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		TSCA Section	8ECP
Submitting Organization	ROHM & HAAS CO		
Contractor			
Document Title	INITIAL SUBMISSION: ACUTE TOXICITY SCREENING STUDIES OF MIXTURE OF SIX COMPONENTS INCLUDING ACRYLIC POLYMER, 1,2-ETHANEDIAMINE, * WITH COVER LETTER DATED 08/19/92 (SANITIZED)		
Chemical Category	MIXTURE CONTAINING ACRYLIC POLYMER, 1,2-ETHANEDIAMINE, *		

8EHQ - 1092 - 12152

August 19, 1992



**ROHM  
&  
HAAS**  
COMPANY

8EHQ-92-12152  
889200103895

**COMPANY SANITIZED**

Document Processing Center (TS-790)  
Office of Toxic Substances  
Attn: Section 8(e) Coordinator (CAP Agreement)  
Environmental Protection Agency  
401 M Street, S.W.  
Washington, DC 20460

SANITIZED INIT

Dear Sir or Madam:

Re: 8(e) CAP-0103; Data Submission

The enclosed document is submitted pursuant to the TSCA Section 8(e) Compliance Audit Program and the CAP Agreement between Rohm and Haas Company and the Environmental Protection Agency. This document does contain confidential business information.

The following is a summary of the contents of the submission under Unit II.C.3 of the CAP Agreement:

Tested Mixture of Six Components:	Component A, 49.8%, [ acrylic polymer ] Component B, 0-2%, 1,2-ethanediamine Component C, 0.3%, 1,2-ethanediamine, N-methyl Component D, 2.4%, 1-butanol Component E, 43.9%, dipropyleneglycol, methyl ether Component F, 3.2%, water
CASRN:	Component A - Unknown; Component B - 107-15-3; Component C - 109-81-9; Component D - 71-36-3 Component E - 34590-94-8; Component F - 7732-18-5
Title of Report or Study: Reportable Effect:	Acute Toxicity Screening Studies (Report No. 78R-105) Severe eye irritation observed in rabbit Eye Irritation study.

If additional information is required, please contact the undersigned at (215) 592-3139.  
Thank you.

Sincerely,

*Ronald L. Keener*  
Ronald L. Keener, Ph.D.  
Regulatory Affairs Director  
Product Integrity Department

RLK:so  
Enclosure

78-109

SANITIZED

N. Hamada  
P.J. McNulty  
A. Mercurio  
L.J. Shestack  
J.M. Smith  
P.R. Sperry  
T.E. Stavens  
~~QAU~~  
TD Central File

TD 78-570

Spring House, July 24, 1978

TO: Dr. J. Wilczynski  
FROM: R.C. Baldwin  
SUBJECT: Results of Toxicity Tests on QR-765

The attached report summarizes the results of the range-finding toxicity tests on your sample. The results indicate that your sample was practically non-toxic when administered orally to rats or applied to rabbit skin. While only minimal skin irritation developed, the sample caused eye irritation of moderate intensity but of at least 14 day duration. The corneal opacity lasting for 14 days is the criterion for classifying QR-765 as a severe eye irritant.

Should you have any questions about the results or their interpretation feel free to contact me.

Robert Baldwin  
R.C. Baldwin

RCB/vp

Attachment

0 0 0 4

# TOXICITY DATA

RESEARCH DIVISION



REPORT NO. 78-105 DATE June 27, 1978 PAGE 209  
 PRODUCT: OR-765 (TW-0484)

