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July 22, 2010

TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
Phone: (202)564-8940

RE: 1-Dodecanethiol (CAS# 112-55-0) – Acute Dermal Irritation in Rabbits

Dear Section 8(e) Coordinator,

Chevron Phillips Chemical Company LP (CPChem) submits the attached study report in accordance with the requirements under Section 8(e) of the Toxic Substances Control Act.

Both a Confidential and a Sanitized copies are provided. Redacting does not include chemical identity information.

You may contact me in case there are any questions.

Sincerely yours,

Fred Marashi

88100000379

8EHQ-0710-18054A
DCN:88100000379s



8EHQ-10-18054

Company Sanitized



Safety & Health Research Laboratories

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SPONSOR

Chevron Phillips Chemical Company LP
10001 Six Pines Dr. Suite 4106
The Woodlands, TX 77380
USA
&

TEST ITEM

n-Dodecyl mercaptan
(CAS No. 112-55-0)

STUDY TITLE

ACUTE DERMAL IRRITATION
IN RABBITS

STUDY DIRECTOR

DATE OF ISSUE

20 July 2010

TEST FACILITY

CIT
BP 563 - 27005 Evreux - France

LABORATORY STUDY NUMBER

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CIT
SAS au capital de 2 030 000 €
783 060 465 RCS Evreux
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Agence Crédit Impôt Recherche

SANITIZED COPY**CONTENTS**

GLP COMPLIANCE STATEMENT OF THE STUDY DIRECTOR	3
SCIENTIST INVOLVED IN THE STUDY	4
STATEMENT OF QUALITY ASSURANCE UNIT	5
SUMMARY	6
1. INTRODUCTION	8
2. MATERIALS AND METHODS	8
2.1 TEST ITEM	8
2.1.1 Identification	8
2.1.2 Dosage form preparation	8
2.2 TEST SYSTEM	9
2.2.1 Animals	9
2.2.2 Environmental conditions	9
2.2.3 Food and water	9
2.3 TREATMENT	10
2.3.1 Preparation and selection of the animals	10
2.3.2 Application of the test item	10
2.4 CUTANEOUS EXAMINATIONS	10
2.4.1 Duration of the observation period	10
2.4.2 Description and evaluation of cutaneous reactions	10
2.5 BODY WEIGHT	11
2.6 SACRIFICE	11
2.7 INTERPRETATION OF RESULTS	11
2.8 ARCHIVING	11
2.9 CHRONOLOGY OF THE STUDY	12
2.10 STUDY PLAN ADHERENCE	12
3. RESULTS	13
4. CONCLUSION	13
Table 1. 3-minute exposure - Cutaneous examinations and mean values of the scores recorded for the first animal (24, 48 and 72 hours)	14
Table 2. 1-hour exposure - Cutaneous examinations and mean values of the scores recorded for the first animal (24, 48 and 72 hours)	15
Table 3. 4-hour exposure - Individual cutaneous examinations and mean values of the scores recorded for each animal (24, 48 and 72 hours)	16
Table 4. Individual body weight (g)	18
APPENDICES	19
1. Test article description and analysis certificate	20
2. Diet formula	23
3. CIT GLP certificate	25
4. Study Specific Supplement and CIT General Study plan	27 to 42

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GLP COMPLIANCE STATEMENT OF THE STUDY DIRECTOR

The study was performed in compliance with CIT's standard operating procedures and the following principles of Good Laboratory Practice:

- . OECD Principles of Good Laboratory Practice (as revised in 1997), ENV/MC/CHEM (98) 17 and all subsequent OECD consensus documents,
- . Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the Principles of Good Laboratory Practice and the verification of their applications for tests on chemical substances (OJ No. L50 of 20.2.2004),
- . Décret n° 2006-1523 du 04 décembre 2006 concernant les Bonnes Pratiques de Laboratoire (Journal Officiel du 06 décembre 2006), Ministère de l'Economie, des Finances et de l'Industrie.

The study was also conducted in compliance with the following Animal Protection regulations:

- . Council Directive 86/609/EEC of 24th November 1986 on the harmonization of laws, regulations or administrative provisions relating to the protection of animals used for experimental or other scientific purposes.

I declare that this report constitutes a true and faithful record of the procedures undertaken and the results obtained during the performance of the study.

This study was performed at CIT, BP 563, 27005 Evreux, France.

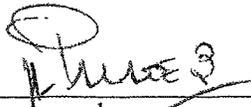
Study Director
Master of Toxicology

Study completion date: 19 July 2010

SCIENTIST INVOLVED IN THE STUDY

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CIT Management


A. Simonnard Bernard Palate
Date: 19 July 2010
Doctor of Pharmacy, Ph.D. in Toxicology
Director of Toxicology and Operations

STATEMENT OF QUALITY ASSURANCE UNIT

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Inspections performed at CIT

The CIT Quality Assurance Unit conducted the inspections detailed below:

Type of inspection	Dates		
	Inspection	Reported to the Study Director	Reported to Management
Study plan	23 December 2009	23 December 2009	24 December 2009
Report	25 March 2010	25 March 2010	26 March 2010
Final check of first audited draft report	12 May 2010	12 May 2010	14 May 2010
Final check of report	13 July 2010	13 July 2010	16 July 2010

In addition, study-based inspections were carried out by the Quality Assurance Unit on similar studies performed during the same period, as detailed below:

Type of inspection	Dates		
	Inspection	Reported to the Study Director	Reported to Management
Dosage forms preparation	19 January 2010	19 January 2010	22 January 2010

The inspections were performed in compliance with CIT Quality Assurance Unit procedures and the principles of Good Laboratory Practices.

The final report is considered to constitute an accurate and complete reflection of the study raw data.


Anne LABARRE
 CIT Quality Assurance Unit

Date: 20 JUL, 2010

SUMMARY

At the request of Chevron Phillips Chemical Company LP, The Woodlands, TX, USA & Arkema France, Colombes, France, the potential of the test item n-Dodecyl mercaptan (batch No. 9500NDM09, purity 99.0%) to induce skin irritation was evaluated in rabbits according to OECD (No. 404, 24th April 2002) and Commission Regulation (EC) (No. 440/2008, B.4, 30 May 2008) guidelines.

The study was conducted in compliance with the principles of Good Laboratory Practice Regulations.

