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ATOFINA CHEMICALS INC		
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EVIC FRANCE		
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INITIAL SUBMISSION: ACUTE DERMAL IRRITATION/CORROSION TEST IN THE RABBIT WITH TURCO 6881, WITH COVER LET" DATED 10/19/2000		
Chemical Category		
BENZYL ALCOHOL, HYDROGEN PEROXIDE, D-LIMONENE, SODIUM NITRA*		

A 03

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ATOFINA
ATOFINA Chemicals, Inc.

October 19, 2000

UPS NEXT DAY DELIVERY

Document Control Office (7407)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M St., S.W.
Washington, D.C. 20460

Subject: TSCA Section 8(e) Submission

Dear Sir/Madam:

ATOFINA Chemicals, Inc. (ATOFINA) is submitting the final report for an acute dermal irritation study in rabbits to the Environmental Protection Agency (EPA) pursuant to Toxic Substances Control Act (TSCA) Section 8(e). This study provides information on Turco 6881, a formulated mixture containing 58.0% benzyl alcohol (CAS# 100-51-6), 13.5% water (CAS# 7732-18-5), 20% of a 35% hydrogen peroxide (CAS# 7722-84-1) solution, 2.0% d-limonene (CAS# 5989-27-5),1% sodium nitrate (CAS# 7631-99-4) and other minor additives. This study does not involve effects in humans.

Nothing in this letter or the enclosed study is considered confidential business information of ATOFINA.

The results of the skin irritation study with the test material showed the material to be corrosive to rabbit skin after a 4-hour exposure.

Further questions regarding this submission may be directed to me at (215) 419-5890.

Sincerely,

Debra Randall

Debra Randall, DABT
Product Safety Manager

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A 04

STUDY : Tg 182 / 00-0863

TURCO FRANCE

ACUTE DERMAL IRRITATION/CORROSION TEST IN THE RABBIT

TURCO 6881 –

- TEST REPORT -

58% benzyl alcohol (CAS# 100-51-6)
13.5% water
20% of a 35% hydrogen peroxide solution (CAS# 7722-84-1)
2% d-limonene (CAS# 5989-27-5)
1% sodium nitrate (CAS# 7631-99-4)

PG/MCC

13 pages in this report including 5 in Appendices

Blanquefort, May 11, 2000

cofrac
ESSAIS
accréditation
n° 1-0042

The accreditation of COFRAC certifies the competence of the laboratory for the tests covered by the accreditation

This report only concerns the object submitted to the test.

Only the french version is legally acceptable.
Seule la version française fait foi.

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CONTENTS

EVALUATION DE L'EFFET IRRITANT/CORROSIF APRES APPLICATION UNIQUE SUR LA PEAU CHEZ LE LAPIN - LIGNE DIRECTRICE 404 DE L'OCDE (17/7/1982)

ACUTE DERMAL IRRITATION/CORROSION TEST IN THE RABBIT - OECD GUIDELINE 404 (17/7/1982)

RESUME/*SUMMARY*

- Produit étudié/*Test product* : TURCO 6881

- Principe de l'essai/*Principle of the test*

L'objectif de l'essai a été d'apprécier qualitativement et quantitativement l'effet irritant ou corrosif et son délai d'apparition après application cutanée unique de 0,5 ml de préparation testée telle quelle sous pansement semi-occlusif pendant 3 minutes et 4 heures chez 1 lapin.

Les réactions cutanées (érythème et oedème) ont été lues 1h, 24h, 48h et 72 heures après enlèvement du pansement et jusqu'à réversibilité des effets. La préparation testée a été classée selon les critères définis dans l'arrêté du 20/04/94 pris en application de la Directive de base 67/548/CEE et ses amendements successifs.

The aim of the study was to assess qualitatively and quantitatively irritancy or corrosion and the delay of appearance after single skin application of 0.5 ml of test preparation as such, under semi-occlusive dressing for 3 minutes and 4 hours, in 1 rabbit.

