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<b>Submitting Organization</b> ROHM & HAAS CO		
<b>Contractor</b>		
<b>Document Title</b> DIMETHYL SULFONE: ACUTE TOXICITY REPORTS IN SPRAGUE-DAWLEY RATS AND NEW ZEALAND RABBITS WITH COVER SHEET AND LETTER DATED 112291		
<b>Chemical Category</b> DIMETHYL SULFONE (67-71-0)		



91 DEC -2 11:11:43  
November 22, 1991

Document Processing Center (TS-790)  
ATTN: 8(d) Health and Safety Reporting  
Rule (Notification/Reporting)  
Room L-100  
Office of Toxic Substances  
Environmental Protection Agency  
401 M Street, S.W.  
Washington, DC 20460

86-92000-306

Gentlemen:

SUBJECT: TSCA Section 8 (d) Submittal  
Isobutyl Acrylate  
Dimethyl Sulfone  
Acetaldehyde

In response to EPA's TSCA Section 8(d) Reporting Rule published in the Federal Register of August 29, 1991, we are herein submitting copies of Health and Safety Studies for the above listed chemical substances. These copies are indexed as Attachments I to VIII.

These studies have been obtained from file searches conducted at all pertinent Rohm and Haas locations and are being submitted on behalf of:

Kohm and Haas Company  
Corporate Headquarters  
Independence Mall West  
Philadelphia, PA 19105

Sincerely,

*George J. Powell / R&H*  
George J. Powell  
Senior Regulatory Specialist  
Product Integrity Department  
215-592-2986

GJP:crb

Documents Submitted to EPA Under Section 8(d)  
58FR42688, August 29, 1991

CONTAINS NO CBI

<u>Attachment Number</u>	<u>Author</u>	<u>Title</u>	<u>Date</u>	<u>CAS No.</u>
<b>Acetaldehyde</b>				
1	Kraus, S. S. and Williams, D. C.	Preliminary Hazard Analysis: Acetaldehyde and Vinyl Acetate Exposure in Vinyl Acetate Containing Latices and Paints	04/19/90	75-07-0
<b><u>Dimethyl Sulfone</u></b>				
2	--	Dimethyl sulfone, acute toxicity	07/07/81	67-71-0
3	Heitmuller, T.	Acute Toxicity of Dimethylsulfone to Fiddler Crabs ( <u>ura pugilator</u> )	01/22/81	67-71-0
4	Hollister, T.	Toxicity of Dimethylsulfone to the Marine Alga <u>Skeletonema costatum</u>	12/29/80	67-71-0
5	Hollister, T.	Acute Toxicity of Dimethylsulfone to Mysid Shrimp ( <u>Mysidopsis bahia</u> )	12/29/80	67-71-0
6	Heitmuller, T.	Acute Toxicity of Dimethylsulfone to Sheepshead Minnows ( <u>Cyprinodon variegatus</u> )	12/29/80	67-71-0
<b><u>Isobutyl Acrylate</u></b>				
7	Harris, L.	Toxicity Screening, Isobutyl Acrylate; 15 ppm, 50 ppm, 100 ppm, MEHQ	08/10/73	106-63-8
8	Hycum, J. S.	Isobutyl Acrylate, Range Finding Toxicity Studies	11/08/67	106-63-8

## TOXICITY REPORT

TOXICOLOGY DEPARTMENT

SPRING HOUSE, PA 19477



THIS REPORT WAS PRINTED  
FROM MIDAS ON 07/07/81

REPORT NUMBER 81R 0098	PAGE NUMBER 1 of 7
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TEST SUBSTANCE

DIMETHYL SULFONE

MATERIAL KEY:896535-5

TD NO:80-320 \*

\*98% A.I. (estimate); no lot number identification was supplied with this sample.

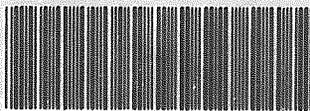
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ACUTE ORAL LD50, RANGE FINDING, rat  
ACUTE DERMAL LD50, RANGE FINDING, rabbit  
ACUTE SKIN IRR., RANGE FINDING, rabbit  
ACUTE EYE IRR., RANGE FINDING, rabbit

Range-finding studies are preliminary investigations designed to roughly estimate toxicity and/or irritation and to provide information needed for dose selection for definitive studies. Such data should be considered approximations only, and further extrapolation is not recommended. When range-finding data are reported, they should be identified as range-finding and, if appropriate, an explanatory note such as this should be included.

These range-finding studies have been reviewed by the Acute Toxicity Testing Group but have not received an audit by the Quality Assurance Unit. If these data are to be submitted to any government regulatory agency, please contact your Product Monitor in order to arrange a complete study audit prior to the submission.