Methods

The test item was first applied for periods of 3 minutes, 1 hour and 4 hours to a single male New Zealand White rabbit. Since the test item was severely irritant but not corrosive on this first animal, it was then applied for 4 hours to another single animal. As the test item showed corrosive properties on this second animal, the study was considered complete and the test item was not evaluated on a third animal.

A single dose of 0.5 mL of the undiluted test item was applied to the closely-clipped skin of one flank. The test item was held in contact with the skin by means of a semi-occlusive dressing.

Cutaneous reactions were observed approximately 1 hour, 24, 48 and 72 hours after removal of the dressing and then daily until the end of the observation period.

The mean values of the scores for erythema and edema were calculated for each animal.

Results

After a 3-minute exposure (one animal)

A very slight to severe erythema was observed all over the observation period. A slight or moderate edema was noted from day 5 until the end of the observation period (day 15). A brownish area was noted from day 5 until day 13. Dryness of the skin was recorded from day 6 until day 15.

After a 1-hour exposure (one animal)

A well-defined to severe erythema was observed all over the observation period. A slight or moderate edema was noted from day 5 until the end of the observation period (day 15). A brownish area was noted from day 7 until day 13 following by scabs (not further described) on days 14 and 15. Dryness of the skin was recorded from day 6 until day 15.

After a 4-hour exposure (two animals)

First animal

A well-defined or moderate erythema was observed all over the observation period. A brownish area was noted from day 10 until day 13. Dryness of the skin was recorded from day 9 until the end of the observation period (day 15).

Second animal

A well-defined to severe erythema and a very slight to severe edema were noted from day 1 until day 8. Brownish area, related to a tissular necrosis and tissue burn on days 7 and 8, was noted from day 5 until day 8, associated with dryness of the skin from day 6 until day 8. According to the severe cutaneous reactions observed, the animal was sacrificed on day 8 for ethical reasons. The study was therefore considered complete and no other animal was tested.

Mean scores over 24, 48 and 72 hours for each animal were 2.3 and 3.0 for erythema and 0.0 and 1.0 for edema.

Conclusion

Under the experimental conditions of this study, the test item n-Dodecyl mercaptan was corrosive when applied topically to rabbits.

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1. INTRODUCTION

The objective of this study was to evaluate the potential of the test item n-Dodecyl mercaptan to induce skin irritation following a single topical application to rabbits.

In the assessment of the toxic characteristics of a test item, determination of the irritant and/or corrosive effects on the skin of mammals is an important initial step. Information derived from this test serves to indicate the possible hazards likely to arise from exposure of the skin to the test item.

This study was conducted in compliance with:

- . OECD guideline No. 404, 24th April 2002,
- . Commission Regulation (EC) No. 440/2008, B.4, 30 May 2008.

2. MATERIALS AND METHODS

2.1 TEST ITEM

2.1.1 Identification

- . Supplier : Arkema Inc - Houston
- . Name : n-Dodecyl mercaptan
- . Other names : n-Dodecylmercaptan, 1-Dodecanethiol,
NORMAL DODECYL MERCAPTAN

All names refer to the same test item.

- . CAS No. : 112-55-0
- . Batch number
- . - on labeling : none
- . - on the test article description
and analytical certificate : 9500NDM09
- . Description : colorless liquid
- . Container : one glass flask
- . Date of receipt : 02 December 2009
- . Storage conditions : at room temperature
- . Purity : 99.0%
- . Expiry date : November 2010.

Data relating to the characterization of the test item are documented in a test article description and an analysis certificate (presented in Appendix 1) provided by the Sponsor.

The batch number, which was absent from the label of the container but specified on the analytical certificate, was confirmed by the Sponsor in a statement dated 05 July 2010 (archived with the study files).

2.1.2 Dosage form preparation

The test item was used undiluted

The pH of the undiluted test item, measured at CIT using pH paper, was approximately 5.

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2.2 TEST SYSTEM

2.2.1 Animals

Sex, species, strain: male KBL New Zealand White rabbits.

Reason for this choice: species generally accepted by regulatory authorities for this type of study.

Breeder: Charles River Laboratories (Châtillon-sur-Chalaronne, France).

Number: two animals.

Age/weight: on the day of treatment, the animals were 5 to 6 months old and had a mean body weight \pm standard deviation of 3.554 ± 0.090 kg.

Acclimation: at least 5 days before the beginning of the study.

Identification: individual metal ear tag.

2.2.2 Environmental conditions

The conditions in the animal room were set as follows:

- . temperature : $18 \pm 3^{\circ}\text{C}$,
- . relative humidity : 30 to 70%,
- . light/dark cycle : 12 h/12 h (7:00 - 19:00),
- . ventilation : approximately 12 cycles/hour of filtered, non-recycled air.

The temperature and relative humidity were under continuous control and recording. The records were checked daily and filed. In addition to these daily checks, the housing conditions and corresponding instrumentation and equipment were verified and calibrated at regular intervals.

The animals were housed individually in Pajon cages (50 cm x 57 cm x 75 cm).

Each cage was equipped with a food container and a water bottle.

2.2.3 Food and water

During the study, the animals had free access to 110 pelleted diet (SAFE, Augy, France).

Food is analyzed regularly by the supplier for composition and contaminant levels.

The diet formula is presented in Appendix 2.

Drinking water filtered by a FG Millipore membrane (0.22 micron) was provided *ad libitum*.

Bacteriological and chemical analyses of water are performed regularly by external laboratories. These analyses include the detection of possible contaminants (pesticides, heavy metals and nitrosamines).

No contaminants were known to have been present in the diet or drinking water at levels which may be expected to have interfered with or prejudiced the outcome of the study.

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2.3 TREATMENT

2.3.1 Preparation and selection of the animals

The day before treatment, both flanks of each animal were clipped using electric clippers and just before treatment, the skin of each animal was examined in order to check the absence of any signs of skin irritation.

Clipping was repeated thereafter on days 5 after the 3-minute treatment, 9, 10, 12 to 15 after the 1-hour treatment and on day 8 after the 4-hour treatment for the animal No. 193.

2.3.2 Application of the test item

The test item was first evaluated on a single animal (No. 193). The durations of exposure were 3 minutes, 1 hour and 4 hours.