The cutaneous reactions (erythema and oedema) were scored 1h and then 24, 48 and 72 hours after patch removal and until complete reversibility of the effects.
The test preparation was classified in accordance with the criteria defined in the decree of 20/04/94 taken in enforcement from the basic Directive 67/548/EEC and its successive amendments.

- Dates de l'essai/*Dates of the test* : du/*from* 10/04/00 au/*to* 27/04/00

- **Résultats/*Results*** :

Animaux/ *Animals*	Score moyen 24h, 48h et 72h après application/ *Mean score 24h, 48h and72h after application*	
	Erythème/*Erythema*	Oedème/*Oedema*
8840	2.7	2.7
	Présence de brûlure/*burning*	

- Conclusion/*Conclusion* :

La préparation testée **est classée** comme **corrosive** avec **risque de brûlures.**
The test preparation is classified as corrosive with burning risks.

1. AIM AND PRINCIPLE OF THE TEST

The aim of the test was to assess qualitatively and quantitatively the irritant or corrosive effect and the rate of onset after single application to skin, of the preparation TURCO 6881, in the Rabbit.

The test preparation was applied in a single dose, under semi-occlusive patch, at 1 animal, one untreated skin area serving as control.

The degree of irritation was read and scored at specified intervals.

The albino Rabbit is the mammalian species commonly used and recommended by the official authorities for the assessment of the cutaneous tolerance of chemical substances by this kind of method.

This test enabled to classify the test preparation in one of the categories defined in the decree of April 20, 1994 taken in enforcement from the basic Directive 67/548/EEC and its successive amendments.

The methodology followed the part B4 appendix V of the Directive 92/69/EEC of July 31, 1992, published in the Official Journal of European Communities of December 29, 1992 (L 383A) and the OECD guideline 404 of July 17, 1992, concerning the tests of chemical products, which defines dermal irritation as the production of reversible inflammatory changes in the skin, and the dermal corrosion as the production of irreversible tissue damage after application of the test preparation.

2. ETHICS AND APPROVALS OF THE TEST FACILITY

The test was entirely performed in the premises of Evic-Tox Department of EVIC france Company in Blanquefort, according to the animal ethical rules mentioned in the European Directive 86/609/EEC of November 24, 1986 and was submitted to the previous agreement of the animal Ethics Committee internal to the Test Facility.

It was covered by the accreditation of COFRAC which certified the technical competence of the Test Facility and by the declaration of confirmity of Evic-Tox Department with the Good Laboratory Practices by the GIPC (decree n° 98-1312 of 31.12.98 published in the Official Journal of the French Republic of January 1st, 1999) and the Agence du Médicament (decree of 20.01.86 published in the Official Journal of the French Republic of February 16, 1986).

3. QUALITY ASSURANCE

All the data collected during the test were recorded by the technician responsible for the test, on the documents reserved for that effect.

Each page of these documents was initialled and dated by the technician responsible for the test.
Any missing data was justified and the corrections were initialled and dated.

The Quality Assurance Unit ensured by periodic inspections that the protocol and working procedures relevant to this type of test were strictly applied.

The experimental data and the test report were audited in accordance with the procedure implemented in the Test Facility.

At the end of the test, the work documents were filed with the test report for 10 years.

At the end of this period, the Test Facility defines with the Sponsor the carrying out of the filing, the restitution of the data or their destruction.

4. DEFINITION OF THE TEST PREPARATION

4.1. Preparation reference

The Sponsor provided for the test 1 glass flask containing approximately 250 ml of the preparation TURCO 6881.

It was a white thick liquid.

This test preparation was coded under the reference 00-0863.

4.2. Storage

The test preparation was stored at ambient temperature and out of the light in a room especially fitted out to that effect.

A sample of the test preparation was filed in the samples library of the Test Facility as a reference where it will be kept until its expiry date or for a maximum period of 10 years.

