

elf atochem

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ELF ATOCHEM NORTH AMERICA, INC.
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King of Prussia, PA 19406-0018

Confidential

Tel: 215-337-6500

8EHQ-0993-12711

September 28, 1993



**FEDERAL EXPRESS
RETURN RECEIPT REQUESTED**



8EHQ-93-12711
INIT 09/29/93

Document Processing Center (TS-790)
Office of Toxic Substances
Environmental Protection Agency
401 M St. S.W.
Washington, D.C. 20460
Attn: Section 8(e) Coordinator



88930000469

Subject: TSCA Section 8(e) Submission

09/29/93 11:40

Dear Sir/Madam:

Elf Atochem North America Inc. is submitting the attached study to the Environmental Protection Agency (EPA) pursuant to Toxic Substances Control Act (TSCA) Section 8(e). This study does not involve effects in humans.

The enclosed study recently came into our possession via our parent company in France and provides information on TPS 44. TPS 44 is Tertiarybutyl trisulfide (CAS No. 68937-96-2). This material is a market development product to be used as a presulfiding agent.

Nothing in this letter or the enclosed study report is considered confidential business information of Elf Atochem.

The title of the enclosed study report is TPS 44 Skin Sensitization Test in Guinea-Pigs. The following is a summary of the adverse effects observed in the skin sensitization test.

TPS 44 was tested for potential to produce allergic skin reaction by intradermal injection and skin application to guinea pigs using a modified Magnusson and Klingman method. The test material produced a 45% (9/20) sensitization rate and was classified as a moderate sensitizer.

RECEIVED
10-25-93

31 pgs.

TSCA 8(e) Submission
TPS 44
September 28, 1993
Page 2

Elf Atochem has not previously filed any 8(e) notices or Premanufacture Notifications (PMNs) on the subject material.

Results from the study report will be incorporated into the current Elf Atochem Material Safety Data Sheet for TPS 44.

Further questions regarding this submission may be directed to me at (215) 337-6892.

Sincerely,



C.H. Farr, PhD, DABT
Manager, Product Safety
and Toxicology

Enclosure

TPS 44

SKIN SENSITIZATION TEST

IN GUINEA-PIGS

(according to Magnusson, B. and Kligman, A.M.)

Addressee

Mr. J.F. Régnier

SNEA(P)

Usine de Lacq

B.P. 22

64170 Artix

France

Date: 30.7.92

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STATEMENT OF THE STUDY DIRECTOR

This study was performed in accordance with the protocol agreed upon by SNEA(P), the maximization method of Magnusson and Kligman, the recommendations of the O.E.C.D. Guideline No. 406 and according to the Principles of Good Laboratory Practice (O.E.C.D., 12th May 1981).

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

This study was performed at the Centre International de Toxicologie (C.I.T), Miserey, 27005 Evreux, France.



Toxicology

J. Clouzeau Date: 30.7.92
Biologist
Head of Short-term Toxicology and
In-vitro Department

OTHER SCIENTIST INVOLVED IN THIS STUDY

Pharmacy
Preparation of test articles



C. Fabreguettes Date: 30.7.92
Doctor of Pharmaceutical Sciences

QUALITY ASSURANCE UNIT
STATEMENT

The protocol, study (main) and report were inspected by the Quality Assurance Unit of the Centre International de Toxicologie on the following dates:

<u>INSPECTION</u>	<u>DATE OF INSPECTION</u>	<u>DATE OF INSPECTION REPORT</u>
Protocol	20.1.92	20.1.92
Test substance/preparation	25.2.92	25.2.92
Report (first draft)	9.7.92	9.7.92
Final report	30.7.92	30.7.92

The other stages (of the same type of studies) were inspected routinely on the following date:

Animals/housing	17.2.92	17.2.92
Treatment	4.2.92	4.2.92

The inspections were performed in accordance with C.I.T. Procedures and the Principles of Good Laboratory Practice (O.E.C.D., 12th May 1981).



M. Labiche Date: 30.7.92
Pharmacist
Head of Quality Assurance Unit
and Scientific Archives

SUMMARY

At the request of SNEA(P), Artix, France, the sensitization of guinea-pigs to the test substance TPS 44 was evaluated in guinea-pigs by intradermal injection and cutaneous application, according to the method of Magnusson and Kligman (1), the O.E.C.D. Guideline for the Test of Sensitization Principles of Good Laboratory Practice (O.E.C.D., 12th March 1978).

