results:

Observations
(number "positive"/number tested)

	Hour	Days						
		1	2	3	4	7	14	21
Cornea Opacity		2/9	1/9	1/9		1/9		
Iris		0/9	0/9	0/9		0/9		
Conjunctivae Redness		8/9	7/9	1/9		0/9		
Chemosis		5/9	5/9	0/9		0/9		
Discharge		0/9	0/9	0/9		0/9		

scores: 2, 1, 0, 1

Comments: 2/9 days, 1/9 through day 7, corneal involvement, no iris irritation. Conjunctival redness absent by day 7. P.I. score washed = 1.7, P.I. score unwashed = 0.00.

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Test Date 11,17,1978

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

Product Manager: (21)
Reviewer:- Woodrow ~~H. Walker~~
MRID No.: 139216
Report Date: 9-2087
Testing Laboratory: BalTech Sci. Services
Report No. 709240
Author(s): Mr. Clutch
Species: Rabbit, N Z white, 14 weeks old
Sex : Male
Wt.: 2.0-3.0 Kg
Test Material: 11-M1
Quality Assurance (40 CFR §160.12): None

Summary:

1. LD_{50} (mg/kg): Males = —; Females = —; Combined = —;
2. The estimated LD_{50} is > 2.0 g/kg.
3. Tox. Category: III. Classification: Guidelines

Procedure (~~Deviations From §81-2~~): 2.0 g/kg applied to clipped backs of 3M & 3F rabbits, under a rubber sleeve. Abraded and intact skin sites were treated. 24 hour contact. Animals examined frequently for 3 hrs post-treatment & 2x daily to 14 days & subsequently.

Results:

Reported Mortality

DOSAGE (g /kg)	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
2.0 g/kg	0/3	0/3	0/6

Symptomology & Gross Necropsy Findings:

No clinical observations reported. One rabbit exhibited white areas on liver.