

CIBA-GEIGY

Textile Products Division

CIBA-GEIGY Corporation
P.O. Box 18300
Greensboro, North Carolina 27419-8300
Telephone 919 632 6000

Contains NO CBI

October 9, 1992

(A)

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

8EHQ -92-12290

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

88920010506

INIT

Attention: Section 8(e) Coordinator (CAP Agreement)

RE: 8E CAP - 0024

Dear Section 8(e) Coordinator:

Enclosed are triplicate copies of a study CIBA-GEIGY Corporation is submitting pursuant to the TSCA Section 8(e) Compliance Audit Program and CAP Agreement number 8E CAP-0024. The information being submitted is not considered Confidential Business Information. We are submitting the following information, as required by the CAP Agreement:

Company Name: CIBA-GEIGY Corporation
444 Saw Mill River Road
Ardsley, New York 10502-2699

uc
RECEIVED
11/26/95

Attention: Mr. Anthony Di Battista
Manager, Regulatory Affairs & Toxic Substances
Compliance
Telephone (914) 479-2776

Tested Chemical: 3H-Indolium, 2-{{(4-methoxyphenyl)methylhydrazono}methyl}-1,3,3-trimethyl-, methyl sulfate; also identified as FAT 92'213/A

CAS No.: 54060-92-3

Report Title: Primary Eye Irritation Study with FAT 92'213/A in Rabbits; (Project No. 233313, dated (reported) 2/28/89)

Summary: The test material was conducted according to OECD Guidelines for Testing of Chemicals, Section 4: Health Effects, No. 405 "Acute Eye Irritation/Corrosion" adopted February 24, 1987, and Directive 84/449 EEC, B.5. "Acute Toxicity - Eye Irritation." The test material (0.1g) was placed into the conjunctival sac of one male and one female New Zealand White rabbit and the eyes were examined 1, 24, 48, and 72 hours and 7



"THE POWER OF PARTNERSHIP"
Textile Products Division

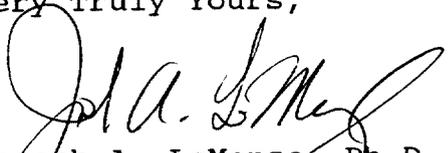
days after administration. Under these conditions the test material caused corneal opacity which was still present 7 days after treatment. This study is being submitted based on this unexpected finding of eye corrosion potential and the potential for human exposure.

Category: Unit II.B.2.b

Prior Reporting: Not Applicable

Please call the undersigned at telephone number (919) 632-2889 if you have any questions about this submittal.

Very Truly Yours,



Joseph A. LoMenzo, Ph.D.
Product Stewardship Director
Textile Products Division

Enclosures

- 2 copies of this letter
- 3 copies of the study

cc: A. Di Battista

Maxilon Golden Yellow GL
Metho sulfate Cande Dry
176108 200

RCC NOTOX
Research and Consulting Company b.v.

R C C

R E S E A R C H & C O N S U L T I N G C O M P A N Y A G

RCC PROJECT 233313

PRIMARY EYE IRRITATION STUDY WITH

FAT 92'213/A

IN RABBITS

REPORT

Authors : L. Ullmann, T. Porricello.

Performing Laboratory: RCC, Research & Consulting Company AG,
P.O. Box, CH 4452 Itingen

- Page 1 out of 27 -

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PREFACE

GENERAL

| | |
|----------------------|---|
| Title | Primary eye irritation study in rabbits. |
| Sponsor | CIBA-GEIGY AG FC 6.1/K-1363.318 Postfach CH-4002 Basel |
| Monitoring Scientist | Frau Dr. S. Uhl |
| Testing Facility | Research & Consulting Company AG CH 4452 Itingen / Switzerland |
| RCC Project Number | 233313 |
| Test Article | FAT 92'213/A |
| Test System | Rabbits |

PROJECT STAFF

| | |
|------------------------|---------------|
| Study Director: | L. Ullmann |
| Technical Coordinator: | T. Porricello |
| Study Veterinarian: | Th. Janiak |

SCHEDULE

| | |
|---------------------------|------------------------|
| Acclimatization | February 3 to 6, 1989 |
| Treatment/ Observation | February 7 to 14, 1989 |
| Termination | February 14, 1989 |
| Reported | February 28, 1989/ vdf |

ARCHIVING

Research and Consulting Company AG, CH 4452 Itingen / Switzerland will archive the following data for at least 10 years:
raw data, report, duplicate of report and test article reference sample.