Methods

Thirty guinea-pigs (15 males and 15 females) were allocated to a control group (5 males and 5 females) and a treated group (10 males and 10 females).

The sensitization potential of the test substance was evaluated during a 10-day induction period during which the animals were treated with either vehicle (control group) or the test substance (treated group) in the presence of Freund's adjuvant, 0.1 ml of the test substance was administered by intradermal route at a concentration of 2 mg/ml in a sterile isotonic solution of 0.9% NaCl. On day 8, 0.5 ml of the test substance in its original form was applied by cutaneous route. After 7 days without treatment, a challenge cutaneous application was performed on the vehicle (left flank) and 0.5 ml of the test substance in its original form (right flank) were then performed on all animals. The test substance was prepared on a dry compress, then applied to the skin and left in place for 24 hours by means of an occlusive dressing. The cutaneous reaction was then evaluated at the challenge application site, 24 hours after removal of the dressing.

No histological examination was performed on the cutaneous reaction.

Reference

- (1) Magnusson, B.; Kligman, A.M.: The identification of sensitization by animal assay. The guinea pig maximization test. *J. Invest. Dermatol.* 52: 268-276 (1969).

Results

During the study, no clinical signs were observed and no death occurred. The body weight of the animals of the treated group was unaffected when compared to that of the control group.

After the challenge application of the test substance, no cutaneous reactions were observed in the animals of the control group. A positive response characterised by a well-defined erythema (score of 2) was observed on the right flank of 9 treated animals after 24 and 48 hours. No oedema was noted. The reactions noted in 10 animals (very slight or well-defined erythema after 24 hours and very slight erythema after 48 hours) were considered to be inconclusive evidence of well-defined sensitization and were considered to be due to a slight sensitization effect.

Conclusion

The test substance TPS 44 induced a positive sensitization reaction in 9 out of 20 guinea-pigs (45%). The allergenicity level of the test substance TPS 44 was **III: moderate** in guinea-pigs.

1. MATERIALS AND METHODS

1.1. TEST ARTICLES

1.1.1 Test substance

The test substance TPS 44 is a yellow liquid and was supplied by Elf-Atochem.

A glass flask containing the test substance was delivered to C.I.T. on the 29.1.92 under the reference "TPS 44 N° 917187 POIDS DE L'ECHANTILLON: 104 g N° D'ARCHIVAGE AU CAL 17/92". The test substance was stored at room temperature and protected from light.

Test article description and test article analysis provided by Elf-Atochem are presented in appendix 1.

1.1.2 Vehicle

The vehicle used was an injectable isotonic solution of 0.9% sodium chloride, batch No. 7865 B (Biosédra, 92240 Malakoff, France).

1.1.3 Other substances

The other substances used were Freund's complete adjuvant batch No. 788199 (Osi, 75739 Paris, France); sodium laurylsulphate batch No. 11620 JX (Aldrich, 67000 Strasbourg, France) and vaseline batch No. 109 (Monot, 21801 Quétigny, France).

1.2. TEST SYSTEM

1.2.1 Animals

Thirty Dunkin Hartley guinea-pigs (15 males and 15 females), supplied by the Lebeau breeding centre (78950 Gambais, France) were used for this study.

Upon their arrival at C.I.T., the animals were acclimatized to the experimental environment for a minimal period of 5 days during which they were observed daily. The animals were individually identified by tattooing the ear.

1.2.2 Housing

During the acclimatization period and throughout the study, the animals were kept in a conventional air-conditioned animal room. The ambient conditions were as follows:

- . Temperature : $22 \pm 3^{\circ}\text{C}$
- . Relative humidity: $50 \pm 20\%$
- . Light/dark cycle : 12 hours of light/12 hours of dark

The air was non-recycled and filtered by absolute filters.

During the acclimatization period and throughout the study, the animals were individually housed in sterilizable polycarbonate cages (48 x 27 x 20 cm) equipped with a polypropylene water bottle. Sifted and dusted sawdust was provided as litter (SICSA, 94142 Alfortville, France). An analysis of the potential residues and major contaminants was performed periodically (Laboratoire Wolff, 92110 Clichy, France).