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This report and associated raw data are stored in the Archives of the Toxicology Department, Rohm and Haas Company.

The following information is based upon studies conducted by the Toxicology Department, Rohm and Haas Company, and is believed to be correct. This information is furnished to others upon the condition that the persons receiving it shall make their own determination of its suitability for their purposes. No warranty is expressed or implied regarding the accuracy of this information or the results to be obtained from its use.

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STUDY INITIATED: 1/08/81  
STUDY TERMINATED: 1/22/81

ACUTE - RANGE FINDING  
ORAL LD50  
> 5.0 g/kg (Range-Finding Estimate)

PROTOCOL NO. 81P-20

RAW DATA PAGE NO. B00285

SPECIES/STRAIN: RAT (SPRAGUE-DAWLEY)

SEX: M

SOURCE: CHARLES RIVER BREEDING LABS

CONDITIONS: Animals, fasted overnight, were  
gavaged with a 20% (W/V) dispersion of the test  
substance in 0.5% solution of Methocel in water.

DOSAGE	ONSET OF SIGNS(S), RECOVERY(R), DEATH(D), DAYS POST-DOSING										DIED/ DOSED	MEAN WT INITIAL	TER
	0	1	2	3	4	5	6	7	8-14				
1. 5.0 g/kg											0/3	167	29
2. 0.5 g/kg											0/3	165	29

MAXIMUM OBSERVED INCIDENCE AT ANY OBSERVATION TIME (NO. POSITIVE/NO. OBSERVED)

SIGNS	D O S A G E L E V E L S	
	5.0 g/kg	0.5 g/kg
1. NO TOXIC SIGNS	3/3	3/3

## GROSS NECROPSY OBSERVATIONS

No gross changes were observed in any animal.

## STUDY CONCLUSIONS:

Based on the magnitude of the LD50 alone, this test substance is "practically non-toxic" by ingestion of a single dose (i.e., the rat oral LD50 is estimated to be greater than 5.0 g/kg).

PRINCIPAL INVESTIGATOR: M. E. DE CRESCENTE

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STUDY INITIATED: 1/06/81  
STUDY TERMINATED: 1/20/81

ACUTE - RANGE FINDING  
DERMAL LD50  
> 5.0 g/kg (Range-Finding Estimate)

PROTOCOL NO. 81P-7

RAW DATA PAGE NO. E00272

SPECIES/STRAIN: RABBIT (NEW ZEALAND WHITE)

SEX: M

SOURCE: SKIPPACK FARMS

CONDITIONS: The test substance, prepared as a paste in saline (1:1), was held under an impervious cuff in continuous 24-hr contact with the closely clipped skin.

DOSAGE	ONSET OF SIGNS(S), RECOVERY(R), DEATH(D), DAYS POST-DOSING										DIED/ DOSED	MEAN WT	
	0	1	2	3	4	5	6	7	8-14	INIT		TER	
1. 5.0 g/kg											0/2	2.23	2.5

MAXIMUM OBSERVED INCIDENCE AT ANY OBSERVATION TIME (NO. POSITIVE/NO. OBSERVED)

D O S A G E L E V E L S

SIGNS  
1. NO TOXIC SIGNS

5.0 g/kg  
2/2

Skin Irritation : Well defined erythema, very slight edema. After the 24-hr exposure, the cuffs were removed and the application sites were gently wiped to remove the test substance. Despite this procedure, some residual test substance remained at the application sites which these rabbits were subsequently observed preening.

### GROSS NECROPSY OBSERVATIONS

No gross changes were observed in either rabbit.

### STUDY CONCLUSIONS:

Based on the magnitude of the LD50 alone, this test substance is "practically non-toxic" by a single skin application (i.e., the rabbit dermal LD50 is estimated to be greater than 5.0 g/kg).

PRINCIPAL INVESTIGATOR: M. E. DE CRESCENTE

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STUDY INITIATED: 12/09/80  
STUDY TERMINATED: 12/16/80

ACUTE - RANGE FINDING  
SKIN IRRITATION

PROTOCOL NO. 80P-661

RAW DATA PAGE NO. J00189

SPECIES/STRAIN: RABBIT (NEW ZEALAND WHITE)

SEX: M

SOURCE: SKIPPACK FARMS

CONDITIONS: 0.5 g of the test substance,  
prepared as a paste in saline (1:1), was held  
under an impervious patch in continuous 24-hr  
contact with the closely clipped skin.

