CONTAINS NO CB

RHÔNE-POULENC

RHÔNE-POULENC INC.

CN 5266, PRINCETON, NJ 08543-5266
TELEPHONE: (908) 297-0100 TELEX: 211056

May 15, 1992

8EHQ-0592-4259 init

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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 - 0101

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 reports provide information on the following chemical substance:

Product Name:	Sipon LSB (Now called Rhodapon LSB)	
Identity:	Sodium lauryl sulfate	29%
	Water/inerts	71%

CAS Registry No: 151-21-3

CAS Registry Name: Sulfuric acid monododecyl ester sodium salt

The titles of the enclosed reports are:

DOT Skin Corrosion and DOT Skin Corrosion in Rabbits

The following is a summary of the adverse effects observed in these reports.

Both studies found the test material to be corrosive at 48 hours. pH = 7.5 to 8.5 of 10% solution

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

RPI has submitted an Eye Irritation Study on this material under the CAP Agreement; see RP CAP Report Nos. RPS-0100.

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 each of the enclosed reports 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

product safety labs
a division of nutrition international inc
340 Commercial Avenue
New Brunswick, N.J. 08901
201-545-1704

DOT SKIN CORROSION

July 13, 1980

REPORT NO.:	T-930
DATE OF TEST:	July 7, 1980
CLIENT:	Mr. George W. Panzer ALCOLAC INC. 3440 Fairfield Road Baltimore, Maryland 21226
PRODUCT IDENTIFICATION:	SIPON LSB, Sodium Lauryl Sulfate 28.2% active, Lot A222A0
PRODUCT DESCRIPTION:	A yellow viscous liquid.
PSL NO.:	E00610-4
DATE RECEIVED:	June 10, 1980
ANIMALS:	Six New Zealand Albino Rabbits (Skippack Farms, Skippack, Pa.)
DIET:	Fisher Rabbit Pellets
QUALITY ASSURANCE REFERENCE:	Q.A. 1, 2, 3
NOTEBOOK NO.:	80-1; page 467

ENVIRONMENTAL CONDITIONS:

During the test period the animals were housed in individual stainless steel wire bottomed cages in an environmentally controlled room. The temperature was kept at 68° - 72°F at a relative humidity of 45 - 55%. They were exposed to 12 hours of flourescent light (8 A.M. - 8 P.M.) and 12 hours of darkness (8 P.M. - 8 A.M.) daily. The animals were housed 1 per cage. Feed and water were provided ad-libitum after dosing.

PROCEDURE:

DOT Skin Corrosion, Department of Transportation CFR Title 49, 173, 1200. Six healthy rabbits were each uniquely identified and then prepared by clipping the trunk free of hair. A 2.5 cm^2 gauze was placed over intact skin on each rabbit. 1.0ml of the test material was placed under each patch. The patches were secured in place with adhesive tape. The entire trunk of each animal was wrapped with a rubberized elastic cloth to retard evaporation (in the case of volatile substances) and as an aid in maintaining test patch position. The rabbits were then immobilized in head stocks for 4 hours after which time the patches were removed. All test sites were washed to prevent further exposure. Corrosion readings were made at 4 hours and 48 hours after exposure. Corrosion was considered to have resulted if the test substance caused destruction or irreversible alteration of the tissue. Tissue destruction was considered to have occurred if, at any of the readings, there was ulceration or necrosis. Epidermal sloughing, erythema, edema or fissuring were not considered tissue destruction.

CAP ID No. 3C12-38K-0520
Reviewed for Sec. 8 (e)
Compliance Program
On 9/17/81 By 38K

SUMMARY OF RESULTS:

OBSERVATIONS: Not remarkable.

CONCLUSION: The test material is a corrosive agent.

Anthony J. Nerlangieri, Ph.D.
Study Supervisor
Toxicologist

Ralph Shapiro, Ph.D.
Director

Arlene Stern
Quality Assurance Unit

Date Jul. 15, 1980

RESULTS:

Animal No.	Corrosion	
	4 hours	48 hours
1313	Negative	Positive
1314	Negative	Positive
1315	Negative	Positive
1316	Negative	Positive
1317	Negative	Positive
1318	Negative	Positive

Consumer Product Testing
Company Incorporated

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

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

FINAL REPORT

CLIENT:	Alcolac Inc. 3440 Fairfield Road Baltimore, Maryland 21226
ATTENTION:	Louis J. Nehmsmann, Ph.D. Manager - Surfactant Research
TEST:	D.O.T. Skin Corrosion in Rabbits
TEST ARTICLE:	SIPON LSB Control No. A-972-P2
EXPERIMENT REFERENCE NO.:	82383-1

Steven Nitka
Laboratory Director

Allen L. Palanker
President

CAP ID No. SCR-BAK-051
Reviewed for Sec. 8 (e)
Compliance Program
On 9/17/91 By BAK

Date November 3, 1982
SN/daw

This report is submitted for the exclusive use of the person, partnership, or corporation to whom it is addressed, and neither the report nor the name of these Laboratories nor of any member of its staff, may be used in connection with the advertising or sale of any product or process without written authorization.

This report details:

a D.O.T. skin corrosion study in albino rabbits,

performed at the behest of:

Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac Inc.

received on:

October 13, 1982

and identified as:

SIPON LSB
Control No. A-972-P2

was used as indicated in the Final Report Summaries.

