

Contains No CBI

①



RHÔNE-POULENC INC.

CN 7500, CRANBURY, NJ 08512-7500
TELEPHONE: (609) 395-8300

Ⓐ

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

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance
Audit Program

CAP ID NO.: 8ECAP - 0004

RP CAP REPORT NO.: RPS - 0216

Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc. (RPI, CN5266, Princeton, NJ 08543-5266) and its subsidiaries, the attached report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA (8ECAP - 0004).

The enclosed report provides information on the following chemical substance:

Product Name: Anatrox BL-225
CAS Registry No: 68603-25-8
CAS Registry Name: Alcohols, C8-10, ethoxylated

RECEIVED
2/7/95

2

The title of the enclosed report is:

Primary Ocular Irritation in Rabbits

The following is a summary of the adverse effects observed in this report.

The test material was classified as a severe ocular irritant. Limited evidence of reversibility was seen. Fibrovascular connective tissue was observed in three rabbits at Day 7.

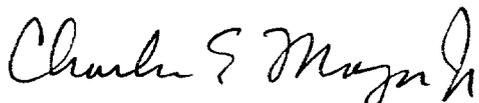
RPI does not claim any portion of the information in this submission to be TSCA confidential business information (TSCA CBI).

RPI has not previously submitted any TSCA Section 8(e) notices or premanufacture notification on the subject chemical substance.

In total, RPI is submitting three copies of the enclosed report and this cover letter: an original and two copies.

Further questions regarding this submission may be directed to Dr. Glenn S. Simon, Director of Toxicology at (919)549-2222 (Rhône-Poulenc, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709).

Sincerely,



Charles E. Moyer, Jr., Ph.D.
Director, Product Safety
(609)860-3589

CEMjr/mm
Enclosures



Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

F I N A L R E P O R T

CLIENT: GAF Corporation
1361 Alps Road
Wayne, New Jersey 07470

ATTENTION: L.W. Burnette, Ph.D. Senior Administrator
Regulated Products, Materials Safety
Department

TEST: Primary Ocular Irritation in Rabbits

TEST
ARTICLE: Antarox BL-225

EXPERIMENT
REFERENCE NO,: 81306-4



Steven Nitka, B.S.
Study Director

CAP ID No. S-CR-BKH-0192
Reviewed for Sec. 8 (e)
Compliance Program
On 3/23/93 By B. J. Horne



Allen L. Palanker
President

Date September 16, 1981
SN/tmc/lp

This report details:

a primary ocular irritation study in albino rabbits,

performed at the behest of:

GAF Corporation
1361 Alps Road
Wayne, New Jersey 07470

The test article(s), supplied by:

GAF Corporation

received on:

August 20, 1981

and identified as:

Antarox BL-225

was used as indicated in the Final Report Summaries.

Study Interval: September 8, 1981 to September 15, 1981

(201) 575-7688
(201) 575-7689



Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B

1275 Bloomfield Avenue • Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

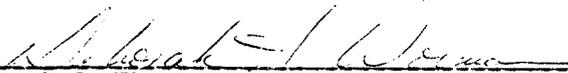
Study No.: 81306-4

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: August 28, 1981 September 9, 1981
 September 3, 1981 September 16, 1981
 September 21, 1981

Professional personnel involved: Steven Nitka, B.S. - Study Director
 Janet K. Johnson, B.S. - Laboratory Supervisor
 Ellen Lally, B.A. - Technician
 Pam Emerson - Technician Assistant

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.



Deborah A. Worman
Director of Quality Assurance

(201) 575-7688
(201) 575-7689



Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue • Fairfield, New Jersey 07006

Final Report Summary

DATE: September 16, 1981
CLIENT: GAF Corporation
STUDY NO.: 81306-4
REFERENCE: L.W. Burnette, Ph.D.
TEST ARTICLE: Antarox BL-225

Primary Ocular Irritation in Rabbits

Method: Six (6) New Zealand white rabbits, free from visible ocular defects, each received a single intraocular application of 0.1 milliliter of the test article in one eye. The contralateral eye, remaining untreated, served as a control. The eyes of all animals remained unwashed for 24 hours. Observations of corneal opacity, iritis, and conjunctivitis were recorded 24, 48, and 72 hours after treatment, and at 4 and 7 days if irritation persisted. The test article was used as received.