Since the test item was severely irritant but not corrosive on this first animal, it was then applied for 4 hours to another single animal (No. 977). As the test item showed corrosive properties on this second animal, the study was considered complete and the test item was not evaluated on a third animal.

Doses of 0.5 mL of the undiluted test item were placed on a dry gauze pad, which was then applied to an area of approximately 6 cm² of the anterior left flank (application for 3 minutes), the anterior right flank (application for 1 hour) or the posterior right flank (application for 4 hours) of the animals.

The gauze pad was held in contact with the skin by means of an adhesive hypoallergenic aerated semi-occlusive dressing and a restraining bandage.

The untreated skin served as control.

After removal of the dressing after the 3-minute application, any residual test item was wiped off by means of a dry cotton pad. No residual test item was observed on removal of the dressing after 1 or 4-hour application.

2.4 CUTANEOUS EXAMINATIONS

2.4.1 Duration of the observation period

The skin was examined approximately 1 hour, 24, 48 and 72 hours after removal of the dressing. Since there were persistent irritation reactions at 72 hours, the observation period was extended. In the absence of complete reversibility of skin reactions on day 15, the study was ended for animal No. 193.

As severe cutaneous reactions effects were observed, the animal (No. 977) was sacrificed on day 8 for ethical reasons.

2.4.2 Description and evaluation of cutaneous reactions

Dermal irritation was evaluated for each animal according to the following scoring scale:

Erythema and eschar formation:

. no erythema.....	0
. 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

Edema formation	
. no edema	0
. very slight edema (barely perceptible).....	1
. slight edema (edges of area well-defined by definite raising).....	2
. moderate edema (raised approximately 1 millimeter)	3
. severe edema (raised more than 1 millimeter and extending beyond area of exposure).....	4

Any other lesions were noted.

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2.5 BODY WEIGHT

Each animal was weighed at the beginning (before treatment) and at the end of the observation period.

2.6 SACRIFICE

At the end of the observation period, the animals were sacrificed by an intravenous injection of 1.2 mL/kg sodic thiopental solution. Any animal showing sign of poor clinical conditions was sacrificed in the same way.

No macroscopic *post-mortem* examination was performed.

2.7 INTERPRETATION OF RESULTS

The results obtained were evaluated in conjunction with the nature and the reversibility of the findings observed.

2.8 ARCHIVING

The following study materials are archived by CIT, 27005 Evreux, France, for 10 years after the end of the *in vivo* phase of the study:

- . study plan,
- . raw data,
- . correspondence,
- . final report and possible amendments.

On completion of this period, the archived study materials will be returned to the Sponsor, or may be archived at CIT for a further period (at additional cost). The total duration of archiving (depending on regulations) will be the responsibility of the Sponsor.

In addition, raw data not specific to the study including, but not limited to, certificates of analyses for food, water and bedding (if applicable) and records of environmental data and equipment calibration, are also archived by CIT for at least 30 years.

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2.9 CHRONOLOGY OF THE STUDY

The chronology of the study is summarized as follows:

Procedure	Date
Study plan approved by:	
. Study Director	23 December 2009
. Sponsor Representative	05 January 2010
Experimental starting date: (day of treatment of the first animal)	
	30 December 2009
End of the observation period	02 February 2010
Experimental completion date:	12 February 2010

2.10 STUDY PLAN ADHERENCE

The study was performed in accordance with study plan No. 36454 TAL and subsequent amendments, with the following deviations from the agreed study plan:

- . the temperature and relative humidity recorded in the animal room were sometimes outside of the target ranges specified in the study plan (up to 23°C for temperature, and down to 16% for relative humidity),
- . on day 1, the animals were more than 4 months old and the body weight of male No. 193 was higher than 3.5 kg (3.6 kg),
- . the animal No. 193 was not sacrificed at the end of the observation period but several days after,
- . due to a typing error in the study plan, the adress of the animal food supplier was SAFE, Augy, France instead of SAFE, Villemoisson, Epinay-sur-Orge, France.

These minor deviations were not considered to have compromised the validity or integrity of the study.

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3. RESULTS

The observations recorded during the study are presented in Tables 1, 2 and 3.

The body weights of the animals are presented in Table 4.

After a 3-minute exposure (animal No. 193)

A very slight to severe erythema (grades 1 to 4) was observed all over the observation period. A slight or moderate edema (grade 2 or 3) was noted from day 5 until the end of the observation period (day 15). A brownish area was noted from day 5 until day 13. Dryness of the skin was recorded from day 6 until day 15.

After a 1-hour exposure (animal No. 193)

A well-defined to severe erythema (grades 2 to 4) was observed all over the observation period. A slight or moderate edema (grade 2 or 3) was noted from day 5 until the end of the observation period (day 15). A brownish area was noted from day 7 until day 13 following by scabs (not further described) on days 14 and 15. Dryness of the skin was recorded from day 6 until day 15.

After a 4-hour exposure (two animals)

First animal (No. 193)

A well-defined or moderate erythema (grade 2 or 3) was observed all over the observation period. A brownish area was noted from day 10 until day 13. Dryness of the skin was recorded from day 9 until the end of the observation period (day 15).

Second animal (No. 977)

A well-defined to severe erythema (grades 2 to 4) and a very slight to severe edema (grades 1 to 4) were noted from day 1 until day 8. Brownish area, related to a tissular necrosis and tissue burn on days 7 and 8, was noted from day 5 until day 8, associated with dryness of the skin from day 6 until day 8. According to the severe cutaneous reactions observed, the animal was sacrificed on day 8 for ethical reasons. The study was therefore considered complete and no other animal was tested.

Mean scores over 24, 48 and 72 hours for each animal were 2.3 and 3.0 for erythema and 0.0 and 1.0 for edema.

4. CONCLUSION

Under the experimental conditions of this study, the test item n-Dodecyl mercaptan was corrosive when applied topically to rabbits.