1.2.3 Food and water

During the study, the animals were fed ad libitum with a certified pellet diet "Guinea-pigs sustenance ref. 106" (U.A.R. 91360 Villemoisson-sur-Orge, France). The diet formula is presented in appendix 2.

Water filtered by a 0.22 micron filter membrane (Société Millipore, 78140 Vélizy, France) and contained in water bottles was given ad libitum during the study. Bacteriological and chemical analyses of the water and detection of the major contaminants (pesticides, heavy metals and nitrosamines) were made periodically (Laboratoire Municipal et Régional de Rouen, 76000 Rouen, France - Centre de Nutrition Humaine, 54000 Nancy, France - Laboratoire Départemental d'Analyses, 27000 Evreux, France).

There was no information available to the Study Director indicating that any non-nutrient substances, at a level likely to influence the effect of the test substance, were present in the diet or water.

1.3. TREATMENT

During a 10-day sensitization period (day 1 to day 10), the test substance was administered by intradermal injection (day 1) and by cutaneous application (day 8). The intradermal administrations of the test substance and vehicle were performed in the presence of an adjuvant in order to maximize any potential cutaneous sensitization reactions.

After a 12-day rest period, another cutaneous application of the test substance was performed (day 22) in order to induce any potential cutaneous sensitization reactions.

1.3.1 Allocation of the animals to the groups

On day -1, the animals were weighed and then allocated to 2 groups: a control group consisting of 10 animals (5 males and 5 females) and a treated group consisting of 20 animals (10 males and 10 females). On day -1, they had a mean weight of 332 ± 18 g for the males and 315 ± 11 g for the females.

1.3.2 Preparation of the animals

On all animals, the application site was clipped before each treatment, on day -1 and day 7 on the scapular area (4 x 2 cm) and clipped again and shaved on day 21 on each flank (2 x 2 cm).

1.3.3 Mode of administration of the test substance

A preliminary test enabled us to define the dose of the test substance to be administered in the main study. The sensitization of the animals by intradermal route was performed with the test substance at the concentration of 25% in the vehicle which is an irritant dose.

The sensitization of the animals by cutaneous route and challenge application were made with the test substance in its original form, which is the maximum non-irritant dose when covered by an occlusive dressing for 24 hours.

1.3.4 Sensitization of the animals

1.3.4.1 Induction by intradermal route

On day 1, 3 doses of 0.1 ml were injected into each side of the spine on 4 x 2 cm of the scapular area using a needle (diameter: 0.50 x 16 mm, Terumo: C.M.L., 77140 Nemours, France) mounted on a 1 ml glass syringe (0.01 ml graduations, Record: Carrieri, 75005 Paris, France).

The animals from both groups received Freund's complete adjuvant at 50% in an isotonic injectable solution of 0.9% sodium chloride (injections 1 - figure 1).

The animals from the control group then received the vehicle alone whereas the animals from the treated group received the test substance suspended in the vehicle (injections 2 - figure 1).

The third set of injections was a mixed solution 50/50 (V/V) of Freund's complete adjuvant at 50% in an isotonic injectable solution of 0.9% sodium chloride and the vehicle given to the control animals, or the test substance in its vehicle to the treated animals (injections 3 - figure 1).