PROJECT STAFF SIGNATURES

Study Director :

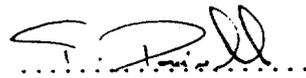
L. Ullmann


.....

Date: Feb. 28, 1989

Technical Coordinator :

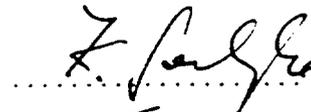
T. Porricello


.....

Date: Feb. 28, 1989

Managing Director :

Dr. K. Sachsse


.....

Date: Feb. 28, 1989

GOOD LABORATORY PRACTICE

STATEMENT OF COMPLIANCE

RCC
PROJECT NUMBER : 233313
TEST ARTICLE : FAT 92'213/A
STUDY DIRECTOR : L. Ullmann
TITLE : Primary eye irritation study in rabbits.

To the best of my knowledge and belief, the study described in this report was conducted in compliance with the following Good Laboratory Practice Standards:

Environmental Protection Agency - Pesticide Programs; Good Laboratory Practice Standards; Final Rule, U.S.A. Federal Register, Vol. 48, No. 230, November 29, 1983.

OECD Principles of Good Laboratory Practice, Paris, France, adopted May 12, 1981.

Study Director

L. Ullmann


Date: Feb. 28, 1989

TEST GUIDELINES

The study procedures described in this report are based on the following guidelines:

OECD Guidelines for Testing of Chemicals, Section 4: Health Effects, No. 405
"Acute Eye Irritation / Corrosion" adopted February 24, 1987.

Directive 84/449 EEC, B.5. "Acute Toxicity - Eye Irritation".

SUMMARY

Under the conditions of this experiment, FAT 92'213/A was found to cause a primary irritation score of 6.63 when applied to the rabbit eye mucosa.

An orange staining of the cornea, conjunctivae, nictitating membrane and eyelashes of the treated eyes by pigment or coloring of the test article was observed.

Corneal opacity was observed in both animals 24 hours to 7 days after test article application.

According to EEC Council Directive, 83/467/EEC, July 1983 Brussels, Belgium, the mean value of the scores for each type of lesion, calculated for each animal separately, is the following:

| Animal No. | Mean 24 - 72 hours | | | |
|------------|--------------------|------|-------------------------------------|------|
| | Cornea Opacity | Iris | Conjunctivae Redness Chemosis | |
| 20 Male | 2.00 | 1.00 | 2.00 | 3.00 |
| 21 Female | 1.67 | 1.00 | 2.00 | 3.00 |

OBJECTIVE

PURPOSE AND RATIONALE

The purpose of this primary eye irritation study was to assess the possible irritation potential when single doses of FAT 92'213/A were placed in the conjunctival sac of rabbit eyes.

This study should provide a rational basis for risk assessment in man.

The test article was administered at the following dose level, determined by the nature of the test article:

Solid: 0.1 g / animal

MATERIALS AND METHODS

Experimental Design

TEST SYSTEM

| | |
|--------------------------------------|--|
| Test system | Rabbits, New Zealand White, KFM (SPF-Quality) |
| Rationale | Recognized by the international guidelines as the recommended test system (e.g. EPA, OECD, EEC). |
| Source | Kleintierfarm Madoerin AG CH 4414 Fuellinsdorf / Switzerland |
| Total number of animals | 1 male 1 female |
| Age at start of treatment | male : 14 weeks female : 15 weeks |
| Body weight at start of treatment | male : 2.8 kg female : 2.7 kg |
| Identification | By unique cage number and corresponding ear tags. |
| Acclimatization | Four days under laboratory conditions after veterinary examination. |

HUSBANDRY

Room No.: 138

Conditions

Standard Laboratory Conditions. Air-conditioned with 10-15 air changes per hour and hourly monitored environment with temperature 20±3 degrees centigrade, relative humidity 40-70 %, 12 hours artificial fluorescent light/12 hours dark, music/light period.