CIT/Study No. 36454 TAL/n-Dodecyl mercaptan/Chevron Phillips Chemical Compagny LP &

Table 1. 3-minute exposure - Cutaneous examinations and mean values of the scores recorded for the first animal (24, 48 and 72 hours)

Rabbit number	Dermal Irritation	Scores				Mean irritation score (1)
		1h D1	24h D2	48h D3	72h D4	
193	Erythema	2	1	1	2	1.3
	Edema	0	0	0	0	0.0
	Other	*	*	*	*	

(1) mean of scores on days 2, 3 and 4

h = hour

D = day

* = none

Rabbit number	Dermal Irritation	Scores										
		D5	D6	D7	D8	D9	D10	D11	D12	D13	D14	D15
193	Erythema	3	3	4	4	4	4	4	4	4	4	3
	Edema	2	2	3	3	3	3	3	3	3	3	3
	Other	ZB	ZB/S	S								

D = day

S = dryness of the skin

ZB = brownish area

CIT/Study No. 36454 TAL/n-Dodecyl mercaptan/Chevron Phillips Chemical Compagny LP &

Table 2. 1-hour exposure - Cutaneous examinations and mean values of the scores recorded for the first animal (24, 48 and 72 hours)

Rabbit number	Dermal Irritation	Scores				Mean irritation score (1)
		1h D1	24h D2	48h D3	72h D4	
193	Erythema	2	2	2	3	2.3
	Edema	0	0	0	0	0.0
	Other	*	*	*	*	

(1) mean of scores on days 2, 3 and 4
h = hour
D = day
* = none

Rabbit number	Dermal Irritation	Scores											
		D5	D6	D7	D8	D9	D10	D11	D12	D13	D14	D15	
193	Erythema	4	4	4	4	4	4	4	4	4	4	3	2
	Edema	2	3	3	3	3	3	3	3	3	3	3	2
	Other	*	S	ZB/S	S/A	S/A							

D = day
* = none
S = dryness of the skin
ZB = brownish area
A = scabs

CIT/Study No. 36454 TAL/n-Dodecyl mercaptan/Chevron Phillips Chemical Compagny LP &

Table 3. 4-hour exposure - Individual cutaneous examinations and mean values of the scores recorded for each animal (24, 48 and 72 hours)

Rabbit number	Dermal Irritation	Scores				Mean irritation score (1)	Interpretation (+) (-)
		1h D1	24h D2	48h D3	72h D4		
193	Erythema	2	2	2	3	2.3	(+)
	Edema	0	0	0	0	0.0	(-)
	Other	*	*	*	*		
977	Erythema	2	3	3	3	3.0	(+)
	Edema	1	1	1	1	1.0	(-)
	Other	*	*	*	*		

(1) mean of scores on days 2, 3 and 4

h = hour

D = day

(+) = irritant according to E.E.C. criteria

(-) = non-irritant according to E.E.C. criteria

* = none

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Table 3 (continued)

Rabbit number	Dermal Irritation	Scores											
		D5	D6	D7	D8	D9	D10	D11	D12	D13	D14	D15	
193	Erythema	3	3	3	3	3	3	3	3	3	3	2	2
	Edema	0	0	0	0	0	0	0	0	0	0	0	0
	Other	*	*	*	*	S	ZB/S	ZB/S	ZB/S	ZB/S	S	S	
977	Erythema	3	3	3	4	-	-	-	-	-	-	-	-
	Edema	2	2	2	4	-	-	-	-	-	-	-	-
	Other	ZB	ZB/S	ZB/S	ZB/S	-	-	-	-	-	-	-	-

D = day

* = none

S = dryness of the skin

ZB = brownish area

- = cutaneous examination not performed

Table 4. Individual body weight (g)

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Sex	Animals	Day of treatment (Day 1)	End of the observation period
Male	193	3617	3937 (day 15)
	977	3490	3486 (day 8)

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APPENDICES

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1. Test article description and analysis certificate

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**TOXICOLOGY DEPARTMENT
CONFIDENTIAL**

DTI 0221
November 2009

TEST ARTICLE DESCRIPTION

n-DODECYL MERCAPTAN

IDENTITY

Test article name	:	n-DODECYLMERCAPTAN
Chemical name	:	dodecane-1-thiol
CAS number	:	112-55-0
EINECS number	:	203-984-1
Purity	:	99 %
Batch number	:	9500NDM09
Origin	:	
Arkema filing number	:	GRL 0081/09

PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	colourless
Odour	:	stinking characteristic
Specific gravity	:	0.84 (20 °C)
Melting point	:	- 7 °C
Boiling point	:	275 °C
Vapour pressure	:	0.002 hPa at 20°C
Flash point	:	127 °C (closed cup Method ASTM D 93)
Solubility	:	in water : < 1mg/l at 20°C
	:	in solvents : soluble in hydrocarbons and alcohols (slightly)

TOXICOLOGICAL INFORMATIONS AND USE SAFETY

See Safety Data Sheet

STORAGE AND DISPOSAL

Storage	:	keep tightly closed in a cool, well-ventilated place
Expiry date	:	November 2010
Disposal	:	incineration

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Arkema Inc.

CERTIFICATE OF ANALYSIS

Ship From:
HOUSTON, TX

Ship-To:
ARKEMA FRANCE
ESTABLISSEMENT DE LACQ
BP 34
64170 LACQ
FRANCE

Customer Number: 44022
Customer PO: sample
Ship Date: 03.11.2009
Delivery Number: 81435619
Order Number: 110063954

Additional Copy/Fax to:

Material: 2684 NORMAL DODECYL MERCAPTAN 1 LB SAMPLE

Container Number: DangerousGoods

Batch : 9500NDM09

Quantity: 1,0 LB

Characteristic	Arkema Specification Limits	Batch Analysis
APPEARANCE	NO TURB OR SUSP MATL	NO TURB OR SUSP M
COLOR, APHA	<=20	4
MERCAPTAN SULFUR, %S	>=15,50	15,76
n-DODECYL MERCAPTAN, %	>=98,5	99,0

TECHNICAL INFORMATION AND DATA REGARDING THE COMPOSITION, PROPERTIES OR USE OF THE PRODUCTS DESCRIBED HEREIN IS BELIEVED RELIABLE. HOWEVER NO REPRESENTATION OR WARRANTY IS MADE WITH RESPECT THERETO EXCEPT AS MADE BY ARKEMA INC. IN WRITING AT TIME OF SALE. ARKEMA INC. CANNOT ASSUME RESPONSIBILITY FOR ANY PATENT LIABILITY WHICH MAY ARISE FROM THE USE OF ANY PRODUCT IN A PROCESS, MANNER OR FORMULA NOT DESIGNED BY ARKEMA INC.