1.3.4.2 Induction by cutaneous route

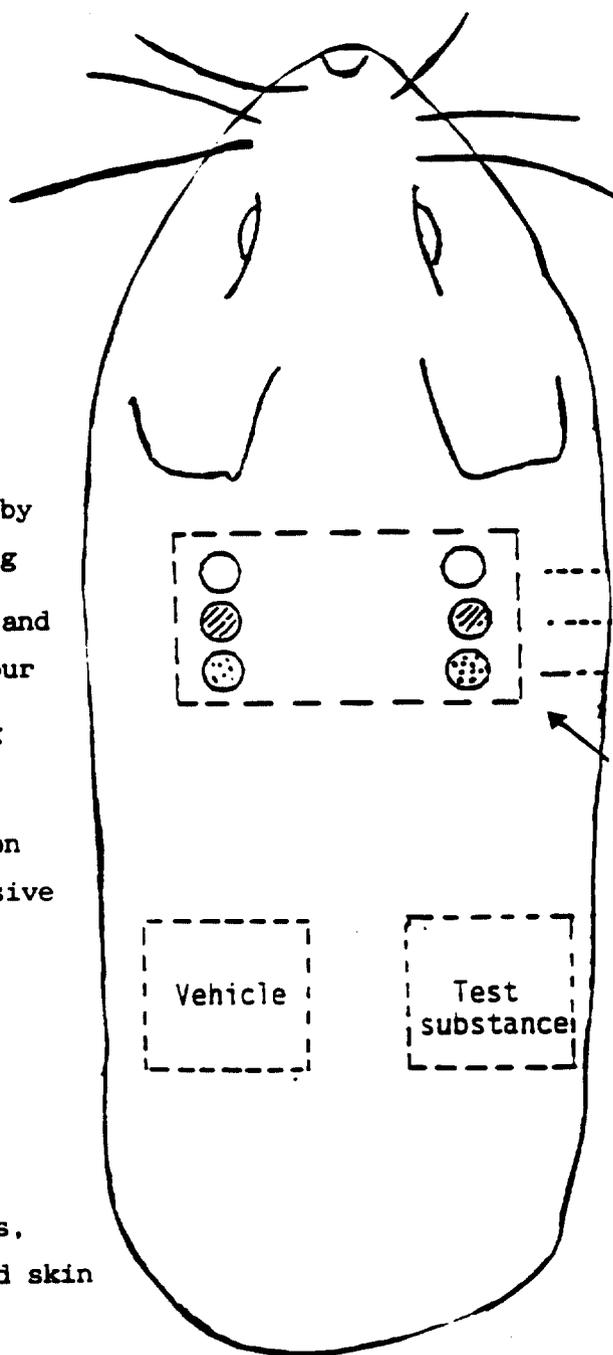
As the test substance in its original form did not show any irritant characteristics by cutaneous application under an occlusive dressing during the preliminary test, a local irritation was induced on day 7 using 0.5 ml of 10% sodium laurylsulphate in vaseline, applied to the scapular region. On day 8, 0.5 ml of the vehicle in the control group, 0.5 ml of test substance in its original form in the treated group was applied to the scapular region. They were held in place for 48 hours by means of an occlusive dressing. One hour after removal of the occlusive dressing, the cutaneous reactions were recorded.

1.3.5 Challenge application

On day 22, the animals from both groups received an application of 0.5 ml of the test substance in its original form on an area of 4 cm² on the posterior right flank and 0.5 ml of the vehicle on the posterior left flank. This application was prepared using a 1 ml plastic glass syringe (0.01 ml graduations, Terumo: C.M.L., 77140 Nemours, France) on a 4 cm² patch (Semes France, 54183 Heillecourt, France). An adhesive hypoallergic dressing (Laboratoires de Pansements et d'Hygiène, 21300 Chenove, France) and an adhesive anallergic plastic waterproof plaster (Laboratoire des Professions Médicales, 92240 Malakoff, France) were placed around the animals' trunk in order to cover the test substance for 24 hours.

1.3.6 Summary diagram (fig. 1)

- Chronology**
- D -1 Clipping of the scapular region
 - D 1 Intradermal injection
 - D 7 Clipping + Sodium laurylsulphate
 - D 8 Application covered by an occlusive dressing
 - D 10 Removal of dressing and scoring after one hour
 - D 21 Clipping and shaving of the flanks
 - D 22 Challenge application covered by an occlusive dressing
 - D 23 Removal of dressing
 - D 24 First scoring
 - D 25 Second scoring, sacrifice of animals, clipping/shaving and skin samples

**Induction site**

- 1
- 2 Intradermal injections
- 3

Cutaneous application
(4 x 2 cm)

Challenge application

Cutaneous application
(2 x 2 cm)

- 1. 50% Freund's adjuvant/ 0.9% sodium chloride solution
- Intradermal injections 2. Test substance and/or vehicle
- 3. Adjuvant mixture + test substance and/or vehicle
(V/V)

1.4. CLINICAL EXAMINATIONS

The animals were observed daily in order to record any eventual clinical signs, which appeared during the study and to check for mortality.

1.5. SCORING OF THE CUTANEOUS REACTIONS

Twenty-four and 48 hours after removal of the occlusive dressing from the challenge application site, the flanks of the treated and control animals were observed in order to evaluate any potential cutaneous reactions according to the following 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) with slight eschar formation (in depth lesions)	4

Oedema formation:

. No oedema	0
. Very slight oedema (barely perceptible)	1
. Slight oedema (edges of area well-defined, visible swellings)	2
. Moderate oedema (raised approximately 1 mm)	3
. Severe oedema (raised more than 1 mm and extending beyond the area of exposure)	4

All other cutaneous reactions were recorded.

