

OCT 09 1987

PRJ. NO. 11H0200/862234

SHEET 1

REPORT ON THE ACUTE IRRITATION TO THE EYE OF THE WHITE RABBIT
BASED ON OECD *

TESTING FACILITY: BASF AKTIENGESELLSCHAFT
DEPARTMENT OF TOXICOLOGY
D-6700 LUDWIGSHAFEN / RHEIN, FRG

AIM OF THE STUDY: ASSESSMENT OF A POSSIBLE IRRITA-
TING POTENTIAL TO THE EYE AND
TO THE EYE MUCOSA

PROJECT NUMBER: 11H0200/862234

NAME OF TEST SUBSTANCE: 2,4,6-TRIANILINO-P-(CARBO-2'-ETHYL-HEXYL**
-1'-OXI)-1,3,5-TRIAZINE

LOT NUMBER: 18301/142

DEGREE OF PURITY: 98 %

PHYSICAL STATE/APPEARANCE: POWDER, WHITE

HOMOGENEITY OF THE TEST SUBSTANCE: PROVIDED BY SHAKING THE TEST SUBSTANCE

STORAGE STABILITY
AT ABOUT 8 DEGREE CELSIUS: ON COMPLETION OF ALL TESTS THE STABILITY
OF THE TEST SUBSTANCE WILL BE VERIFIED
BY A REPEATED ANALYSIS. THE RESULT CAN
BE OBTAINED FROM THE SPONSOR (ME/Z).

Hildebrand 9.5.87
DR. MED. VET. HILDEBRAND
(HEAD OF EXPERIMENTAL TOXICOLOGY)

Kirsch Oct 6, 1987
DR. MED. VET. KIRSCH
(STUDY DIRECTOR)

* METHOD AND ASSESSMENT BASED ON OECD GUIDELINE (405) FOR TESTING OF
CHEMICALS ADOPTED MAY 12TH, 1981

** DETAILED INFORMATION ON THE CHARACTERIZATION OF THE TEST SUBSTANCE
IS INCLUDED IN THE RAW DATA

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THIS REPORT CONSISTS OF 6 PAGES.

ACUTE EYE IRRITATION (OECD)
.....METHOD
.....

ANIMAL SPECIES: RABBIT/WHITE VIENNA

ANIMAL BREEDER: GAUKLER; D-6050 OFFENBACH / MAIN, FRG

TYPE OF CAGE: CAGE MADE OF STAINLESS STEEL
WITH WIRE MESH WALK FLOORS,
FLOOR AREA: 40 CM X 51 CM

NO. OF ANIMALS PER CAGE: 1

ANIMAL IDENTIFICATION: EAR TATTOO (= ANIMAL NO.)

ROOM TEMPERATURE/
RELATIVE HUMIDITY: THE ANIMALS WERE HOUSED IN FULLY
AIR-CONDITIONED ROOMS. CENTRAL
AIR-CONDITIONING GUARANTEED A
RANGE OF 20 - 24 DEGREES CELSIUS
FOR TEMPERATURE AND OF 30 - 70%
FOR RELATIVE HUMIDITY. THERE
WERE NO DEVIATIONS FROM THESE
RANGES WHICH INFLUENCED THE RE-
SULTS OF THE STUDY.

DAY/NIGHT RHYTHM: 12 H/12 H (6.00 - 18.00 HOURS/
18.00 - 6.00 HOURS)

BEDDING: NO BEDDING IN THE CAGES; SAW-
DUST IN THE WASTE TRAYS

DIET: KLIBA 341, 4 MM;
FIRMA KLINGENTALMUEHLE AG
CH-4303 KAISERAUGST, SWITZERLAND
(ABOUT 130 G PER ANIMAL PER DAY)

FEED ANALYSIS: THE FEED USED IN THE STUDY WAS AS-
SAYED FOR CONTAMINANTS. IN VIEW OF
THE AIM AND DURATION OF THE STUDY
THE CONTAMINANTS OCCURING IN COM-
MERCIAL FEED OUGHT NOT TO INFLUENCE
THE RESULTS.