Accommodation

Individually in stainless steel cages equipped with an automatic cleaning and drinking system (Dipl. Ing. W. Ehret GmbH, Versuchstierteknik, D-7830 Emmendingen / FRG).

Diet

Pelleted standard Kliba 341, Batch 42/88 rabbit maintenance diet ("Kliba", Klingentalmuehle AG, 4303 Kaiseraugst, Switzerland) ad libitum. Results of analysis for contaminants are included in this report.

Water

Community tap water from Itingen, ad libitum. Results of analysis for contaminants are included in this report.

TEST ARTICLE

| | |
|----------------|--------------------------|
| Identification | FAT 92'213/A |
| Description | solid |
| Batch Number | Partie 1/88 |
| Purity | AS: approximately 89.6 % |

| | |
|--------------------|--|
| Safety precautions | Gloves, goggles and face mask were sufficient to assure personnel health and safety. |
|--------------------|--|

TEST ARTICLE PREPARATION

The test article was applied undiluted as delivered by the sponsor.

TREATMENT

The eyes of the animals were observed 24 hours prior to test article administration.

The test article (0.1 g) was placed in the conjunctival sac of the left eye of each animal after gently pulling the lower lid away from the eyeball. The lids were then gently held together for about one second to prevent loss of the test article. The right eye remained untreated and served as the reference control.

In cases of equivocal results when comparing the treated and untreated eyes, the illustrated guide from the Consumer Product Safety Commission, Washington, D.C. 20207 was used for additional control purposes.

Rationale:

Ocular contact is one of the probable routes of human exposure.

OBSERVATIONS

Viability / Mortality Daily.

Body Weights Day 1 of test (application day) and
at termination of test on a Mettler
PK 16 balance.

Symptoms

The eyes of each animal were examined 1, 24, 48 and 72 hours and 7 days after administration. The irritation was assessed according to the OECD Guidelines for testing of Chemicals, Section 4, number 405 "Acute Eye Irritation/Corrosion" adopted February 24, 1987.

The corrosive properties of the test article and the staining of the treated eye were described and recorded.

The following numerical scoring system was used to grade the eye lesions:

EVALUATION OF EYE REACTIONS

CORNEAL IRRITATION

Opacity: degree of density (densest area used for assessment)

| | |
|---|-----|
| No ulceration or opacity | 0 |
| Scattered or diffuse areas of opacity (other than slight dulling of normal luster), details of iris clearly visible | 1 * |
| Easily discernible translucent area, details of iris slightly obscured | 2 * |
| Nacrous area, no details of iris visible, size of pupil barely discernible | 3 * |
| Opaque cornea, iris not discernible through the opacity | 4 * |

IRIDIC IRRITATION

| | |
|--|-----|
| Normal | 0 |
| Markedly deepened rugae, congestion, swelling, moderate circumcorneal hyperemia, or injection, any of these or combination thereof, iris still reacting to light (sluggish reaction is positive) | 1 * |
| No reaction to light, hemorrhage, gross destruction (any or all of these) | 2 * |

* Starred figures indicate positive effect

CONJUNCTIVAL IRRITATION

Redness (refers to palpebral and bulbar conjunctivae, cornea and iris).

| | |
|---|-----|
| Blood vessels normal | 0 |
| Some blood vessels definitely hyperemic (injected) | 1 |
| Diffuse, crimson color, individual vessels not easily discernible | 2 * |
| Diffuse beefy red | 3 * |

Chemosis: lids and/or nictating membranes

| | |
|--|-----|
| No swelling | 0 |
| Any swelling above normal (includes nictating membranes) ... | 1 |
| Obvious swelling with partial eversion of lids | 2 * |
| Swelling with lids about half closed | 3 * |
| Swelling with lids more than half closed | 4 * |

The maximum scores are:

| | |
|--------------------------|---------------------------|
| Cornea - 4 | Conjunctival Redness - 3 |
| Iris - 2 | Conjunctival Chemosis - 4 |
| Maximum attainable score | - 13 |

Eye examinations were made with a slit-lamp 30 SL/M (C. Zeiss AG, Zuerich / Switzerland) and a Varta Cliptrix diagnostic-lamp (A. Riegger, Basel / Switzerland).