1.6. PATHOLOGY

1.6.1 Necropsy

On day 25, the animals were weighed then sacrificed after CO₂ inhalation in excess after the 48-hour scoring period. Cutaneous samples were taken (one from each flank) from the challenge application site of each animal and were preserved in 10% buffered formalin.

1.6.2 Microscopic examination

No histological examination was performed.

1.7. DETERMINATION OF THE ALLERGENICITY LEVEL

The animals show a positive reaction if the macroscopic cutaneous reactions are clearly visible or eventually, if the "doubtful" macroscopic reactions are confirmed by the microscopic examination as being due to the sensitization process. The sensitization reactions are manifested in the microscopic examination by basal spongiosis, reactional acanthosis of the epidermis and infiltration of mononucleated cells on the dermis (1).

The allergenicity level of the test substance is calculated by comparing the number of animals showing positive reactions with the number of surviving treated animals at necropsy.

% of animals with a reaction	Allergenicity level	Classification
0 - 8	I	Very weak
9 - 28	II	Weak
29 - 64	III	Moderate
65 - 80	IV	Strong
81 - 100	V	Very strong

(1) Duprat, P.; Delsaut, L.; Gradiski, D; Lepage, M.: Investigations histopathologiques et cytologiques lors de la mise en évidence, chez le cobaye, d'une allergie cutanée de type retardé. Revue Méd. Vét. 127: 7, 1083-1101 (1976).

1.8. CHRONOLOGY OF THE STUDY

This is summarized in the following table:

Procedure	Date	Day
Arrival of the animals	13.2.92	- 5
Allocation of the animals to the groups	17.2.92	- 1
Induction by intradermal injection	18.2.92	1
Laurylsulphate application	24.2.92	7
Induction by cutaneous route	25.2.92	8
Removal of occlusive dressings	27.2.92	10
Challenge application	10.3.92	22
Removal of occlusive dressings	11.3.92	23
Scoring of cutaneous reactions after		
. 24 hours	12.3.92	24
. 48 hours	13.3.92	25
Weighing, sacrifice of the animals and cutaneous samples	13.3.92	25

1.9. ARCHIVES

The study documents:

- . protocol and any amendments,
- . all raw data,
- . correspondence,
- . study report (final) and any amendments,

are stored in the archives of C.I.T., Miserey, 27005 Evreux, France for 5 years after the end of the in vivo study. The flasks containing the organs, histological blocks and any slides are stored in the archives for one year after the end of the in vivo study. At the end of these periods, the study archives will, with the Sponsor's agreement, be either transferred to the Sponsor's premises or destroyed.

2. RESULTS**2.1. PRELIMINARY STUDY****2.1.1 Administration by intradermal route**

The maximal administrable concentration by intradermal route was 50% of the test substance in the vehicle. Several tests were performed to determine the maximal irritant concentration which did not provoke necrosis or ulceration.

Concentration of the test substance %	Scoring after treatment	
	24 hours	48 hours
50	Necrosis	Necrosis
25	Irritation	Irritation
10	Irritation	Irritation
1	Irritation	Irritation

2.1.2 Application by cutaneous route

Several tests were performed to determine the maximal non-irritant concentration after application of the test substance covered by an occlusive dressing for 24 hours.

Concentration of the test substance	Scoring 24 hours after removal of the dressing
50% In its original form	No cutaneous reactions No cutaneous reactions

2.2. MAIN STUDY

2.2.1 Clinical examinations

No clinical signs were observed throughout the study.

No deaths occurred.

The body weight gain of the treated animals was normal when compared to that of the control animals (appendix 3).

2.2.2 Scoring of the cutaneous reactions (appendix 4)

2.2.2.1 End of induction period

On day 10, after removal of the dressing, a slight irritation in control group and necrosis in treated group were observed at the sites of induction by interdermal route.

2.2.2.2 Challenge application

After the challenge application of the test substance, no cutaneous reactions were observed in the animals of the control group.

A positive response characterized by a well-defined erythema (score of 2) was observed on the right flank of 6 males (Nos. 06, 07, 10, 11, 12, 14) and 3 females (Nos 21, 24, 25) of the treated group after 24 and 48 hours. No oedema was noted.