TIME	REACTION	RABBIT NUMBER, VALUE				MEAN	PRIMARY IRRITATION SCORE <u>0.3</u> *
		1	2			VALUE	
24 HOURS	ERYTHEMA						The primary irritation score is the sum of the mean values for 24 and 72 hours (and not 7 days) divided by 4.
24 HOURS	INTACT	0	0			0.0	
72 HOURS	INTACT	0	0			0.0	
07 DAYS	INTACT	0	0			0.0	
24 HOURS	ABRADED	1	1			1.0	
72 HOURS	ABRADED	0	0			0.0	
07 DAYS	ABRADED	0	0			0.0	
24 HOURS	EDEMA						
24 HOURS	INTACT	0	0			0.0	
72 HOURS	INTACT	0	0			0.0	
07 DAYS	INTACT	0	0			0.0	
24 HOURS	ABRADED	0	0			0.0	
72 HOURS	ABRADED	0	0			0.0	
07 DAYS	ABRADED	0	0			0.0	

#### STUDY FOOTNOTES:

\*Range-Finding estimate.

#### STUDY CONCLUSIONS:

Based on the Primary Irritation Score alone, this test substance is "slightly" irritating to the skin of rabbits (i.e., the Primary Irritation Score is between 0 and 2.0).

PRINCIPAL INVESTIGATOR: M. E. DE CRESCENTE

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STUDY INITIATED: 12/15/80  
STUDY TERMINATED: 12/22/80

ACUTE - RANGE FINDING  
EYE IRRITATION

PROTOCOL NO. 80P-666

RAW DATA PAGE NO. K00233

SPECIES/STRAIN: RABBIT (NEW ZEALAND WHITE)

CONDITIONS: 0.1 g of the ground test substance  
was introduced into the conjunctival sac.

SEX: M

SOURCE: SKIPPACK FARMS

TIME	STRUCTURE	R A B B I T N U M B E R, V A L U E							MEAN VALUE †
		1	2 a						
04 hr	CORNEA	0.0	0.0						0.0
	IRIS	2.5	2.5						2.5
	CONJUNCTIVAE	14.0	12.0						13.0
25 hr	CORNEA	0.0	0.0b						0.0
	IRIS	0.0	0.0						0.0
	CONJUNCTIVAE	0.0	6.0						3.0
48 hr	CORNEA	0.0	0.0						0.0
	IRIS	0.0	0.0						0.0
	CONJUNCTIVAE	2.0	2.0						2.0
72 hr	CORNEA	0.0	0.0						0.0
	IRIS	0.0	0.0						0.0
	CONJUNCTIVAE	0.0	2.0						1.0
96 hr	CORNEA	0.0	0.0						0.0
	IRIS	0.0	0.0						0.0
	CONJUNCTIVAE	0.0	0.0						0.0
07 day	CORNEA	0.0	0.0						0.0
	IRIS	0.0	0.0						0.0
	CONJUNCTIVAE	0.0	0.0						0.0

† The mean value is calculated from rabbits numbered 1 and 2 inclusive (unwashed eyes).

The eye irritation rating for this material is: Moderate. (Range-finding estimate.) Based on a classification system outlined in protocol 78P-103.

#### STUDY FOOTNOTES:

- This animal vocalized after the introduction of the test substance.
- Although no corneal opacity was observed in this rabbit, fluorescein instillation resulted in an area < 25% of the cornea staining. This uptake of dye suggests that a superficial, transient irritation of the corneal epithelium occurred. This staining of the cornea did not occur at the next scheduled examination at 48 hr after dosing.

#### STUDY CONCLUSIONS:

Based on only the duration of the ocular effects, this test substance is "moderately" irritating to the eyes of rabbits (i.e., all irritation was reversible within 7 days, but

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not within 24 hr after dosing).

PRINCIPAL INVESTIGATOR: M. E. DE CRESCENTE

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## REPORT CONCLUSIONS:

Based on range-finding lethality data, this test substance is considered to be "practically non-toxic" both by ingestion of a single dose and by a single dermal application.

Range-finding irritation data indicate this test substance is "moderately" irritating to the eyes of rabbits and "slightly" irritating to their skin.

WRITTEN/SIGNED BY: M. E. DE CRESCENTE R. E. WARGO *me De Crescente 7/7/81 R.E. Wargo*  
REVIEWED/SIGNED BY: K. M. KRZYWICKI *K.M. Krzywicki 7/8/81*  
APPROVED/SIGNED BY: R. D. PARSONS *R.D. Parsons 7/8/81* R. C. BALDWIN  
APPROVED/SIGNED BY: A. W. HAYES

*AW Hayes 7/13/81*

*RC Baldwin 7/8/81*

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