TREATMENT OF RESULTS

Data are summarized in tabular form, showing for each individual animal the irritation scores at the designated observation time, a description of the degree and nature of irritation, the presence of serious lesions and non-ocular effects.

To calculate the irritation effect all scores of each animal at each of the following reading times (24, 48, 72 hours) were used in calculating the respective mean values (Council Directive 83/467/EEC, July 1983, Brussels, Belgium).

* Starred figures indicate positive effect

EVALUATION OF RESULTS

The ocular irritation scores were evaluated in conjunction with the nature and reversibility or otherwise of the responses observed. The individual scores do not represent an absolute standard for the irritant properties of a material, and they are viewed as reference values and are only meaningful when supported by a full description and evaluation of these observations.

PATHOLOGY

Necropsy

The observation was terminated 7 days after administration of the test article. All rabbits were killed by an intravenous injection of T61 (Hoechst/AG) into the ear vein and discarded.

DATA COMPILATION

The following data were recorded on data sheets and transcribed for compilation and analysis:

irritation scores,
coloration,
corrosion,
toxic symptoms.

The primary irritation score was calculated by totaling the individual cumulative scores at 1, 24, 48 and 72 hours and then dividing by the number of figures.

RESULTS

TOXIC SYMPTOMS / MORTALITY

No acute toxic symptoms were observed in the animals during the test period, and no mortality occurred.

IRRITATION

FAT 92'213/A showed a primary irritation score of 6.63 when applied to the rabbit eye mucosa.

COLORATION

In the area of application a orange staining of the cornea, conjunctivae, nictitating membrane and eyelashes by pigment or coloring of the test article was observed.

CORROSION

Corneal opacity was observed in both animals 24 hours to 7 days after test article application.

BODY WEIGHTS

The body weight gain of all rabbits was similar.

NECROPSY

No necropsy was performed. All animals were killed and discarded.

INDIVIDUAL FINDINGS

hours/days after application

Animal No. 20, male

| | | |
|-----------------|----------------|---|
| after 1 hour: | Conjunctivae: | generally severe edema visible; |
| | Sclera: | not visible; |
| | Discharge: | severe; |
| | Discoloration: | cornea, conjunctivae, nictitating membrane and eyelashes orange; |
| after 24 hours: | Cornea: | ventral clearly visible opacity; |
| | Iris: | slight reaction to light; |
| | Conjunctivae: | generally clearly visible erythema; generally severe edema visible; |
| | Sclera: | not visible; |
| | Discharge: | slight; |
| | Discoloration: | eyelashes clearly visible orange; |
| after 48 hours: | Cornea: | ventral clearly visible opacity; erythema; |
| | Iris: | slight reaction to light; |
| | Conjunctivae: | generally clearly visible erythema; generally severe edema visible; |
| | Sclera: | not visible; |
| | Discharge: | slight; |
| | Discoloration: | eyelashes clearly visible orange; |

INDIVIDUAL FINDINGS

hours/days after application

Animal No. 20, male

| | | |
|-----------------|----------------|---|
| after 72 hours: | Cornea: | generally clearly visible opacity; |
| | Iris: | slight reaction to light; |
| | Conjunctivae: | generally clearly visible erythema; generally severe edema visible; |
| | Sclera: | not visible; |
| | Discharge: | slight; |
| | Discoloration: | eyelashes clearly visible orange; |
| after 7 days: | Cornea: | generally severely visible opacity; cornea slight deformed; |
| | Iris: | slight reaction to light; |
| | Conjunctivae: | generally clearly visible erythema; generally severe edema visible; |
| | Sclera: | not visible; |
| | Discharge: | slight; |
| | Discoloration: | eyelashes clearly visible orange; |

INDIVIDUAL FINDINGS
hours/days after application

Animal No. 21, female

| | | |
|-----------------|----------------|---|
| after 1 hour: | Conjunctivae: | generally severe edema visible; |
| | Sclera: | not visible; |
| | Discharge: | severe; |
| | Discoloration: | cornea, conjunctivae, nictitating membrane and eyelashes orange; |
| after 24 hours: | Cornea: | generally slight opacity visible; |
| | Iris: | slight reaction to light; |
| | Conjunctivae: | generally clearly visible erythema; generally severe edema visible; |
| | Sclera: | not visible; |
| | Discharge: | moderate; |
| | Discoloration: | eyelashes clearly visible orange; |
| after 48 hours: | Cornea: | ventral clearly visible opacity; cornea generally erythema; |
| | Iris: | slight reaction to light; |
| | Conjunctivae: | generally clearly visible erythema; generally severe edema visible; |
| | Sclera: | not visible; |
| | Discharge: | moderate; |
| | Discoloration; | eyelashes clearly visible orange; |