CERTIFIED BY _____ DATED: _____

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2. Diet formula

CIT/Study No. 36454 TAL/n-Dodecyl mercaptan/Chevron Phillips Chemical Compagny LP

Ref: 110

**COMPLETE DIET
RABBIT BREEDING DIET**

Appearance: 3 mm diameter granules

Conditioning: bags of 20 kgs

Daily portion: Rabbits 150 g, water *ad libitum*.

FORMULA %

Cereals.....	33.8
Grain biproducts and leguminous plants.....	48
Vegetable protein (soya bean meal, yeast)	14
Vitamin and mineral mixture...	4.2

AVERAGE ANALYSIS %

Calorific value (Kcal/kg).....	3100
Moisture.....	10
Proteins.....	15
Lipids.....	2.3
Carbohydrates (N.F.E.)	48.2
Fibre.....	17
Minerals (ash).....	7.5

MINERALS (calculated in mg/kg)			
	Nat. val.	CMV val.	Total
P	3600	2900	6500
Ca	4200	5800	10000
K	12000	0	12000
Na	400	2000	2400
Mg.....	2500	100	2600
Mn	50	40	90
Fe	150	150	300
Cu	Traces	15	15
Zn	30	45	75
Co	0.1	1.5	1.6
I	0.1	0	0.1
Cl	300	3000	3300

**AMINO ACID VALUES
(calculated in mg/kg)**

Arginine.....	11300
Cystine.....	3400
Lysine.....	9300
Methionine.....	2800
Tryptophan	2400
Glycine	8700

**FATTY ACID VALUES
(calculated in mg/kg)**

Palmitic acid.....	6400
Palmitoleic acid.....	0
Stearic acid	600
Oleic acid.....	6400
Linoleic acid.....	12100
Linolenic acid.....	2400

VITAMINS (calculated per kg)			
	Nat. val.	CMV val.	Total
Vitamin A	Traces	10000 IU	10000 IU
Vitamin D3	0 IU	1000 IU	1000 IU
Vitamin B1	5 mg	0 mg	5 mg
Vitamin B2	4 mg	0 mg	4 mg
Vitamin B3	20 mg	0 mg	20 mg
Vitamin B6	1 mg	1 mg	2 mg
Vitamin B12	0 mg	0 mg	0 mg
Vitamin E	15 mg	25 mg	40 mg
Vitamin K3	0 mg	1 mg	1 mg
Vitamin PP	60 mg	5 mg	65 mg
Folic acid	0 mg	0 mg	0 mg
Biotin	0 mg	0 mg	0 mg
Choline	1000 mg	1000 mg	2000 mg

Available under quality "Control Ref.: 110"

SAFE, route de Saint Bris, 89290 Augy
Tel: 01.69.04.03.57 - Fax : 01.69.04.81.97
(Ref. Doc. UAR: 2000)

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3. CIT GLP certificate

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Paris, le 13 JAN. 2009

Objet : Evaluation de la conformité aux Bonnes Pratiques de Laboratoires (BPL) selon les directives 2004/9/CE et 2004/10/CE du 11 février 2004

Subject : Assessment of compliance with Good Laboratory Practices (GLP) under the EC directives 2004/9 and 2004/10 of 11 February 2004.

Consécutivement à votre engagement vis-à-vis du GIPC et du COFRAC et en application du décret n° 2006-1523 du 4 décembre 2006 concernant les bonnes pratiques de laboratoires et modifiant le décret n° 81-278 du 25 mars 1981 portant création d'un groupe interministériel des produits chimiques, je vous confirme que le GIPC, au vu des résultats du contrôle exercé par le Comité français d'accréditation (COFRAC) - Section Laboratoires a décidé pour votre installation du statut suivant :

Following your engagement vis-à-vis the GIPC and COFRAC and in application of the decree n° 2006-1523 of 4 December 2006 relating to the good laboratory practices and modifying the decree n° 81-278 of 25 March 1981 giving birth to an interministerial group of chemical products (GIPC), I confirm to you that the GIPC, given the results of the inspection realised by the French Committee of accreditation (COFRAC) - Laboratory Section has taken the following decision relating to your installation:

Respect des principes de BPL
Respect of the GLP principles

Date d'inspection : 1 octobre 2008
Date of inspection : 1 October 2008

Domaines de reconnaissance:
1 - essais physico-chimiques
2 - études de toxicité
3 - études de mutagénicité
4 - études écotoxicologiques sur les organismes aquatiques et terrestres
8 - méthodes de chimie analytique et clinique

Inspection de contrôle périodique (i.p)
Periodic check inspection (i.p)

Date de décision du GIPC : 12 décembre 2008
Date of GIPC decision: 12 December 2008

Date de prise d'effet : 1 octobre 2008
Date of implementation: 1 October 2008

Areas of expertise :
1 = *Physico-chemical testing*
2 = *Toxicity studies*
3 = *Mutagenicity studies*
4 = *Environmental toxicity studies on aquatic or terrestrial organisms*
8 = *Analytical and clinical chemistry*

Année de première conformité : 1989
Year of the first conformity. 1989

Durée de validité: 18 mois
Time of validity: 18 months

Le Président.



Jean-Pierre FALQUE-PIERROTIN

CENTRE INTERNATIONAL DE TOXICOLOGIE
(CIT)
MISEREY - BP 563
27005 EVREUX CEDEX



MINISTÈRE DE L'ÉCONOMIE
DE L'INDUSTRIE ET DE L'EMPLOI

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4. Study Specific Supplement and CIT General Study plan

n-Dodecyl mercaptan

ACUTE DERMAL IRRITATION IN RABBITS

Study specific supplement for
CIT/Study No. 36454 TAL

According to general study plan No. 4A, Version 2 of 25 August 2004

Test Facility : CIT
BP 563 – 27005 Evreux
France

Sponsor : Chevron Phillips Chemical Company LP
10001 Six Pines Dr. Suite 4106
The Woodlands, TX 77380
USA
&

Sponsor Representative :

Address :

Study Director :

Deputy Study Director :

Complete or modify the general study plan as follows:

1. INTRODUCTION

1.2 Regulatory compliance

Replace by the following:

The study has been designed to comply with the following guidelines:

- OECD Guideline No. 404, 24th April 2002,
- Commission Regulation (EC) No. 440/2008, B.4, 30 May 2008.