<u>Group</u>	-----Draize Scores-----				
	<u>Hours</u>			<u>Days</u>	
	<u>24</u>	<u>48</u>	<u>72</u>	<u>4</u>	<u>7</u>
Unwashed	33.3	33.5	37.7	34.2	29.0

This test article is a severe ocular irritant to rabbits under conditions of this test.

Primary Ocular Irritation in Rabbits

This test was designed to determine the ocular irritation potential of substances in rabbits. The procedure followed was a modification of that described by J.H. Draize.¹

In the technique of determining toxicity of substances to ocular mucosa, observation of injuries was made on the cornea, iris, and the bulbar and palpebral conjunctivae. Numerical scores were assigned to lesions observed according to the Draize scale. (Refer to appended table.) In this system of scoring, the injuries to the cornea and iris account for approximately 80% of the score; these structures are purposely weighted because of their vital role in vision. The presence of lesions not described in the Draize scale was also noted.

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, were obtained through a suitably licensed dealer. The animals were checked carefully upon receipt for ocular defects, diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition. Any animal exhibiting visible ocular defects or irritation, or poor condition, was not used in this test.

Animals were acclimated for at least 3 days prior to test initiation. They were housed in galvanized or stainless steel cages and identified through individual markings on the outer ear of each animal, as well as a cage label. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum.

Immediately prior to test initiation, the animals were placed in wooden restrainers. A dose of one-tenth (0.1) of a milliliter of the test article was placed in one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test article was dropped. The eyelids were gently held together for 1 second. The contralateral eye, remaining untreated, served as a control. If any of the test article remained in the eye at 24 hours, the eye was washed out with lukewarm water after the 24 hour reading.

Observations of ocular irritation were recorded 24, 48, and 72 hours following instillation of the test article. Additional readings were made at 4 and 7 days after application if irritation persisted.

An animal was considered as exhibiting a positive reaction if the test article produced any of the following: ulceration of the cornea other than a fine stippling, opacity of the cornea other than a slight dulling of the normal luster, inflammation of the iris other than a slight deepening of the folds or slight circumcorneal injection of the blood vessels, obvious conjunctival swelling with partial eversion of the lids or a diffuse crimson-red with individual vessels not discernible.

If two (2) or more animals exhibited a positive reaction, the test article was considered an ocular irritant (unless the test was repeated with another six (6) animals without positive reactions).

¹J.H.Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), pp. 49-51.

Primary Ocular Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Summaries of all results are found preceding the text.

Table 1
 Eye Irritation Test
 Scale of Weighted Scores for
 Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Cornea	<u>Opacity (A)</u>	
	Opacity - degree of density (area which is dense is taken for reading)	
	Scattered or diffuse area, details of iris clearly visible.	1
	Easily discernible translucent areas, details of iris slightly obscured.	2
	Opalescent areas, no details of iris visible, size of pupil barely discernible.	3
	Opaque, iris invisible.	4
	<u>Area of Cornea Involved (B)</u>	
	One-quarter (or less), but not zero.	1
	Greater than one-quarter, but less than one-half.	2
	Greater than one-half, but less than three-quarters.	3
Greater than three-quarters, up to whole area.	4	
	Score equals A x B x 5	Total maximum = 80
Iris	<u>Values (A)</u>	
	Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combinations of any thereof), iris still reacting to light.	
	Sluggish reaction is positive.	1
	No reaction to light hemorrhage, gross destruction, (any or all of these).	2
		Score equals A x 5