INDIVIDUAL FINDINGS

hours/days after application

Animal No. 21, female

| | | |
|-----------------|----------------|--|
| after 72 hours: | Cornea: | generally clearly visible opacity; |
| | Iris: | slight reaction to light; |
| | Conjunctivae: | generally clearly visible erythema; generally severe edema visible; |
| | Sclera: | not visible; |
| | Discharge: | moderate; |
| | Discoloration: | eyelashes clearly visible orange; |
| after 7 days: | Cornea: | opacity; cornea slight deformed; |
| | Iris: | no reaction to light; iris not visible; |
| | Conjunctivae: | generally clearly visible erythema; generally severe edema with half to totally closed lids; |
| | Sclera: | not visible; |
| | Discharge: | severe; |
| | Discoloration: | eyelashes clearly visible orange. |

RCC PROJECT 233313
FAT 92'213/A

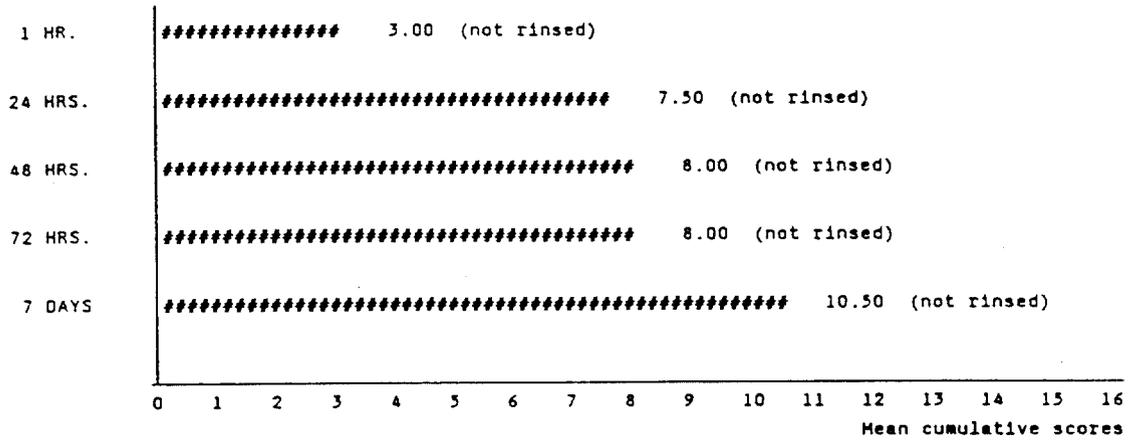
APPENDIX A

EYE IRRITATION SCORES

EYE IRRITATION SCORES

| ANIMAL | SEX | | CORNEA OPACITY | IRIS | CONJUNCTIVAE REDN. | CHEM. | CUMUL. SCORE | MEAN CUMUL. SCORE |
|---------|-----|------------|-------------------|------|-----------------------|-------|-----------------|----------------------|
| 1 HR. | | | | | | | | |
| 20 | M | NOT RINSED | 0 | 0 | 0 | 3 * | 3 | 3.00 |
| 21 | F | NOT RINSED | 0 | 0 | 0 | 3 * | 3 | |
| 24 HRS. | | | | | | | | |
| 20 | M | NOT RINSED | 2 * | 1 * | 2 * | 3 * | 8 | 7.50 |
| 21 | F | NOT RINSED | 1 * | 1 * | 2 * | 3 * | 7 | |
| 48 HRS. | | | | | | | | |
| 20 | M | NOT RINSED | 2 * | 1 * | 2 * | 3 * | 8 | 8.00 |
| 21 | F | NOT RINSED | 2 * | 1 * | 2 * | 3 * | 8 | |
| 72 HRS. | | | | | | | | |
| 20 | M | NOT RINSED | 2 * | 1 * | 2 * | 3 * | 8 | 8.00 |
| 21 | F | NOT RINSED | 2 * | 1 * | 2 * | 3 * | 8 | |
| 7 DAYS | | | | | | | | |
| 20 | M | NOT RINSED | 3 * | 1 * | 2 * | 3 * | 9 | 10.50 |
| 21 | F | NOT RINSED | 4 * | 2 * | 2 * | 4 * | 12 | |