Approx. Wt. %

TRD NO. 78-107 COMPOUND NO. --- DISTRI. ---

**STUDIES IN THIS REPORT:**

- |   |  |
|---|--|
| <input type="checkbox"/> RAT ORAL LD <sub>50</sub> - STANDARD                 | <input type="checkbox"/> RABBIT DERMAL LD <sub>50</sub> - STANDARD                 |
| <input checked="" type="checkbox"/> RAT ORAL LD <sub>50</sub> - RANGE-FINDING | <input checked="" type="checkbox"/> RABBIT DERMAL LD <sub>50</sub> - RANGE-FINDING |
| <input type="checkbox"/> MOUSE ORAL LD <sub>50</sub>                          | <input type="checkbox"/> RABBIT DERMAL LD <sub>50</sub>                            |
| <input type="checkbox"/> EYE IRRITATION - STANDARD                            | <input type="checkbox"/> SKIN IRRITATION - STANDARD                                |
| <input checked="" type="checkbox"/> EYE IRRITATION - RANGE-FINDING            | <input checked="" type="checkbox"/> SKIN IRRITATION - RANGE-FINDING                |

### ACUTE ORAL LD<sub>50</sub>

SINGLE ORAL LD <sub>50</sub> > 5.0 g/kg (RF estimate)		CONDITIONS	
SPECIES Albino rat (Charles River - CD)		Animals fasted approximately 18 hours	
SEX Male		were dosed with the undiluted product.	
TRD PROTOCOL NO. 77P-17 BOOK 1 PAGE 1103			

DOSAGE	ONSET OF (S) SIGNS, (D) DEATH, HOURS AND DAYS										DIED DOSED	MEAN WT.		TIME OF (R) RECOVERY, DAYS						
	0-6	6-24	2	3	4	5	6	7	8-14	I		T	1	2	3	4	5	6	7-14	
1. 5.0 g/kg											0/3	235	339							
2. 3.2											0/3	238	342							
3. 1.6											0/3	233	345							
4. 0.8											0/3	232	332							
5. 0.4											0/3	229	341							

SIGNS OF INTOXICATION      None observed.

GROSS AUTOPSY              No visible lesions.

### ACUTE DERMAL LD<sub>50</sub>

SINGLE DERMAL LD <sub>50</sub> > 5.0 g/kg (RF estimate)		CONDITIONS	
SPECIES Rabbit (NZW)		The undiluted product was held under	
SEX Male		an impervious cuff in continuous 24-hour contact	
TRD PROTOCOL NO. 77P-12 BOOK 7 PAGE 674		with the closely clipped skin.	

DOSAGE	ONSET OF (S) SIGNS, (D) DEATH, HOURS AND DAYS										DIED DOSED	MEAN WT.		TIME OF (R) RECOVERY, DAYS						
	0-6	6-24	2	3	4	5	6	7	8-14	I		T	1	2	3	4	5	6	7-14	
1. 5.0 g/kg											0/2	2.60	2.95							
2. 3.2											0/2	2.90	3.23							
3.																				
4.																				
5.																				

SIGNS OF INTOXICATION      None observed.

SKIN IRRITATION      Well defined erythema, slight edema. Test substance dried within 24 hours.  
 At cuff removal, the test material adhered to the skin and hair.

GROSS AUTOPSY      No visible lesions.

0005

**SKIN IRRITATION**

TRD PROTOCOL NO. 77P-19 CONDITIONS 0.5 ml of the undiluted product was held under an impervious patch in continuous 24-hour contact with the closely clipped skin.  
 BOOK 4 PAGE 452

TIME, HOURS	REACTION	RABBIT NUMBER, VALUE						MEAN VALUE	PRIMARY IRRITATION SCORE 0.8 <sup>a</sup> (RF estimate)
		1	2	3	4	5	6		
24	Erythema Intact	0	0					0	
	72 Intact	1	1					1.0	
7 days	24 Intact	0	0					0	
	72 Abraded	1	1					1.0	
7 days	24 Abraded	1	1					1.0	
	72 Abraded	0	0					0	
24	Edema Intact	0	0					0	
	72 Intact	0	0					0	
7 days	24 Intact	0	0					0	
	72 Abraded	0	0					0	
7 days	24 Abraded	0	0					0	
	72 Abraded	0	0					0	

RABBIT EYE IRRITATION TRD PROTOCOL NO. 77P-18 CONDITIONS 0.1 ml of the undiluted product was introduced into the conjunctival sac.  
 BOOK 5 PAGE 450