Table 1 (cont'd.)
 Eye Irritation Test
 Scale of Weighted Scores for
 Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Conjunctivae	<u>Redness (A)</u>	
	Redness (refers to palpebral conjunctivae only). Vessels definitely injected above normal.	1
	More diffuse, crimson red, individual vessels not easily discernible.	2
	Diffuse beefy red.	3
	<u>Chemosis (B)</u>	
	Any swelling above normal (includes nictitating membrane).	1
	Obvious swelling with partial eversion of the lids.	2
	Swelling with lids about half-closed.	3
	Swelling with lids about half-closed to completely closed.	4
	<u>Discharge (C)</u>	
	Any amount different from normal (does not include small amount observed in inner canthus of normal animals).	1
	Discharge with moistening of the lids and hairs just adjacent to the lids.	2
Discharge with moistening of the lids and hairs and considerable area around eye.	3	

Score equals (A + B + C) x 2

Total maximum = 20

Note: The maximum total score is the sum of all scores obtained for the cornea, iris and conjunctivae.

Table 1
(continued)

Scoring Criteria for Eye Reaction - Addendum

Notation	Condition
B	Blanching
BD	Bloody discharge
CE	Corneal Edema
En	Encroachment of Sclera
FVCN	Fibrovascular connective tissue
H	Hair loss around eye
Hm	Hematoma
M	Nodular Mass Subjacent to Meibomian Gland
N	Necrosis
TAC	Test Article Adhering to conjunctivae

Table 2

Eye Irritation
 Relative Classification of Test Articles
 Based on Grading of Irritation

Rating	Range	Definition
Non-irritating	0.0 - 0.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Practically non-irritating	0.5 - 2.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Minimally irritating	2.5 - 15.0	To maintain this rating, all scores at the 72 hour reading must be zero; otherwise, increase rating one level.
Mildly irritating	15.0 - 25.0	To maintain this rating, all scores at the 7 day reading must be zero; otherwise, increase rating one level.
Moderately irritating	25.0 - 50.0	To maintain this rating, scores at 7 days must be less than 10 for 3 or more of the animals and mean 7 day scores must be less than 25, otherwise, raise rating one level.
Severely irritating	50.0 - 80.0	To maintain this rating, scores at 7 days must be less than 30 for 3 or more of the animals and mean 7 day score must be less than 45, otherwise, raise rating one level.
Extremely irritating	80.0 - 110.0	

STUDY: 81306-4
 CLIENT: GAF CORPORATION
 DATE: 9/08/81

TABLE 3

PRIMARY EYE IRRITATION-RABBITS
 SUMMARY OF EYE IRRITATION

ANTAROX BL-225

L EYE

RABBIT NUMBER	DAY	CORNEA: AxBx5(ST1)+		IRIS: Ax5(ST2)+		CONJUNCTIVAE: (A+B+C)x2(ST3)=		T SC
UNWASHED								
19	1	1	4	20	1	5	2 2 1	10 En
	2	1	2	10	1	5	2 1 1	8 En
	3	1	2	10	1	5	2 1 1	8 En
	4	1	2	10	1	5	1 1 1	6 En
	7	0	0	0	0	0	1 0 0	2
20	1	1	3	15	1	5	1 3 1	10
	2	1	2	10	1	5	1 2 0	6
	3	1	2	10	1	5	1 1 0	4 En
	4	1	2	10	1	5	1 2 1	8
	7	1	1	5	1	5	1 0 0	2
21	1	1	1	5	1	5	2 2 1	10 En
	2	1	4	20	1	5	1 1 0	4 En
	3	1	4	20	1	5	1 1 0	4 En
	4	1	4	20	1	5	1 1 0	4 En
	7	4	1	20 FVCN	0	0	1 0 0	2 En
22	1	2	4	40	1	5	2 3 1	12
	2	3	3	45	1	5	2 1 1	8
	3	3	4	60	1	5	2 3 1	12
	4	3	4	60	1	5	2 2 0	8 En
	7	4	3	60 FVCN	1	5	1 0 0	2 En
23	1	1	4	20	1	5	2 2 1	10
	2	1	4	20	1	5	2 2 1	10
	3	2	3	30	1	5	2 1 1	8 En
	4	1	3	15	1	5	1 1 0	4 En
	7	4	3	60 FVCN	1	5	1 1 0	4 En
24	1	2	1	10	1	5	2 2 0	8
	2	1	4	20	1	5	2 2 1	10
	3	1	4	20	1	5	2 2 1	10
	4	1	4	20	1	5	2 2 1	10 En