DRINKING WATER: ABOUT 250 ML TAP WATER PER
ANIMAL PER DAY

DRINKING WATER ANALYSIS: THE DRINKING WATER IS REGULARLY ASSAYED
FOR CONTAMINANTS BY THE MUNICIPAL
AUTHORITIES OF FRANKENTHAL AND THE
TECHNICAL SERVICES OF BASF AKTIENGE-
SELLSCHAFT. IN VIEW OF THE AIM AND
DURATION OF THE STUDY THERE ARE NO
SPECIAL REQUIREMENTS EXCEEDING THE
SPECIFICATIONS OF THE DRINKING WATER.

ACCLIMATIZATION PERIOD: AT LEAST 8 DAYS BEFORE THE BE-
GINNING OF THE STUDY; SAME HOUSING
CONDITIONS AS DURING THE STUDY

ACUTE EYE IRRITATION (OECD)
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WEIGHT DETERMINATION: SHORTLY BEFORE APPLICATION OF THE TEST SUBSTANCE

NUMBER OF ANIMALS MA: 2
FE: 1

MEAN WEIGHT (KG) MA: 3.40
FE: 3.34

APPLICATION VOLUME: 0.1 ML BULK VOLUME (ABOUT 41 MG OF THE COMMINUTED TEST SUBSTANCE)

APPLICATION SITE: SINGLE APPLICATION TO THE CONJUNCTIVAL SAC OF THE RIGHT EYELID; THE SUBSTANCE WAS NOT WASHED OUT

OBSERVATION PERIOD: 72 H

READINGS: 1 H, 24 H, 48 H, 72 H, AFTER APPLICATION

NEGATIVE CONTROL: UNTREATED EYE

RETENTION OF RECORDS: THE RAW DATA AS WELL AS THE ORIGINAL OF THE PROTOCOL AND THIS REPORT, ARE RETAINED AT BASF AKTIENGESELLSCHAFT AT LEAST FOR THE PERIOD OF TIME SPECIFIED IN THE GLP-REGULATIONS. THE CONDUCT OF THE STUDY IN CONFORMANCE WITH GLP WAS MONITORED BY THE QUALITY ASSURANCE UNIT.

DATA INPUT: BENZ

DATA CONTROL: Reinhard Sep. 16, 87

DATE OF APPLICATION: AUG. 18, 87

RESULTS ACUTE EYE IRRITATION (OECD)

ANIMAL	:	1	2	3
ANIMAL NO.	:	0938	0887	0918
A. WEIGHT(KG)	:	3.34	3.48	3.32
SEX	:	FE	MA	MA

READ-INGS	ANI-MAL	CORNEA		IRIS	CONJUNCTIVA			SYMPTOMS
		OP	AR		RED	SW	DI	
1 H	1	0	0	0	1	0	1	
	2	0	0	0	2	1	1	
	3	0	0	0	2	0	1	
24 H	1	0	0	0	0	0	0	
	2	0	0	0	0	0	0	
	3	0	0	0	2	0	0	
48 H	1	0	0	0	0	0	0	
	2	0	0	0	0	0	0	
	3	0	0	0	0	0	0	
72 H	1	0	0	0	0	0	0	
	2	0	0	0	0	0	0	
	3	0	0	0	0	0	0	
ME	1	0.0		0.0	0.0	0.0		
	2	0.0		0.0	0.0	0.0		
	3	0.0		0.0	0.7	0.0		
ME		0.0		0.0	0.2	0.0		

RESULTS ACUTE EYE IRRITATION (OECD)

SCALE FOR SCORING OCULAR LESIONS:

CHEMOSIS (SW) AND CORNEA (OP)
(OPACITY-DEGREE OF DENSITY):

- 0 = NONE
- 1 = SLIGHT
- 2 = WELL-DEFINED
- 3 = SEVERE
- 4 = VERY SEVERE

AREA OF CORNEA INVOLVED (AR):