The study will be performed in compliance with CIT's standard operating procedures and the following principles of Good Laboratory Practice:

- OECD Principles of Good Laboratory Practice (as revised in 1997), ENV/MC/CHEM (98) 17 and all subsequent OECD consensus documents,
- Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the Principles of Good Laboratory Practice and the verification of their applications for tests on chemical substances (OJ No. L50 of 20.2.2004),
- Décret n° 2006-1523 du 04 décembre 2006 concernant les Bonnes Pratiques de Laboratoire (Journal Officiel du 06 décembre 2006), Ministère de l'Economie, des Finances et de l'Industrie.

The study will be conducted in compliance with Animal Health regulations, in particular:

- Council Directive No. 86/609/EEC of 24th November 1986 on the approximation of laws, regulations and administrative provisions regarding the protection of animals used for experimental and other scientific purposes.

Add the following paragraph:

1.3 In-house ethics review procedure

CIT has an in-house ethics review procedure, which covers animal welfare within the facility. The activities of the ethical committee, which are not within the scope of GLP, were reviewed as part of the AAALAC accreditation procedure and FELASA recommendations.

The CIT Ethical Committee (CEC) reviews all study plans, in order to ensure that:

- animal use is carefully considered and fully justified,
- all possibilities for reduction, refinement and replacement have been evaluated,
- every effort is made to achieve a high standard of animal welfare.

The present study plan was submitted for ethical review before the initiation of the study. The review has been documented in the Ethical Committee database under the reference number 00009.

During the study, the CEC will regularly be informed of:

- any amendments to the study plan which could have an impact on animal welfare.
- any clinical findings or unexpected situations which could lead to animal stress or discomfort.

Any decisions or requests will be made after consultation with a veterinarian, or after taking expert advice, and will be reported to the Study Director.

2. TEST ITEM

2.1 Identification

Replace by the following:

Name: n-Dodecyl mercaptan

Synonym: n-Dodecylmercaptan, 1-Dodecanethiol

All names refer to the same test item. The name retained in the study report will be n-Dodecyl mercaptan.

CAS No.: 112-55-0

Batch No.:

On labeling: none

On the test article description and analytical certificate: 9500NDM09

Supplier: .

Description: colorless liquid

Storage conditions: at room temperature

Expiry date: November 2010

Purity, composition, stability and expiry date which refer to the batch(es) to be used and handling conditions will be indicated in the test item data sheet (to be completed by the Sponsor). An analytical certificate will also be provided by the Sponsor.

Confirmation of identity of the test item is the responsibility of the Sponsor.

All remaining test item will be destroyed within 2 months after issue of the final report. In the case where more than one study is conducted with the same test item, it will be destroyed one year after issue of the final report of the last study.

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3. TEST SYSTEM

Modify the following paragraphs according to the underlined words:

3.1 Animals

Sex, strain, species: male and/or female KBL New Zealand White rabbits.

[...]

Breeder: Charles River Laboratories France (Châtillon-sur-Chalaronne, France).

[...]

Selection: on the day before treatment, the animals will be clipped and just before treatment, the skin of each animal will be examined in order to use only animals with healthy intact skin. Animals showing signs of cutaneous lesions will not be used.

3.2 Environmental conditions

The animals will be housed individually in polystyrene (48.2 cm x 58 cm x 36.5 cm), Techniplast (49 cm x 62 cm x 30 cm or 64 cm x 63 cm x 30 cm) or Pajon (50 cm x 57 cm x 75 cm) cages.

Add the following paragraphs:

6. BODY WEIGHT

Each animal will be weighed at the beginning and at the end of the observation period.

7. SACRIFICE

At the end of the observation period, if the animals are not used subsequently for the evaluation of the ocular irritation potential on the same test item, they will be euthanized by an intravenous injection of 1.2 mL/kg sodic thiopental solution. Throughout the study, any moribund animal will be euthanized in the same way.

No macroscopic *post-mortem* examination will be performed in the animals euthanized at the end of the study, euthanized due to poor clinical conditions or found dead during the study.

Modify the numbering of the following paragraphs:

8. INTERPRETATION OF RESULTS

Replace by the following:

The scores obtained will be evaluated in conjunction with the nature and the reversibility of the lesions observed, whilst taking into account all the reactions of the treated animals.

9. AMENDMENTS TO THE STUDY PLAN

10. REPORTING

Replace by the following:

The Sponsor Representative will be promptly informed of any significant findings during the course of the study.

Proposed issue of the draft report: 5 weeks after completion of the *in vivo* part of the study (10 weeks if a microscopic examination is performed).

Six months after issue of the audited draft report, if no requests for revision or instructions to finalize have been communicated by the Sponsor, the draft report will be considered as final and issued as the final report.

The final report will contain all data collected during the study.

Number of copies of the final report: 1 unbound + 1 electronic version (pdf file) with scan by mail.

A robust study summary (independent of the report), in IUCLID 5 format, will also be supplied to the Sponsor in electronic format.

11. QUALITY ASSURANCE UNIT

Replace by the following information:

The study will be subjected to Quality Assurance inspections in order to ensure compliance with GLP regulations, specifically:

- (i) The study plan and subsequent amendment(s) will be verified for compliance with GLP requirements.
- (ii) Study-based inspections will be carried out specifically on this study or on similar studies taking place during the same period, in order to ensure that the conduct of the study complies with standard operating procedures and the study plan.
- (iii) The study report and subsequent amendment(s) will be inspected in order to ensure that the report faithfully reflects the data generated during the study and that the methods, procedures and observations are accurately and completely described.

The types of inspections and their dates, and the dates when inspection results are reported to the Study Director and to CIT Management will be specified in the statement of the Quality Assurance Unit. This statement will be included in the study report.

12. ARCHIVING

Add the following information:

The study archives will be stored on the premises of CIT for 10 years after the end of the *in vivo* phase of the study.

13. PROPOSED TIME SCHEDULE

Add the following information:

Experimental starting date: 30 December 2009,

End of *in vivo* phase: 19 January 2010.

The present study plan has been attributed the reference 36454 TAL and includes:

- a standard section,
- a specific section.

The Sponsor Representative should sign this document to acknowledge the contents of the above.