EYE IRRITATION: MEAN CUMULATIVE SCORES



EYE IRRITATION: MEAN SCORES

| ANIMAL | SEX | | CORNEA OPACITY | IRIS | CONJUNCTIVAE REDN. | CHEM. | CUMUL. SCORE | MEAN CUMUL. SCORE |
|--------|-----|------------|-------------------|------|-----------------------|-------|-----------------|----------------------|
| 20 | M | NOT RINSED | 2.00 | 1.00 | 2.00 | 3.00 | 8.00 | |
| 21 | F | NOT RINSED | 1.67 | 1.00 | 2.00 | 3.00 | 7.67 | 7.83 |

SELECTED OBSERVATIONS FOR MEAN SCORES: 24 HRS.
48 HRS.
72 HRS.

PRIMARY IRRITATION SCORE

NOT RINSED: 6.63

SELECTED OBSERVATIONS FOR PRIMARY IRRITATION SCORES: 1 HR.
24 HRS.
48 HRS.
72 HRS.

RCC PROJECT 233313
FAT 92'213/A

APPENDIX B

ATTACHMENTS

WATER ANALYSES -
Bacteriological and Chemical Assays

CONTAMINANT ANALYSIS OF FEED

RCC PROJECT 233313
FAT 92'213/A

BACTERIOLOGICAL ASSAY OF DRINKING WATER, ITINGEN

Official Laboratory
Basel-Landschaft

Liestal, 28.04.88
Ref.no. 88040178
88040179
88040181
88040182

Sampling points: 1) 59.1.AU, source water, UV-irradiated
2) 59.70.N, water from Sissach, connection
to reservoir Sonnenberg
3) 59.90.N, running fountain, Alte Landstr. 61
4) 59.A.1, Pumping station "Gstaadmatt"

Sampled on: 21.04.88

| Sample: | 1) | 2) | 3) | 4) |
|-------------------------------------|-------|-------|-------|-------|
| Time of Sampling | 07.40 | 08.05 | 08.15 | 07.55 |
| Water temperature (°C) | 8.2 | 10.3 | 10.0 | 11.4 |
| Air temperature (°C) | 6.0 | 6.0 | 6.0 | 6.0 |
| Weather condition prior to sampling | rainy | | | |
| Weather condition during sampling | clear | | | |

BACTERIOLOGICAL TEST:

| | | | | |
|------------------------------------|---|----|----|---|
| Aerobic mesophilic bacteria /ml | 7 | 20 | 11 | 1 |
| E.coli /100 ml | 0 | 0 | 0 | 0 |
| Enterococci /100 ml | 0 | 0 | 0 | 0 |

ASSESSMENT:

At the time of sampling, the tested bacteriological parameters were flawless, and met the requirements for drinking water according to article 260 of the "Eidg. Lebensmittelverordnung".

Official Laboratory
The Official Chemist
(signed Dr. W. Stutz)

RCC PROJECT 233313
FAT 92'213/A

CHEMICAL WATER ANALYSIS, ITINGEN

Official Laboratory
Basel-Landschaft

Liestal, 28.04.88
Ref.No. 88040182

Location:

59.A.1, Pumping station "Gstaadmatt"

Date of sampling
Time of sampling
Water temperature (°C)
Air temperature (°C)
Weather condition prior to sampling
Weather condition during sampling

