

US EPA ARCHIVE DOCUMENT



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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
<u>Active Ingredient(s):</u>	<u>3 by wt.</u>	
<u>Barium metaborate as BaB<sub>2</sub>O<sub>4</sub>·H<sub>2</sub>O</u>	<u>52.0</u>	<u>50.0</u>
_____	_____	_____
_____	_____	_____
<u>Inert Ingredient(s):</u>	<u>48.0</u>	<u>50.0</u>
	Total	100.0%

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100

## 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<sub>50</sub> = 850mg/kg (M), 530mg/kg (F)

Lab # 84674 Toxicity Category III

Acute dermal LD<sub>50</sub> = > 2.0g/kg Lab # 709240

Acc. # 139216 Toxicity Category III

Acute inhalation LC<sub>50</sub> = 3.54mg/l. Acc. # 25206

Toxicity Category III

Primary eye irritation Lab. # 709240 Vol. 10000

corneal involvement by day 7, irritation absent by day 7 (washed 10:1, unwashed 0:00)

Toxicity Category III

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11-m3 (continued)

Primary dermal irritation ACC# 139192 Lab# 70924C

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 11-m3 product were submitted:

Acute oral toxicity MRID# 401518-02

Toxicity category III

See Marg Lobbler May 11, 1988 review (EPA NO. 1448-RNL)

Primary eye irritation MRID# 401518-03

Lab. # BUC-AT-043. No corneal otitis

involvement. Irritation absent by day 2.

Toxicity category III

### RECOMMENDATIONS:

1) The Registrant requests for acute toxicity waivers for: Busan 11-m3 (EPA 1448-RNL; Modified Barium Metaborate), and Busan-11-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-m<sup>3</sup>, and Busan 11-m<sup>4</sup> are the fact that registered Busan 11-m<sup>1</sup> is supported by studies all within Toxicity category III, except Category IV for dermal irritation, and that 11-m<sup>3</sup> and 11-m<sup>4</sup> are made largely from 11-m<sup>1</sup>

In addition, the two acute toxicity studies conducted with 11-m<sup>3</sup> also were classed in Toxicity category III, just as were comparable 11-m<sup>1</sup> studies. Thus, it is quite probable that further acute toxicity testing of Busan 11-m<sup>3</sup>, or 11-m<sup>4</sup> would result in Toxicity categories identical to comparable 11-m<sup>1</sup> studies.

LABELING: (for both Busan 11-m<sup>3</sup>, and Busan 11-m<sup>4</sup>; 1448-RNL and 1448-RNA, respectively).

1) The CAUTION signal word is appropriate

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### Labelling (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 sentence, 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 45 hour irritation scoring results were omitted.

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

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Product Manager: ( 21 )  
 MRID No.: 139192  
 Testing Laboratory: Ralltech Sci. Services  
 Author(s): not given  
 Species: Rabbit, N 2 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: 9-20-79  
 Report No.: 709240

Date of study: 1-31-79

Summary:

The Primary Irritation Index : 0.02

Toxicity Category: IV (exposed contact time not stated)

Classification: Category minimum 48 hour scoring not done

Procedure (Deviations From §81-5): 0.5ml undiluted test material  
to backs of 3M & 3F subjects. Presume a 6 hour skin  
contact. Animals examined 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 subjects.

Special Comments:

1/6 subjects 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) Reviewer: Woodrow M. Waller  
 MRID No.: NONE Report Date: 12-11-89  
 Testing Laboratory: Raltech Sci-Serv. Report No. 709240  
 Author(s): not stated  
 Species: Rabbit, N 2 White  
 Sex: 4M, 5F Weight: Not given  
 Source: Lessee's Rabbitry, W.V.  
 Dosage: 0.1g (100 mg), undiluted  
 Test Material: 11-M1, undiluted liquid  
 Quality Assurance (40 CFR §160.12):

## 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				Scores = 2, 1, 5, 1
Iris	0/9	0/9	0/9		0/9				
Conjunctivae Redness	8/9	7/9	4/9		0/9				
Chemosis	5/9	5/9	0/9		0/9				
Discharge	0/9	0/9	0/9		0/9				

Comments: 2/9 days; 1/9 through day 7, corneal opacities, no iris irritation. Conjunctival redness absent by day 7.  
P.T. score unwashed = 1.7, P.T. 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 )  
 MRID No.: 139216  
 Testing Laboratory: Ballhouch Sci. Services  
 Author(s): Neil Stutch  
 Species: Rabbit, N 2 white, 14 weeks old  
 Sex: Male Wt.: 2.0-3.0 kg  
 Test Material: 11-M1  
 Quality Assurance (40 CFR §160.12): None

Reviewer: Woodrow  
~~H. Waller~~  
 Report Date: 9-20-87  
 Report No. 709240

Summary:

- LD50 (mg/kg): Males = \_\_\_\_\_; Females = \_\_\_\_\_; Combined = \_\_\_\_\_;
- The estimated LD50 is 2.0 g/kg.
- 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.  
 Results: 7 survivors.

Reported Mortality

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

Symptomology & Gross Necropsy Findings:

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

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