- 1 = > 0 ; < 1/4
- 2 = >= 1/4 ; < 1/2
- 3 = >= 1/2 ; < 3/4
- 4 = >= 3/4

CONJUNCTIVAE REDNESS (RED):

- 0 = NORMAL
- 1 = SLIGHT
- 2 = WELL-DEFINED
- 3 = SEVERE

DISCHARGE (DI):

- 0 = NORMAL
- 1 = SLIGHTLY INCREASED
- 2 = CLEARLY INCREASED
- 3 = DISTINCTLY INCREASED

IRIS:

- 0 = NORMAL
- 1 = CIRCUM-CORNEAL INJECTION
- 2 = IRITIS

CALCULATION OF THE MEAN ACCORDING TO 83/467/EEC CRITERIA OF JULY 29TH. 1983
(FOR CALCULATION OF THE MEANS OF OPACITY, IRIS, REDNESS AND SWELLING
ONLY THE READINGS OF 24, 48 AND 72 HOURS ARE USED).

KEY: MA = MALE
FE = FEMALE
ME = MEAN
H = HOUR

Report: Project No.: 11H0200/862234

STATEMENT
OF THE QUALITY ASSURANCE UNIT

Number of test substance: 86/200

Name of test substance: 2,4,6-Triamino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-
1,3,5-Triazine

Title: Report on the acute irritation to the eye of the white rabbit
based on OECD

The Quality Assurance Unit performed the inspections given below, and reported findings to the Study Director and to Management. The conduct of this short-term study was not inspected; the processes of the laboratory and of the study involved are inspected in regular intervals.

Phase of study/ inspection	Date of inspection	Report to Study Director and to Management
Protocol:	Aug.13,1987	Oct.5,1987
Audit of report:	Oct.5,1987	Oct.5,1987

Ludwigshafen, Oct. 9, 1987

Fleig
.....
Dr.rer.nat. H. Fleig
(Head of Quality Assurance Unit)