The reactions observed in 3 males (Nos. 08, 09, 13) and 7 females (Nos. 22, 23, 26, 27, 28, 29, 30) were very slight or well-defined after 24 hours and very slight after 48 hours, and were considered to be inconclusive evidence of sensitization. The slight macroscopic reactions were considered to be due to a slight sensitization effect of the test substance in 10 animals.

A dryness of the skin was observed in one animal after 24 hours and in 16/20 animals after 48 hours.

No histological examinations were conducted on the cutaneous samples.

After the challenge application, a very slight (1) to well-defined (2) erythema was observed at the following frequency:

Erythema

Group	Sex	Erythema score	Scoring of the cutaneous parameters			
			24 hours		48 hours	
			LF	RF	LF	RF
Control	male	0	5/5	5/5	5/5	5/5
Treated	male	0	10/10	1/10	10/10	1/10
		1	-	2/10	-	3/10
		2	-	7/10	-	6/10
Control	female	0	5/5	5/5	5/5	5/5
Treated	female	0	10/10	0/10	10/10	0/10
		1	-	3/10	-	7/10
		2	-	7/10	-	3/10

LF: left flank

RF: right flank

2.3. PATHOLOGY

No microscopic examination was performed on the cutaneous samples.

APPENDICES

1. TEST ARTICLE DESCRIPTION AND TEST ARTICLE ANALYSIS

TOXICOLOGY DEPARTMENT
 CONFIDENTIAL
 JANUARY 1992

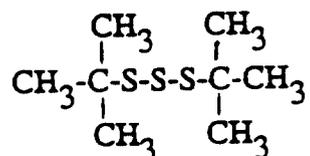
elf atochem s.a.

La défense 10, cedex 42
 92091 Paris-la-Défense, France

TEST ARTICLE DESCRIPTION

TPS 44

STRUCTURAL FORMULA



IDENTITY

Test article name	:	TPS 44
Chemical name	:	di tert-butyl trisulfide
CAS number	:	4253-90-1
EINECS number	:	2242266
Molecular formula	:	C ₈ H ₁₈ S ₃
Molecular weight	:	210
Origin and batch	:	CAT/Lacq, 917187
ATOCHEM filing number	:	CAL 17/92

PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Viscosity	:	3.33 cSt at 20°C
Specific gravity	:	1.007
Melting point	:	-17°C
Boiling point	:	178°C
Flash point	:	89°C (closed cup)
Solubility in water	:	no data
in DMSO	:	no data

TOXICOLOGICAL INFORMATIONS AND USE SAFETY

No data available.

STORAGE AND DISPOSAL

Storage	:	in dark and at room temperature
Expiry date	:	January 1993
Disposal	:	incineration

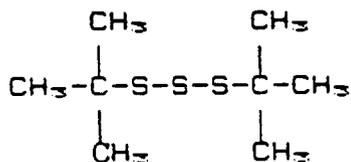
TOXICOLOGY DEPARTMENT
CONFIDENTIAL

elf atochem
Elf Aquitaine group
La défense 10, cedex 42
92091 Paris-la-Défense
FRANCE

TEST ARTICLE ANALYSIS

TPS. 44

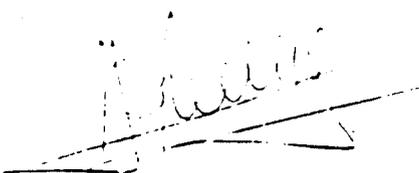
Batch 917187



ANALYSIS 17069L from SNEA(P) dated 11/12/91

Acetate test	Negative
Flash point	89°C
Gardner colour	3
S(RSH)	2 ppm
Total sulfur	45.2 %
Corrosivity copper plate	1 B

14 January 1992



Jean-François REGNIER.

2. DIET FORMULA

COMPLETE DIET**GUINEA-PIGS SUSTENANCE**

Appearance: 4.5 mm diameter pellets

Conditioning: bags of 25 kgs

Daily portion: to sustain Guinea-pigs 35 - 50 g according to age and body weight, water ad libitum.