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110

STUDY: 81306-4
CLIENT: GAF CORPORATION
DATE: 9/08/81

TABLE 3
(CONTINUED)
PRIMARY EYE IRRITATION-RABBITS
SUMMARY OF EYE IRRITATION

ANTAROX BL-225

L EYE

RABBIT NUMBER	DAY	CORNEA: AxBx5(ST1)+		IRIS: Ax5(ST2)+		CONJUNCTIVAE: (A+B+C)x2(ST3)=		T	SC
		UNWASHED							
	7	0	0	0	0	0	1 0 0	2	En
AVERAGE	1								
	2								
	3								
	4								
	7								

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110



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

Charles E. Moyer, Jr., Ph.D.
Director, Product Safety
Rhône-Poulenc Inc.
CN 7500
Cranberry, New Jersey 08512-7500

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 18 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., SEHQ-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

12082A



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contains at least 50% recycled fiber

Triage of 8(e) Submissions

Date sent to triage: AUG 24 1985

NON-CAP

CAP

Submission number: 12082A

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

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Contractor reviewer:	<u>UPS</u>	Date:	<u>3/10/95</u>		

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHO 1092-12082 SEQ A

TYPE: INT SUPP FLWP

SUBMITTER NAME: Rhone-Poulenc Inc.

INFORMATION REQUESTED: FLWP DATE:

- 0501 NO INFO REQUESTED
- 0502 INFO REQUESTED (TECH)
- 0503 INFO REQUESTED (VOL ACTIONS)
- 0504 INFO REQUESTED (REPORTING RATIONALE)
- DISPOSITION: REFER TO CHEMICAL SCREENING
- 0678 CAP NOTICE

0601 NO ACTION REPRINTED

- 0402 STUDIES PLANNED/IN PROGRESS
- 0403 NOTIFICATION OF WORK RESUMED
- 0404 LABEL/MSDS CHANGES
- 0405 PROCESS/PLANNING CHANGES
- 0406 APP USE DISCONTINUED
- 0407 PRODUCTION DISCONTINUED
- 0408 CONFIDENTIAL

SUB DATE: 10/16/92 OTS DATE: 10/31/92 CSRAD DATE: 02/05/95

CHEMICAL NAME:

Anatrox BL-225

CAS#

68603-25-8

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPICTIN	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. OCCUREL/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	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04	MSDS	01 02 04
0210 ACUTE TOX (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	OTHER	01 02 04
0211 CHR. TOX (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0213 ACUTE TOX (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0214 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (ANIMAL)	01 02 04		
		0240 METAB/PHARMACO (HUMAN)	01 02 04		

TRIAGE DATA: NON-CBI INVENTORY

YES

ONGOING REVIEW

YES (DROP/REFER)

SPECIES

RAT

TOXICOLOGICAL CONCERN:

LOW

CAS SR NO

NO (CONTINUE)

IN TMMINI

REFER

MED

HIGH

USE:

PRODUCTION:

UNCLASSIFIED

-CPSS-

> <ID NUMBER>
8(E)-12082A

> <TOX CONCERN>
H

> <COMMENT>
EYE IRRITATION IN NEW ZEALAND WHITE RABBITS IS OF HIGH CONCERN.
SINGLE 0.1 ML INTRAOCULAR INSTILLATION (UNWASHED 24 HOURS) INTO ONE
EYE EACH OF 6 NEW ZEALAND WHITE RABBITS WAS ASSOCIATED WITH SIGNS
OF IRRITATION INCLUDING CORNEAL OPACITY, IRITIS AND CONJUNCTIVITIS
COMPRISING A 24-HOUR MEAN DRAIZE SCORE OF 33.3. OCULAR DAMAGE
PERSISTED TO 72 HOURS (MEAN DRAIZE SCORE = 37.7) AND 7-DAY
INSPECTION (MEAN DRAIZE SCORE = 29.0).

\$\$\$\$