5. REACTIVE SYSTEM

Species : New Zealand albino rabbit

Origin : Charles River supplier (76410 Saint Aubin les Elbeuf, France)

Weight : superior to 1.8 kg, the day before application of the product

Number and sex : 1 male

Acclimatization : for at least 5 days before the beginning of the test

Identification : the animal was identified by auricular ring and the corresponding number was written on a label put on its cage.

Housing : the animal was individually housed, in stainless steel cage on floor grid (60 cm x 45 cm x 32 cm).

The cage was placed in limited-access premises, of 7 m x 4 m x 3 m, maintained in slight overpressure (a minimum of 10 mm of water), under air-conditioned temperature (t = 20 ± 3°C) and controlled relative humidity (RH = 50 ± 20 %) except during washing cycles and whose renewal in non recycled filtered air (on 99 % filter) was performed at the rate of about 10 cycles per hour.

The artificial lighting ensured a sequence of 12 hours light, 12 hours dark.

Feeding : the complete diet was supplied under pelleted form Ergilap Anco, delivered by the Cofna (37018 Tours, France)

Drinking : tap water distributed in polypropylene bottle with stainless steel teat. A sample of water is taken after each technical intervention from the pipes and every 6 months at least and sent for chemicophysical and bacteriological analysis to a specialized control organization.

Preparation of the animals and selection

Approximately 24 hours before application of the test preparation, fur was removed by close-clipping the dorsal area of the trunk of the animal. Care is taken to avoid abrading the skin and only an animal with healthy intact skin was retained for the test.
If possible, areas of dense hair growth were not used as patch sites.

6. TEST PROCEDURE

6.1. Test preparation

The test preparation was applied as such.

6.2. Experimental chronology

As the test preparation was suspected to cause corrosion, two semi-occlusive patches were applied simultaneously to the animal. The first patch was removed after three minutes. If no serious skin reaction was observed, the second patch was removed after 4 hours and the responses were graded.

6.3. Application of the test preparation

A dose of 0.5 ml of test preparation was applied to two squares of gauze patch of 2.5 cm x 2.5 cm (i.e. 6 cm^2) each one put on a Micropore® tape of 5 cm x 5 cm (i.e. 25 cm^2).

After removal of the 3-minute patch, the rabbit was put back into its cage for the 4-hour exposure period and then the patch was removed. Residual test substance was removed using an absorbent cotton moistened with distilled water.

6.4. Clinical observations and grading of skin reactions

The animal was examined for signs of erythema and oedema and the responses scored at 1 hour, and then at 24, 48, and 72 hours after patch removal. Skin reactions were scored according to the grades below and recorded in the work document reserved for that effect.

Further observations were needed to establish the reversibility of the effects, the daily observation period was 17 days.

In addition to the observation of irritation, all lesions and other toxic effects were recorded and fully described in the work document reserved for that effect.

Grading of skin reactions

*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 eschar formation preventing grading of erythema 4

* *Erythema : redness of skin produced by a vascular congestion or an increased perfusion.*
Eschar (scab) = superficial dry scab at the site of a thermal or caustic burning and which contains cell remains, a dried tissue exsudate and covers the skin in healing.

*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 mm) 3
Severe oedema (raised more than 1 mm and extending beyond area of exposure) 4

* *Oedema = presence of abnormally important quantities of liquid in the intercell spaces of the epidermic, dermal and under-cutaneous tissues.*

6.5. Interpretation of the results

The test preparation was classified according to the criteria of classification and labelling of the dangerous chemical substances defined in the EEC 67/548 basic Directive and its successive amendments.