MAY 10 1995

BASF

Abteilung Toxikologie
Department of Toxicology
D-67056 Ludwigs-
hafen, FRG

cp; 0121

AMENDMENT No. 1

to the

REPORT ON THE ACUTE DERMAL IRRITATION/CORROSIVITY TO THE INTACT
DORSAL SKIN OF THE WHITE RABBIT BASED ON OECD

of

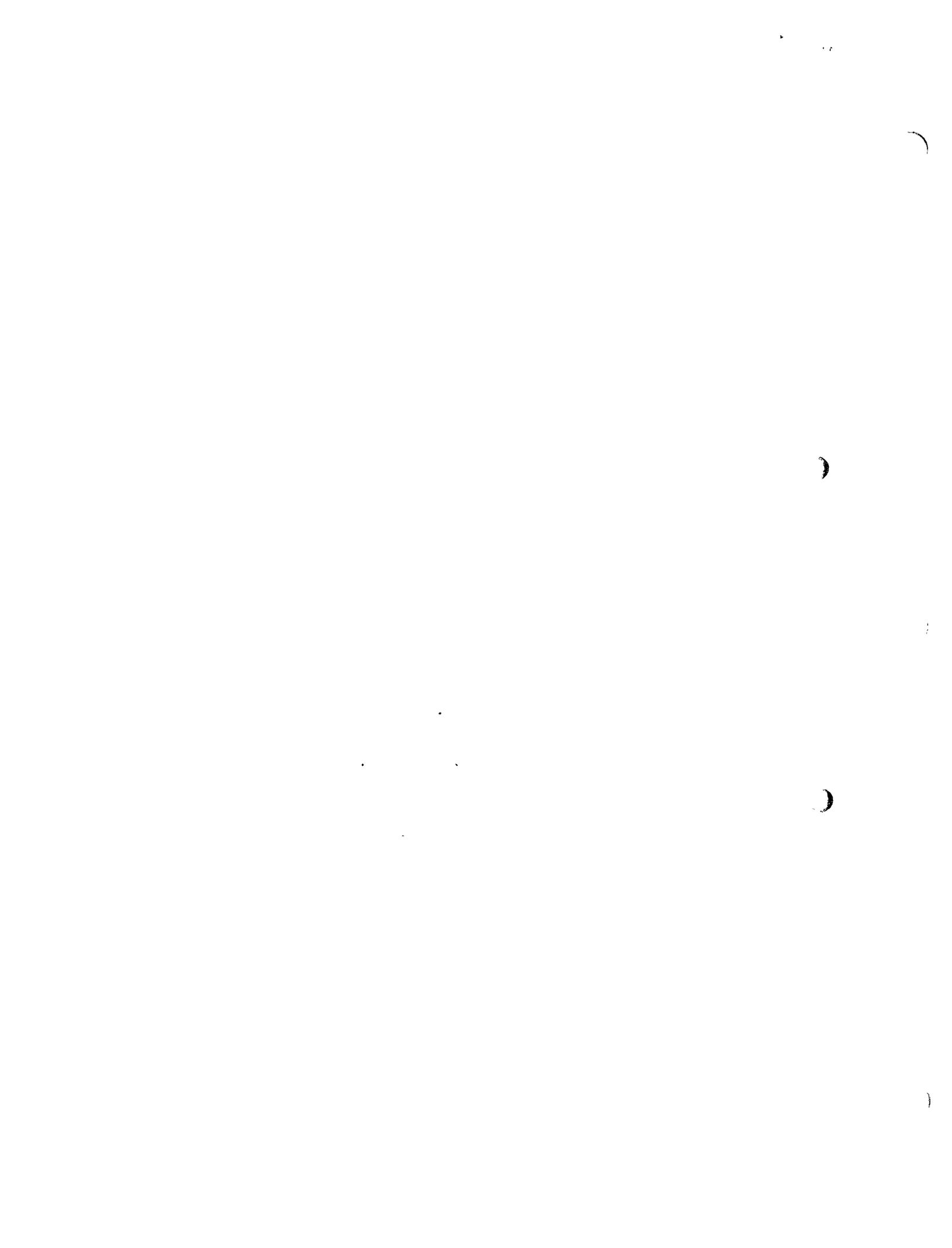
2,4,6-Trianiilino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine

(Project. No. 18H0200/862233)

This amendment contains 3 pages

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Amendment No. 1 to the Report of Oct 09, 1987
Project No.: 18H0200/862233

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STATEMENT
of the Quality Assurance Unit

Number of test substance: 86/200

Name of test substance: 2,4,6-Triamylino-p-(carbo-2'-ethyl-
hexyl-1'-oxi)-1,3,5-triazine