Study Interval: October 19, 1982 to October 27, 1982

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Consumer Product Testing
Company Incorporated

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

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 82383 - 1

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: October 20, 1982
November 4, 1982

Professional personnel involved:

Steven Nitka, B.S.	- Laboratory Director (Study Director)
Sheila Johnson, B.S.	- Laboratory Supervisor
Pamela Spooner, B.A.	- Technician
Leslie Stanton, A.A.S.	- Technician
Deborah A. Worman	- Office Manager

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.

Barbara A. Adamczyk, B.S.
Director of Quality Assurance

(201) 575-7688
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Consumer Product Testing
Company Incorporated

Bldg. No. 2-15B
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Final Report Summary

DATE: November 3, 1982
CLIENT: Alcolac Inc.
STUDY NO.: 82383 - 1
REFERENCE: L.J. Nehmsmann, Ph.D.
TEST ARTICLE: SIPON LSB
Control No. A-972-P2

D.O.T. Skin Corrosion in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on one intact test site. The test site was occluded for 4 hours, and was observed for erythema, edema, and other effects 4 and 48 hours and 7 days after application. The test article was used as received.

Observations: Crust formation on all sites by day seven.

Under 49CFR:173.1200 Appendix A, and conditions of this test, this test article is corrosive to rabbit skin.

D.O.T. Skin Corrosion in Rabbits

This test was designed to determine if a product is corrosive to rabbit skin under 49 CFR:173.1200 Appendix A.

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were used for each test article. Animals were obtained through a suitably licensed dealer, and were carefully checked upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, skin lesions, and general condition.

Animals were acclimated for 4 days prior to test initiation. They were housed in galvanized 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.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animal in poor condition, particularly animals with skin lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Just prior to test initiation, the animals were placed in wooden restrainers. One test site, 2.5 centimeters square, was chosen on either side of the vertebral column. A single application of 0.5 milliliter of the test article, was introduced to the test site under a 2.5 cm^2 surgical gauze pad. The patch was then secured in place with adhesive tape, and the entire trunk of each animal encased in an impermeable wrapping, also secured with adhesive tape. The wrap aided in maintaining the test article and patch in position and prevented the evaporation of possible volatile components of the test article. The animals were fitted with plastic collars to prevent disturbance of the test site and returned to their cages.

The wrapping and test article were removed 4 hours following application. Each test site was individually examined and scored for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted. Following the 4 hour reading, the test sites were gently wiped to remove any remaining test article. Readings were made again at 48 hours after application, and at 7 days to evaluate the irreversibility of irritation earlier observed.

If at any readings, there was ulceration or necrosis, irreversible tissue destruction was considered to have occured. This does not include sloughing of the epidermis (hyperkeratosis), erythema, edema or fissuring.

The test article was considered corrosive if tissue destruction, as described above occurred on any test site.

D.O.T. Skin Corrosion in Rabbits

The scoring scale used is presented in Table 1. Individual results are presented in Table 2.

Summaries of all results are found preceding the text.

Table I

Scoring Criteria for Skin Reactions

Erythema Formation	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Total possible erythema score = 4	
Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4
Total possible edema score = 4	
Total possible primary irritation score = 8	

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
Bu	Bulla	A vesicle greater than 1 cm in diameter.
C	Crust	Scab. Dried exudate on the surface of a lesion.
D	Dry	Skin feels dry to the touch (dehydrated).
Dy	Dye	Dye from the test article remains after excess removed. (Noted because it may cause difficulty in scoring.)
F	Fissure	A linear cleavage into the epidermis, or through epidermis into dermis. May be single or multiple tiny cracks, or large clefts.
P	Pustule	Small circumscribed elevation of skin filled with pus, usually yellow.
R	Red ring	Red ring formed around test site where blanching and possible necrosis/irreversible damage observed at 24 and/or 72 hours. Ring forms between 5 to 7 days, indicative of irreversible damage.
	Scab	See crust.
S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
Sc	Scar	An area of fibrous tissue that has replaced damaged dermis or subcutaneous tissues. Found after a crust has sloughed off. Usually does not develop with 72 hours.
U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

CONSUMER PRODUCT TESTING CO., INC.

STUDY: 82393-1
CLIENT: ALCOLAC INC.
DATE: 10/19/82

TABLE 2

D.O.T. SKIN CORROSION-RABBITS
SUMMARY OF SCORES FOR SKIN IRRITATION

SIPON LSB
CONTROL NO. A-972-P2

0.5 ML NEAT

RABBIT NUMBER	DAY	SITE 1 I ER	ED	
1	4 HR	2	4	S
	48 HR	4	4	Dy,B
	7	4	4	C
2	4 HR	2	2	
	48 HR	4	4	Dy,B
	7	4	4	C,S
3	4 HR	3	3	B
	48 HR	4	4	D,B,F
	7	4	4	C,U
4	4 HR	2	3	
	48 HR	3	4	D,B
	7	4	4	C,S
5	4 HR	2	2	B
	48 HR	3	4	D,B
	7	4	4	C
6	4 HR	2	2	
	48 HR	2	4	D,F
	7	4	4	C

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

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