Criteria of classification	Sentences of risk
Substances or preparations classified as corrosive whether they produce tissue damages on the whole depth of skin, in one animal at least, when they are applied to healthy and intact skin, during the test, or whether the result can be predicted : ***reaction strongly acid (pH ≤ 2) or strongly alkaline (pH ≥ 11,5).***	
• These tissue damages appear after an exposure time not exceeding 3 minutes ; or such a result is foreseeable.	R 35 Produces severe burns
• These tissue damages appear after an exposure time not exceeding 4 hours ; or such a result is foreseeable.	R 34 Produces burns
Non corrosive substances or preparations classified as irritant if they produce an inflammation of the skin, present at least 24h after an exposure period not exceeding 4 hours. ****judged important from the indexes observed during the test :***	
• If for nb of animals > 3 : mean value of the scores for erythema and eschar formation or oedema formation calculated for all the animals and the 3 times of observation (24, 48 and 72h) ≥ 2	R 38 Irritant to skin
• If for nb of animals = 3 : mean individual scores for erythema and eschar formation or oedema formation calculated on the 3 times of observation (24, 48 and 72h) ≥ 2 in 2 animals at least.	
*or in case of persistence at the end of the observation *period :n 2 animals at least*	

7. RESULTS

The weight of the animal at the beginning (D-1) and at the end of the test (De) is supplied in Appendix I.

The results of the clinical observations are summarized in the table enclosed in Appendices II.

Cutaneous irritation results summarised in tabular form, showing for the animal, the irritation scores for erythema and oedema at 1, 24, 48 and 72 hours after patch removal, the description of the observed effect and its reversibility are enclosed in Appendices III.

8. DISCUSSION

The application for 4 hours of the product TURCO 6881 to the intact skin of the rabbit induced the appearance of severe oedema and of a well defined erythema since the first reading.
On D2, the appearance of a burning on the whole surface of the patch is observed as well as a moderate oedema. From D4, a serofibrinous scab covers the burning and lasts until D16 where a cicatricial area is observed showing that there had been a tissue destruction after application of the product.

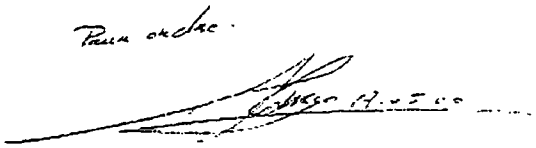
9. CONCLUSION

Taking into account the criteria defined by the EEC 67/548 Directive and its successive amendments, the preparation TURCO 6881 was classified corrosive with burning risks.

10. STUDY RESPONSIBLE PERSONNEL'S STATEMENT

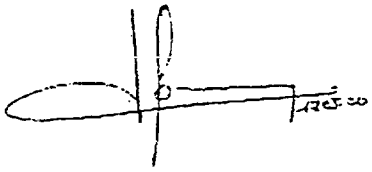
Test Facility Management

I the undersigned, **Philippe MASSON**, declare to have designated **Patrick GOMOND** as the Study Director and ensured that he approved the study plan with full knowledge of the facts and made it available to the Quality Assurance personnel.



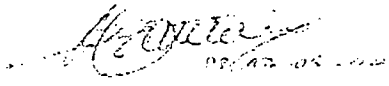
Study Director

I the undersigned, **Patrick GOMOND**, declare that the overall conduct of the study was carried out under my responsibility and in accordance with the principles of Good Laboratory Practices (decree n°98-1312 of 31.12.98 published in the Official Journal of the French Republic of January 1st, 1999 and decree of 20.01.86 published in the Official Journal of the French Republic of February 16, 1986).



Quality Assurance Personnel

I the undersigned, **Nathalie DROSS**, declare that :
- this kind of study was inspected according to the procedure of the Test Facility on April 11, 2000,
- the report of the inspection was transmitted to the Management and to the Study Director on April 17, 2000,
- the final report was examined on May 15, 2000,
- the results reported accurately and completely reflect the raw data of the study.



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Appendix I

Body Weight

Animal n°	Weight (in kg)	
	D-1	De
8840	2.490	2.550

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Appendix II-1

Clinical examinations
Exposure time 3 minutes

Reading time	Comments
	Animal n° 8840
D-1	NTR
D1 (1h)	NTR
D2	NTR
D3	NTR
D4	NTR
D5	/
D6	/
D7	/
D8	/
D9	/
D10	/
D11	/
D12	/
D13	/
D14	/
D15	/
D16	/
D17	/

Legend : / : no reading
NTR : nothing to report