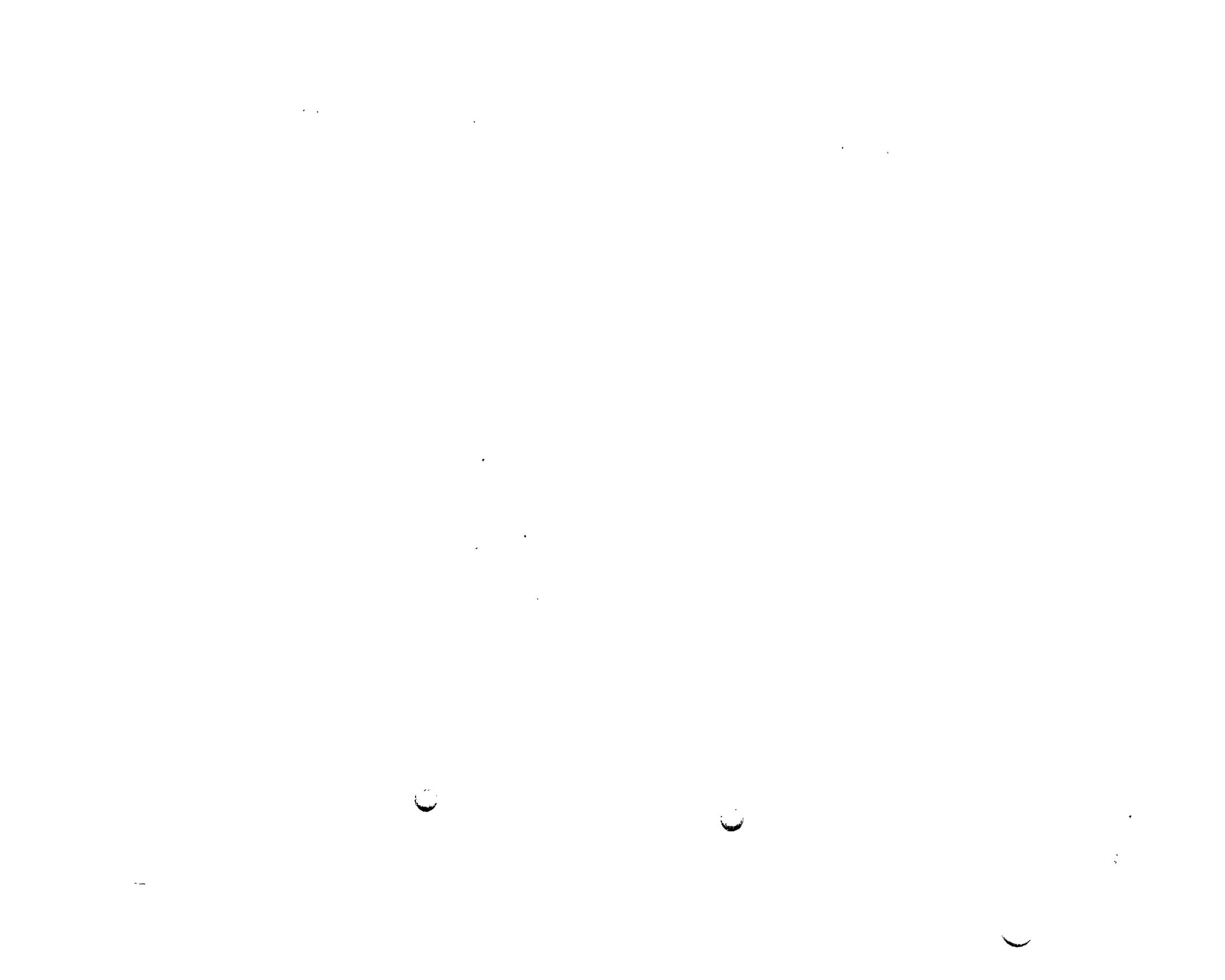
Title: REPORT ON THE ACUTE DERMAL
IRRITATION/CORROSIVITY TO THE INTACT
DORSAL SKIN OF THE WHITE RABBIT
BASED ON OECD

The Quality Assurance Unit audited the amendment dated *May 10, 1995*
to the report of Oct. 09, 1987.

Date of audit: *May 10, 1995*

Ludwigshafen, *May 10, 1995*

.....
J. Hajok
(Quality Assurance Unit)



Amendment No. 1 to the Report of Oct 09, 1987
Project No.: 18H0200/862233

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Sheet 3: APPLICATION VOLUME

The test patch of 2.5 cm x 2.5 cm was covered with a 50 % (w/w) aqueous suspension of the test substance. The suspension was carefully applied to the patch in such manner that the whole patch was fully covered with a layer of the suspension. Thus, a close contact of the moistened test substance with the animals' skin was guaranteed over the whole test area. By visual inspection, the layer was approx. 0.5 mm thick, thus a volume of approx. $2.5 \times 2.5 \times 0.05 \text{ cm}^3 = 0.3 \text{ cm}^3$ was applied to the skin. Considering a density of $> 1 \text{ g/cm}^3$ of the test substance and considering that it was shown in previous studies with similar formulations that the test patches are loaded with approx. 0.5 g of formulations, it was assumed that also in this study the amount of the test substance preparation was approx. 0.5 g.

Hildebrand. 9. V. 87
Dr. med. vet. Hildebrand
(Head of Experimental Toxicology)

Kirsch May 9, 1995
Dr. med. vet. Kirsch
(Study Director)