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Study plan approved by:



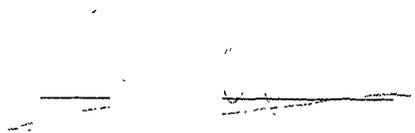
Date: 23 December 2009



Alain SIMONNARD

CIT Management

Date: 28 DEC 2009



Sponsor Representative

Date: 05/01/2010



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CIT GENERAL STUDY PLAN No. 4A

Version 2 of 25 August 2004

ACUTE DERMAL IRRITATION IN RABBITS

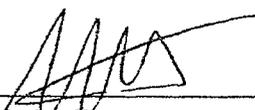
This General Study plan defines the entire scope of the Skin irritation test in rabbits as conducted by CIT.

For each individual test, a Study-Specific Supplement, which provides information not given in the General Study plan (specifically regulatory guidelines, test item information, Sponsor-requested procedures and options, study number and proposed time schedule), will be prepared by CIT.

The Study-Specific Supplement will be approved and signed by the designated Study Director and the Study Monitor.

This General Study plan will be distributed to the Sponsor and, at the test facility, to all Study Directors of Short-Term Toxicology, Quality Assurance and Archives.

Approved by:



S. de Jouffrey
CIT Scientific Management
Date: 01 September 2004

Page 1 of 9

1. INTRODUCTION

1.1 Objective

The objective of this study is to evaluate the potential irritant properties of the test item for the skin when applied to rabbits.

In the assessment of the toxic characteristics of a test item, the determination of the irritant effects on the skin of mammals is an important initial step. Results obtained from this test provide information on health hazards likely to arise in humans from exposure of the skin to the test item.

The test item will be applied in a single dose to the skin of each experimental animal. The degree of irritation will be evaluated at specific intervals.

All information on the test item will be given careful consideration to minimize testing under conditions that are likely to produce severe reactions:

- . test item with a demonstrated pH ≤ 2 or ≥ 11.5 ,
- . acidic or alkaline reserve of the test item,
- . results of an *in vitro* test,
- . results of acute toxicity study by cutaneous route.

1.2 Regulatory compliance

The study has been designed to comply with the following guidelines:

- . OECD Guideline No. 404, 24 April 2002,
- . Directive 2004/73/EEC, B.4, 29 April 2004.

Other guideline(s) may be added in the Study-Specific Supplement.

The study will be conducted in compliance with Animal Protection regulations, in particular:

- . Council Directive 86/609/EEC of 24th November 1986 on the harmonization of laws, regulations or administrative provisions relating to the protection of animals used for experimental or other scientific purposes,
- . Guidance document on the recognition, assessment, and use of clinical signs as humane endpoints for experimental animals used in safety evaluation, OECD Environmental Health and Safety Publications, No. 19.

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2. TEST ITEM

2.1 Identification

The identity of the test item, as well as any other relevant information, will be specified in the Study-Specific Supplement.

Purity, composition, stability and expiry date which refer to the batch(es) to be used, as well as any specific handling conditions, will be indicated in the test item data sheet to be completed by the Sponsor.

If available, an analytical certificate will also be provided by the Sponsor.

Confirmation of identity of the test item will be the responsibility of the Sponsor.

At the end of the study or utilization, all remaining test and/or control items will be destroyed, unless otherwise instructed by the Sponsor.

2.2 Dosage form preparation

The test item will be used in its original form.

If necessary, solid materials may be ground to a fine powder before application.

3. TEST SYSTEM

3.1 Animals

Sex, strain, species: male and/or female New Zealand White rabbits.

Reason for this choice: species generally accepted by regulatory authorities for this type of study.

Breeder: CEGAV, Saint Mars d'Egrenne, France.

Number: one to three animals will be used.

Age/weight: at the beginning of the study, the animals will be 2 to 4 months old and their body weight should be comprised between 2.2 kg and 3.5 kg.

Acclimation: at least 5 days before the beginning of the study. Upon their arrival at CIT, the animals will be given a clinical examination to ensure that they are in good condition.

Selection: on the day before treatment, the animals will be clipped and the skin of each animal will be examined in order to use only animals with healthy intact skin. Animals showing signs of cutaneous lesions will not be used.

Identification: individually with a metal ear tag or ear-tattoo.

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3.2 Environmental conditions

The animal room conditions will be set as follows:

- . temperature : $18 \pm 3^{\circ}\text{C}$
- . relative humidity : 30 to 70%
- . light/dark cycle : 12 h/12 h (7:00 - 19:00)
- . ventilation : approximately 12 cycles/hour of filtered, non-recycled air.

The corresponding instrumentation and equipment are checked and calibrated at regular intervals. The temperature and relative humidity are recorded continuously and the records are checked daily and filed.

The animals will be housed individually in polystyrene cages (48.2 cm x 58 cm x 36.5 cm or 49 cm x 62 cm x 30 cm or 64 cm x 63 cm x 30 cm).

3.3 Food and water

All animals will have free access to an adapted rabbit diet (SAFE, Villemoisson, Epinay-sur-Orge, France) and tap water (filtered using a 0.22 micron filter) contained in bottles.

Each batch of food is analyzed by the supplier for composition and contaminant levels.

Bacteriological and chemical analyses of water are performed regularly by external laboratories. These analyses include the detection of possible contaminants (pesticides, heavy metals and nitrosamines).

No contaminants are known to be present in the diet or drinking water at levels that may be expected to interfere with or prejudice the outcome of the study.

4. TREATMENT

4.1 Preparation of the animals

On the day before treatment, an area of the skin (3.5 cm x 5 cm) will be clipped on both flanks of each animal, using electric clippers.

The animals may be clipped again during the study, whenever necessary.

4.2 Study design

The study design will be as follows:

The test item will be applied for 3 minutes to a single animal:

if severe skin reactions (e.g. necrosis) are observed, the test will be considered complete.

in the absence of severe skin reactions, a second pad will be applied to another area of skin for 1 hour.

After the 1-hour application time:

if severe skin reactions (e.g. necrosis) are observed, the test will be considered complete

in the absence of severe skin reactions, a third pad will be applied to another area of the skin for 4 hours.

The treatment sites will be as follows:

	Left flank	Right flank
Anterior	3-minute exposure	1-hour exposure
Posterior	-	4-hour exposure

If the results of the three sequential exposures in one rabbit suggest that the test item is severely irritant or corrosive to the skin, further testing in subsequent animals will not be carried out.

