

(1)

8EHQ-1194-13248

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

September 29, 1994

(A)

Document Processing Center (TS-790)
Section 8(e) Coordinator
Office of Toxic Substances
US. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Contains No CBI



NOV 10 1994

Dear Sir:

RE: TSCA 8(e) Submission for A Primary Dermal Irritation Study in Rabbits for O-Benzylhydroxylamine

AlliedSignal is submitting summary information contained in a Final Report for a dermal irritation study in rabbits with O-Benzylhydroxylamine (OBHA), a research material. The study indicated that OBHA is a severe dermal irritant for an exposure at 24 hours. In addition, mortality was observed in all three test animals of the 24-hour exposure group. The corresponding LD₅₀ for this exposure group is determined to be less than 200 mg/kg.

AlliedSignal has determined this information is reportable under TSCA 8(e) as substantial risk information and is submitting the attached summary. AlliedSignal is not currently producing this material. This information is being forwarded to parties that may have conducted research & development on the material.

We do not claim confidentiality for this report.



88950000038

Very truly yours,

R. Greg Watson
Supervisor, Product Safety

Attachment: 9/19/94 Transmittal Memo for Final Report

10/13/94

DATE: September 19, 1994
TO: T.A. Gray
FROM: C.E. Finegan
SUBJECT: SUMMARY OF FINAL REPORT
O-Benzylhydroxylamine (OBHA)
TOX-0110

**A Primary Dermal Irritation Study in Rabbits with
OBHA (432-93A)
Protocol No.: 93095 September 12, 1994
TOX-0110-89-112 MA-RR-94-2093**

O-Benzylhydroxylamine (432-93A) was assessed for its potential irritant and/or corrosive effects on the skin of rabbits. A single dose of 0.5 mL of OBHA was administered to the backs of three New Zealand white rabbits for either a 3 minute (Group I), 1 hour (Group II), 4 hour (Group III) or 24 hour (Group IV) exposure period. The untreated gauze patch and 1% sodium lauryl sulfate served as the negative control and positive control, respectively.

Mortality was observed in all three of the test animals of the 24-hour exposure group (Group IV) by study day 3. One of the three Group IV test animals died prior to the conclusion of the 24-hour exposure interval and two of the three Group IV test animals died prior to the 48-hour scoring interval. All animals in the remaining Groups I - III survived. The most notable gross internal necropsy findings included dark brown, thin and watery blood, multiple dark brown/black pinpoint to 0.3 cm in diameter foci on the pyloric and/or fundic mucosa of the stomach and all internal visceral and subcutaneous tissue appearing brown.

Based on the results of this study, the Primary Dermal Irritation Indices (PDII) of OBHA (432-93A) exposed for a 3-minute, 1-hour, 4-hour and 24-hour interval were 0.0 (non-irritant), 2.2 (moderate irritant), 2.4 (moderate irritant) and 6.3 (severe irritant), respectively. The PDII for the 24-hour exposure was based on 2 of the 3 test animals' (Group IV) 1 and 24 hour scores. The PDII of the negative control groups exposed for a 3-minute, 1-hour, 4-hour and 24-hour interval were 0.0 (non-irritant) for all exposure intervals. The PDII for the positive control groups exposed for the same time intervals were 0.4 (negligible irritant), 1.8 (mild irritant), 2.3 (moderate irritant) and 7.5 (severe irritant), respectively. Based on the results of the negative and positive controls, this test was considered valid.

CEF:rl

cc: D.J. Billmaier, MD
R. Coombs
C.T. Mathews
S. O'Leary
G.A. Roy - Archives*
L.R. Taunton
Tox Staff
Library*
File: TOX-0110


CEF - 5298

*Copy of Report



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

R. Greg Watson
Supervisor, Product Safety
Allied Signal Inc.,
Health, Safety & Environmental Sciences
101 Columbia Turnpike
Morristown, New Jersey 07692-1139

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAN 12 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

13248 A



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Triage of 8(e) Submissions

Date sent to triage: APR 06 1995

NON-CAP

CAP

Submission number: 13248A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only	
entire document: <u>0</u> 1 2 pages <u>—</u>	pages <u>1,2</u>
Notes:	
Contractor reviewer: <u>LPS</u>	Date: <u>1/30/95</u>

CECATS DATA: Submission # BEHD: 1194-13248 SEQ. A
 TYPE: INT SUPP FLWP
 SUBMITTER NAME: Allied Signal Inc.