21.04.88
07.55 a.m.
11.4
6.0
rain
clear

Appearance
Odor
Taste

clear, colorless
not remarkable
not remarkable

| | | |
|---------------------------------------|-------|---------|
| Total hardness | fr.H° | 41.5 |
| Alkaline hardness | fr.H° | 29.2 |
| Non carbonate hardness | fr.H° | 12.3 |
| Conductivity at 20 °C | µS/cm | 706.0 |
| Oxygen demand (KMnO4 cons.) | mg/l | 1.8 |
| Free ammonia NH4+ | mg/l | <0.0100 |
| Nitrite NO2- | mg/l | <0.0050 |
| Nitrate NO3- | mg/l | 32.0 |
| Chloride Cl- | mg/l | 25.7 |
| Sulphate SO4-- | mg/l | |
| Calcium Ca++ | mg/l | |
| Magnesium Mg++ | mg/l | |
| Dry residue | mg/l | |
| pH electrometrically | | |
| Free carbonic acid CO2 potentiometric | | |
| Free carbonic acid CO2 | mg/l | |
| Excess carbonic acid CO2 | mg/l | |
| Oxygen | mg/l | |
| Oxygen % saturation | | |

The water sample meets the chemical requirements for drinking water according to article 260 of the "Eidg. Lebensmittelverordnung". The values for nitrate and chloride exceed the recommended limits slightly.

Official Laboratory
The Official Chemist
(signed Dr. W. Stutz)

RCC PROJECT 233313
FAT 92'213/A

CONTAMINANT ANALYSIS OF DRINKING WATER, ITINGEN

Date of sampling: 06.04.88
Sample: Tap water RCC Itingen, Room U 10

| Parameter | Assay level mg/kg |
|-----------|----------------------|
|-----------|----------------------|

| | |
|---|--------|
| Lindane | <0.005 |
| Heptachlor | <0.005 |
| Malathion | <0.5 |
| DDT, total | <0.025 |
| Dieldrin | <0.005 |
| PCB's | <0.025 |
| Cadmium | <0.02 |
| Arsenic | <0.15 |
| Lead | <0.25 |
| Mercury | <0.05 |
| Selenium | <0.15 |
| Copper | <0.15 |
| Nitrosamines (DMN, DEN, NPIP, NMORPH), total | <0.01 |

< 0.001 = less than 0.001 milligram per kilogram

May 2, 1988
signed Dr. P. Mladenovic

ANALYTICAL TEST REPORT

Project 228137
02.12.1988

Prepared for : Klingentalmuehle AG
CH-4303 Kaiseraugst

Attention of : Dr. A. Oharek

Materials tested : Kliba 341, Batch 42/88
01.12.1988

Tests performed : AAS, GC, GC-MS, HPLC

Test results : See attached Table 1

Submitted : M. Kern

Issued by : Dr. P. Mladenovic


.....
December 16, 1988 /sad

The undersigned confirms that analysis of KLIBA-feed (number 341, Batch 42/88, manufactured 01.12.1988) was performed, and that this certificate represents accurately the analysis results of the feed delivered.

Date: 19.12.1988

KLINGENTALMUEHLE AG





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

Joseph A. LoMenzo, Ph.D.
Product Stewardship Director
Textile Products Division
CIBA-GEIGY Corporation
P.O. Box 18300
Greensboro, North Carolina 27419-8300

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 24 1995

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

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

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

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

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

Sincerely,

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

Enclosure

12290A



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Triage of 8(e) Submissions

Date sent to triage: 12/14/95

NON-CAP

CAP

Submission number: 12290 A

TSCA Inventory:

Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

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

Notes:

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

| | |
|---|-------------------------|
| For Contractor Use Only | |
| entire document: <u>(0)</u> 1 2 pages <u>1, 2</u> | pages <u>1, 2, tabs</u> |
| Notes: | |
| Contractor reviewer : <u>LPS</u> | Date: <u>4/11/95</u> |

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:

Submission # BEHQ-1192-12290 SEQ. A

TYPE: (NT) SUPP FLWP

SUBMITTER NAME: Ciba-Geigy
Corporation

INFORMATION REQUESTED: FLWP DATE: _____

- 0501 NO INFO REQUESTED
- 0502 INFO REQUESTED (TEC1)
- 0503 INFO REQUESTED (VOL ACTIONS)
- 0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:

- (650) REFER TO CHEMICAL SCREENING
- (670) CAP NOTICE

VOLUNTARY ACTIONS:

- (0401) NO ACTION REPORTED
- 0402 STUDIES PLANNED/IN PROGRESS
- 0403 NOTIFICATION IN WORKING STATUS
- 0404 LABELS/MSDS CHANGES
- 0405 PROCESS/ANALYSIS CHANGES
- 0406 APP/USE DISCONTINUED
- 0407 PRODUCTION DISCONTINUED
- 0408 CONFIDENTIAL

SUB. DATE: 10/09/92 OTS DATE: 11/02/92 CSRAD DATE: 01/26/95

CHEMICAL NAME:

FAT 92'213/A

CASE

54060-92-3

| INFORMATION TYPE: | P.F.C. | INFORMATION TYPE: | P.F.C. | INFORMATION TYPE: | P.F.C. |
|---------------------------------|----------|--------------------------------|----------|---------------------------|----------|
| 0201 ONCO (HUMAN) | 01 02 04 | 0216 EPICLEN | 01 02 04 | 0341 IMMUNO (ANIMAL) | 01 02 04 |
| 0202 ONCO (ANIMAL) | 01 02 04 | 0217 HUMAN EXPOS (PROD CONTAM) | 01 02 04 | 0342 IMMUNO (HUMAN) | 01 02 04 |
| 0203 CELL TRANS (IN VITRO) | 01 02 04 | 0218 HUMAN EXPOS (ACCIDENTAL) | 01 02 04 | <u>0343</u> CHEMPHYS PROP | 01 02 04 |
| 0204 MUTA (IN VITRO) | 01 02 04 | 0219 HUMAN EXPOS (MONITORING) | 01 02 04 | 0344 CLASTO (IN VITRO) | 01 02 04 |
| 0205 MUTA (IN VIVO) | 01 02 04 | 0220 ECOTOXIC TOX | 01 02 04 | 0345 CLASTO (ANIMAL) | 01 02 04 |
| 0206 REPRO/TERATO (HUMAN) | 01 02 04 | 0221 ENV. OCCUREL/FATE | 01 02 04 | 0346 CLASTO (HUMAN) | 01 02 04 |
| 0207 REPRO/TERATO (ANIMAL) | 01 02 04 | 0222 EMER INCI OF ENV CONTAM | 01 02 04 | 0347 DNA DAM/REPAIR | 01 02 04 |
| 0208 NEURO (HUMAN) | 01 02 04 | 0223 RESPONSE REQEST DELAY | 01 02 04 | 0348 PRODUSE/PROC | 01 02 04 |
| 0209 NEURO (ANIMAL) | 01 02 04 | 0224 PROD/COMP/CHEM ID | 01 02 04 | 0251 MSDS | 01 02 04 |
| 0210 ACUTE TOX. (HUMAN) | 01 02 04 | 0225 REPORTING RATIONALE | 01 02 04 | 0299 OTHER | 01 02 04 |
| 0211 CHR. TOX. (HUMAN) | 01 02 04 | 0226 CONFIDENTIAL | 01 02 04 | | |
| <u>0212</u> ACUTE TOX. (ANIMAL) | 01 02 04 | 0227 ALLERG (HUMAN) | 01 02 04 | | |
| 0213 SUB ACUTE TOX (ANIMAL) | 01 02 04 | 0228 ALLERG (ANIMAL) | 01 02 04 | | |
| 0214 SUB CHRONIC TOX (ANIMAL) | 01 02 04 | 0239 METAB/PHARMACO (ANIMAL) | 01 02 04 | | |
| 0215 CHRONIC TOX (ANIMAL) | 01 02 04 | 0240 METAB/PHARMACO (HUMAN) | 01 02 04 | | |

| IRIS DATA | NON-CBI INVENTORY | ONGOING REVIEW | SPECIES | TOXICOLOGICAL CONCERN: | USE: | PRODUCTION: |
|-----------|-------------------|------------------|------------|------------------------|------|-------------|
| | <u>YES</u> | YES (DROP/REFER) | <u>Rbt</u> | LOW | | |
| CAS SR | NO | NO (CONTINUE) | | MED | | |
| | IN PROGRESS | REFER | | <u>HIGH</u> | | |

UNCLASSIFIED

12290A

H

Eye irritation in the rabbit is of high concern. Application of 0.1 g of material into the eye of one male and one female New Zealand white rabbit resulted in severe edema of the conjunctivae with discharge and discoloration. Corneal opacity with erythema and edema persisted for seven days.