Otherwise, the study will be completed with one or two other animals (simultaneously or in a sequential manner), which will receive the test item for 4 hours.

Exceptionally, one to three animals may be treated directly with a single patch which is removed after 4 hours.

4.3 Application of the test item

The quantity of test item administered will be 0.5 mL for liquids and 500 mg for solids or semi-solids.

The test item will be placed on a gauze pad (moistened with the smallest amount of purified water for powders), which will be then applied to an area of the skin of approximately 6 cm². The gauze pad will be held in place by a non-irritating semi-occlusive dressing and a restraining bandage.

For the 4-hour exposure, a dry gauze pad will be applied to the opposite flank, which will act as control.

After the required period of contact with the skin, the dressings will be removed.

Where necessary, residual test item will be removed with a cotton pad, either dry or saturated with water or an appropriate solvent. This will be done carefully so that the existing response and the integrity of the epidermis are not altered.

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4.4 Examination of the skin

For each exposure period, cutaneous reactions will be evaluated approximately 1 hour, 24, 48 and 72 hours after removal of the dressing.

If there is no evidence of irritation after 72 hours, the study will be terminated.

If there are persistent irritation reactions at the 72-hour reading, the observation period will be extended to a maximum of 14 days (until day 15) in order to determine the progress of the lesions and their reversibility.

In the case of persistent coloration of the skin by the test item, decision to stop the study will be taken by the Study Director.

All observations other than the cutaneous reactions will also be noted.

If marked effects are observed or if animals show signs of distress and/or severe and durable pain, they will be humanely killed.

5. DESCRIPTION AND EVALUATION OF CUTANEOUS REACTIONS

Dermal irritation will be evaluated in each animal according to the following scoring scale:

Erythema and eschar formation:

- . no erythema..... 0
- . 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

Oedema formation

- . no oedema..... 0
- . very slight oedema (barely perceptible) 1
- . slight oedema (edges of area well-defined by definite raising) 2
- . moderate oedema (raised approximately 1 millimetre) 3
- . severe oedema (raised more than 1 millimetre and extending beyond area of exposure)..... 4

Any other lesion will be noted.

6. INTERPRETATION OF RESULTS AND CLASSIFICATION

The results obtained will be evaluated in conjunction with the nature and the reversibility or irreversibility of the scores observed, whilst taking into account all the reactions of the treated animals.

If appropriate, the test item will be classified according to the criteria laid down in Council Directive 67/548/EEC (and subsequent adaptations) on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

The test item will be classified irritant or corrosive according to the following criteria:

Criteria of irritation

The test item will be considered irritant if it induces skin inflammation lasting at least 24 hours after a 4-hour exposure period and corresponding to the following values determined in the rabbit:

- when the test is performed with six animals, if the mean value of the scorings is equal to or higher than 2 for the erythema and eschar formation or the oedema formation in all treated animals,
- or else, when the test is performed with three animals, if the mean value of the scorings is equal to or higher than 2 for the erythema and eschar formation or the oedema formation in at least two of them.

In both cases, the test item will be assigned the symbol Xi, the indication of danger "Irritant" and the risk phrase R 38: "Irritating to skin".

Inflammation of the skin is also significant if it persists in at least two animals at the end of the observation period.

Criteria of corrosion

The test item will be considered corrosive if, when applied to the sound and intact skin, it induces tissular destruction of the whole depth of the skin in at least one animal, or if the result can be predicted (for example: strong acid or alkaline reactions).

- If tissular destruction is observed after an exposure period not exceeding 3 minutes, the test item will be assigned the symbol C, the indication of danger "Corrosive" and the risk phrase R 35: "Causes severe burns".
- If tissular destruction is observed after an exposure period not exceeding 4 hours, the test item will be assigned the symbol C, the indication of danger "Corrosive" and the risk phrase R 34: "Causes burns".

All the scores obtained for an effect at each reading (24, 48, 72 h) will be used to calculate the respective mean values.

7. AMENDMENTS TO THE STUDY PLAN

If necessary, amendments to the Study plan will be made after agreement between the Study Director and the Study Monitor.

8. REPORTING

The Study Director will contact the Study Monitor when necessary.

The final report in English, will contain all data collected throughout the study.

Number of copies of the final report: 1 (unbound) + one electronic version (PDF file) on a CD-rom (except for special request made by the Sponsor).

Proposed issue of the draft report: 5 weeks after completion of the *in vivo* part of the study.

On issue of the final report, an electronic version can be provided as a PDF file. In the event that an electronic copy of the CIT study report is requested, the Sponsor will be asked to provide an electronic copy of the test item analytical certificate and of any other information needed for the report which is generated outside of CIT.

9. QUALITY ASSURANCE UNIT

The study will be subjected to Quality Assurance monitoring in order to ensure compliance with GLP, specifically:

- (i) The Study plan will be checked for compliance with GLP requirements.
- (ii) Specific and/or process-based inspections will be performed in order to ensure that the conduct of the study complies with Standard Operating Procedures.
- (iii) Data audit will be undertaken to ensure the reliability and integrity of the study data.
- (iv) The study report will be reviewed by the Quality Assurance Unit in order to ensure that the report faithfully reflects the data generated during the study and the study findings.

The dates on which the findings of critical inspections and reviews are reported to the Study Director and CIT Management will be specified in the study report.

10. ARCHIVING

The following study documentation will be archived at CIT, 27005 Evreux, France:

- . Study-Specific Supplement and possible amendments,
- . raw data,
- . correspondence,
- . final report and possible amendments.

On completion of the period specified in the Study-Specific Supplement, the archived study materials will be returned to the Sponsor, or may be archived by CIT for a further period (at additional cost). The total duration of archiving (depending on regulations) will be the responsibility of the Sponsor.

In addition, the corresponding General Study Plan and raw data not specific to the study including, but not limited to, *certificates of analyses for food, water and bedding* (if applicable) and records of environmental data and equipment calibration, will also be archived at CIT and retained for at least 30 years.

11. PROPOSED TIME SCHEDULE

A proposed time schedule will be added to the Study-Specific Supplement.

In the case of modification, the dates of the study will be documented in the raw data and specified in the study report.