INFORMATION REQUESTED: FLWP DATE: _____
 0501 NO INFO REQUESTED
 0502 INFO REQUESTED (TECH)
 0503 INFO REQUESTED (VOL ACTIONS)
 0504 INFO REQUESTED (REPORTING RATIONALE)
 DISPOSITION:
 (0639) REFER TO CHEMICAL SCREENING
 0678 CAP NOTICE

VOLUNTARY ACTIONS:
 0401 NO ACTION REPORTED
 0402 STUDIES PLANNED/IN PROGRESS
 0403 NOTIFICATION OF WORK IN PROGRESS
 0404 LABELS/MSDS CHANGED
 0405 PROCESS/AND/OR CHANGED
 0406 AP/PAUSE DISCONTINUED
 0407 PRODUCTION DISCONTINUED
 0408 CONFIDENTIAL

SUB. DATE: 09/29/94 OTS DATE: 11/10/94 CSRAD DATE: 12/15/94

CHEMICAL NAME: O-Benzylhydroxylamine
Hydroxylamine, O-(benzylmethyl) -
 CASE: 022-33-3
11

INFORMATION TYPE:	P E C	INFORMATION TYPE:	P E C	INFORMATION TYPE:	P E C
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCUR/REL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQUEST DELAY	01 02 04	0251 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PRODCOMP/CHEM ID	01 02 04	OTHER	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04		
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0240 METAB/PHARMACO (HUMAN)	01 02 04		

TRIAOE DATA: NON-CBI INVENTORY YES YES ONGOING REVIEW YES (DROPPED) NO SPECIES RET TOXICOLOGICAL CONCERN: LOW USE: Research PRODUCTION: _____
 CAS SR NO NO (CONTINUE) MED HIGH Dev

-CPSS- 1205951500

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> <ID NUMBER>

8(E)-13248A

> <TOX CONCERN>

H

> <COMMENT>

ACUTE DERMAL TOXICITY IS HIGH CONCERN WITH AN ESTIMATED LD50 OF < 200 MG/KG.

PRIMARY IRRITATION IN RABBITS IS OF HIGH CONCERN. APPLICATION OF 0.5 ML TO THE BACKS OF 4 GROUPS OF 3 EACH NEW ZEALAND WHITE RABBITS FOR PERIODS OF 3 MINUTES, 1 HOUR, 4 HOURS OR 24 HOURS WAS ASSOCIATED WITH DEATH OF ALL 3 ANIMALS OF THE 24-HOUR EXPOSURE GROUP. ONE ANIMAL DIED DURING THE 24-HOUR EXPOSURE PERIOD AND TWO DIED PRIOR TO 48-HOUR OBSERVATION. INTERNAL VISCERAL AND SUBCUTANEOUS TISSUE APPEARED BROWN UPON NECROPSY, BLOOD WAS DARK BROWN, THIN AND WATERY AND MULTIPLE DARK BROWN TO BLACK FOCI UP TO 0.3 CM WERE NOTED ON THE PYLORIC AND/OR FUNDIC MUCOSA OF THE STOMACH. ALL OTHER ANIMALS SURVIVED EXPOSURES OF LESSER DURATION. THE PRIMARY DERMAL INDEX ASSIGNED THE 24-HOUR EXPOSURE GROUP WAS 6.3 (SEVERE IRRITANT) BASED ON SCORES DETERMINED AT HOURS 1 AND 24 FOR TWO OF THREE ANIMALS PRIOR TO THEIR DEATH. ONE-HOUR AND 4- HOUR EXPOSURE GROUPS WERE ASSIGNED INDICES OF 2.2 AND 2.4 (MODERATE IRRITANTS) RESPECTIVELY. SODIUM LAURYL SULFATE, THE POSITIVE CONTROL, IS OF HIGH CONCERN RELATIVE TO PRIMARY IRRITATION IN RABBITS. PARALLEL PROTOCOL USING 1% SOLUTION IN NEW ZEALAND WHITE RABBITS WAS ASSOCIATED WITH PRIMARY DERMAL INDICES UP TO 7.5 (SEVERE IRRITANT) FOR A 24-HOUR EXPOSURE.

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