TIME, HOURS	STRUCTURE	RABBIT NUMBER, VALUE									MEAN VALUE	1. Is this material considered an eye irritant according to the Hazardous Substances Labeling Act? Not Determined <input type="checkbox"/> YES <input type="checkbox"/> NO
		1	2	3	4	5	6	7	8	9		
24	CORNEA	0	10								5.0	
	IRIS	0	0								0	
	CONJUNCTIVAE	14	14								14.0	
72	CORNEA	10	15								12.5	2. Rate the eye irritation according to:  <input type="checkbox"/> NONE <input type="checkbox"/> MILD <input type="checkbox"/> MODERATE <input checked="" type="checkbox"/> SEVERE (RF estimate)
	IRIS	5	5								5.0	
	CONJUNCTIVAE	16	16								16.0	
7 days	CORNEA	5 <sup>b</sup>	15 <sup>b</sup>								10.0	
	IRIS	5	5								5.0	
	CONJUNCTIVAE	6	8								7.0	
14 days	CORNEA	5 <sup>b</sup>	10 <sup>b</sup>								7.5	
	IRIS	0	0								0	
	CONJUNCTIVAE	0	0								0	

THE SCORING SYSTEM USED HEREIN FOR SKIN AND EYE IRRITATION REACTIONS IS THAT OF DRAIZE, J.H., WOODWARD, G., AND CALVERT, H.O.: J. PHARMACOL. EXPTL. THERAP., 82:37, 1944. THE MAXIMUM POSSIBLE VALUE FOR A SKIN REACTION (EXCLUDING NECROSIS) IS 4. THE "PRIMARY IRRITATION SCORE" IS THE SUM OF THE MEAN VALUES DIVIDED BY 4. THE MAXIMUM POSSIBLE SCORES FOR EYE IRRITATION REACTIONS (AGAIN EXCLUDING NECROSIS) ARE: CORNEA, 80; IRIS, 10; CONJUNCTIVAE, 20.

**Results:**

Based on "range-finding" toxicity tests, this product is considered to be practically non-toxic (LD<sub>50</sub> greater than 5.0 g/kg) both by ingestion in a single dose and by a single skin application.

"Range-finding" irritation data indicates this product to be slightly irritating (Primary Irritation Score 0-2.0) to the skin of rabbits & severely irritating (corneal opacity not reversible within 7 days) to the eyes of rabbits.

**Comments:**

The Toxicity & irritation tests reported herein are considered to be "range-finding" (exploratory) type experiments and the data obtained from them should be treated as such. Further extrapolation or interpretation of these data is not recommended without additional testing.

Because this product is severely irritating to rabbits' eyes, precautions must be observed to prevent ocular contact with it.

Since this product is slightly irritating to rabbit skin, precautions should be observed to avoid prolonged or repeated skin contact with it.

**Notations:** <sup>a</sup>The Primary Irritation Score is the sum of the mean values for 24 and 72 hours (not 7 days) divided by 4.

<sup>b</sup>Blood vessels on cornea.

Written by: *Edward T. ...* 7/4/578 Approved by: *G. ...* 7/5/198



August 19, 1992

Document Processing Center (TS-790)  
(Attn: Section 8(e) Coordinator)  
Office of Toxic Substances  
U.S. Environmental Protection Agency  
401 "M" Street, S.W.  
Washington, DC 20460

SANITIZED

Dear Sir:

Re: Substantiation of Confidentiality Claims Made in Rohm and Haas  
Submittal of August 19, 1992 Under Section 8(e) of TSCA [ ],  
Report #78R-105

In the reference document submitted in accordance with Section 8(e) of the Toxic Substances Control Act, the specific chemical identity and the experimental designation were claimed as CONFIDENTIAL BUSINESS INFORMATION. A sanitized version of the submittal was included for use in the public file. The generic name "acrylic polymer" was provided.

In accordance with EPA's guide document, "Support Information for Confidentiality Claims," we provide the following answers to the seven questions asked to support the claim of confidentiality.

1. *For what period of time do you assert this claim of confidentiality? If a claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why the information should remain confidential until such event or time.*

Confidentiality of the specific chemical identity and the experimental designation should be maintained indefinitely. It is impossible to estimate the time span over which this specific chemical technology might be utilized. Knowledge of the chemical identity with the link to the experimental designation could enable competitors to identify the type of chemistry under consideration by Rohm and Haas Company in research stage and thus would provide an unfair competitive disadvantage to Rohm and Haas Company.

2. *Have there been any confidentiality determinations made by EPA, other Federal agencies or courts in connection with this information? If so, please enclose copies.*

Confidentiality for this experimental chemical was claimed in a confidentiality statement of formula to the United States Department of Agriculture (letter from John J. Walker to Mr Charles R. Edwards, October 11, 1983).

3. *Has any of the information that you are claiming as confidential been disclosed to individuals outside your company? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information?*

The chemical identity of this substance and the Rohm and Haas experimental designation have not been disclosed outside of the company. No disclosure of the confidential information is anticipated at this time.

4. *Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming as confidential. What other steps, if any, have you taken to prevent undesired disclosure of the information during its use or when an employee leaves the company?*

Information on the chemical identity and other data for this substance is held "COMPANY CONFIDENTIAL" which means it may not be disclosed outside the company. Accessibility to "Company Confidential" documents is limited to people within the company who have a real need-to-know. Documents so classified are clearly stamped, may not be reproduced without permission, and are filed in security-locked cabinets. Each of our products are assigned a coded name designation so that in normal business and operational activities the chemical identities are not identified, and there is no link between the chemical identity and the coded designation. Most persons within the company that have access to confidential information are under contract which states that intellectual property may not be disclosed upon leaving the organization.

5. *Does information claimed as confidential appear or is referred to in any of the items listed below: advertising or promotional materials for the*

*chemical or the end product containing it; safety data sheets or other similar materials for the chemical or end product containing it; professional or trade publications any other media available to the public or to your competitors?*

The chemical identity of the subject material has not been disclosed in any of the documents listed in the question; the experimental designation obviously must be disclosed to those persons working on the research effort involved to date, but there is no link between the experimental designation and the chemical identity.

6. *Would disclosure of this information be likely to result in substantial harm to your competitive position? If so, you must describe specifically the alleged harmful effects and indicate why they should be considered to be substantial. Also, you must describe how disclosure of the information would cause harm.*

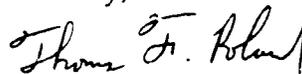
We do assert that disclosure of the chemical identity would be likely to result in substantial harm to our competitive position. The exact chemical identity is a trade secret known only to certain persons within Rohm and Haas Company having a need to know. Disclosure of the composition would enable competitors skilled in the art to recognize that the chemistry is relatively new. Substantial research effort has gone into this chemistry. Disclosure of the chemical identity would allow competitors to duplicate materials without the need for extensive research and development efforts. This would enable them to compete without incurring the invention, discovery, and research costs that Rohm and Haas has incurred, thus doing significant potential economic harm to the company.

7. *If the information in question is "health and safety data pursuant to 40 CFR Part 2.306(3)(i), do you assert that disclosure of the information would reveal: (a) confidential process information; (b) confidential portions of a mixture; or (c) information unrelated to the effects of the substance on human health and the environment? If the answer to any of the above questions is yes, you must explain how such information would be revealed?*

Disclosure of the information would not reveal confidential process information or confidential portions of a mixture. Disclosure of the confidential chemical identity would not be unrelated to the effects of the substance on human health since the data could help establish Structure-Activity Relationships; however, the generalized generic terminology used for the substance should be sufficient at this stage for the public interest.

We believe it is critical to the business interests of Rohm and Haas Company, to maintain as confidential business information the chemical identity and the experimental designation of the substance involved in this TSCA Section 8(e) submittal.

Sincerely,



Thomas F. Roland  
Regulatory Specialist  
Product Integrity Department

TFR:so

### CERTIFICATE OF AUTHENTICITY

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**END**