FORMULA %

Cereals, sugar	42
Milled vegetables	46
Vegetable proteins (pellets, yeast)	9
Mineral and vitamin composition .	3

MEAN ANALYSIS %

Calorific value (Cal/kg)	2600
Water	10
Protids	17
Lipids	3
Carbohydrates (N.F.E.)	49
Cellulose (Weende)	13
Minerals	8

AMINO ACIDS (calculated in mg/kg)

Arginine	8500
Cystine	2500
Lysine	7200
Methionine	2100
Tryptophan	2000
Glycine	6000

	MINERALS (calculated in mg/kg)		
	Nat. input	Input /MC	Total
P	7400	1400	8800
Ca	5400	5600	11000
K	12000	0	12000
Na	1300	1950	3250
Mg	3270	130	3400
Mn	60	40	100
Fe	170	150	320
Cu	10	15	25
Zn	40	45	85
Co	0.1	1.5	1.6

	VITAMINS (calculated in kg)		
	Nat. input	Synth. input	Total
Vitamin A	3400 IU	6000 IU	9400 IU
" D3	30 "	2000 "	2030 "
" B1	6 mg	6.40 mg	12.40 mg
" B2	5 "	6.40 "	11.40 "
" B3	22 "	26 "	48 "
" B6	0.70 "	2.70 "	3.40 "
" B12	0.003 "	0.012 "	0.015 "
" C	0 "	200 "	200 "
" E	15 "	60 "	75 "
" K3	5 "	12.60 "	17.60 "
" PP	97 "	14.50 "	111.50 "
Folic acid	2.20 "	1.30 "	3.50 "
P.A.B. acid	0 "	2.50 "	2.50 "
Biotin	0.02 "	0.06 "	0.08 "
Choline	1010 "	060 "	1070 "
Meso-Inositol	0 "	62.50 "	62.50 "

This food is supplemented with stabilized coated vitamin C, avoiding the need of other food substances (greenery, ascorbic acid) if used within 2 months of date of manufacture

STUDY No. 8618 TSG

Body weight
(g)

Group	Sex	Animals	Days			
			-1	25	(1)	
Control	Male	01	356	528	172	
		02	354	499	145	
		03	323	522	199	
		04	328	458	130	
		05	333	432	99	
		M	339	488	149	
		SD	15	42	38	
		Female	16	316	450	134
			17	321	443	122
			18	302	456	154
			19	307	421	114
			20	339	499	160
		M	317	454	137	
		SD	14	29	20	
	Treated	Male	06	346	497	151
07			328	509	181	
08			302	478	176	
09			339	501	162	
10			314	447	133	
		11	366	522	156	
		12	309	439	130	
		13	336	487	151	
		14	326	485	159	
		15	318	417	99	
		M	328	478	150	
		SD	19	34	24	
		Female	21	317	441	124
			22	314	430	116
			23	312	397	85
	24		300	406	106	
	25		329	441	112	
	26	308	433	125		
	27	317	411	94		
	28	308	413	105		
	29	303	420	117		
	30	329	428	99		
	M	314	422	108		
	SD	10	15	13		

ght gain

Deviation

4. INDIVIDUAL OBSERVATIONS OF THE CUTANEOUS REACTIONS

MACROSCOPIC EXAMINATIONS OF THE CUTANEOUS REACTIONS

Group	Sex	Animals	24-hour scoring period				48-hour scoring period			
			Erythema		Oedema		Erythema		Oedema	
			LF	RF	LF	RF	LF	RF	LF	RF
Control	Males	01	0	0	0	0	0	0	0	0
		02	0	0	0	0	0	0	0	0
		03	0	0	0	0	0	0	0	0
		04	0	0	0	0	0	0	0	0
		05	0	0	0	0	0	0	0	0
	Females	16	0	0	0	0	0	0	0	0
		17	0	0	0	0	0	0	0	0
		18	0	0	0	0	0	0	0	0
		19	0	0	0	0	0	0	0	0
		20	0	0	0	0	0	0	0	0
Treated	Males	06	0	2/S	0	0	0	2/S	0	0
		07	0	2	0	0	0	2/S	0	0
		08	0	1	0	0	0	1	0	0
		09	0	2	0	0	0	1/S	0	0
		10	0	2	0	0	0	2/S	0	0
		11	0	2	0	0	0	2/S	0	0
		12	0	2	0	0	0	2/S	0	0
		13	0	1	0	0	0	1/S	0	0
		14	0	2	0	0	0	2/S	0	0
	15	0	0	0	0	0	0	0	0	
	Females	21	0	2	0	0	0	2/S	0	0
		22	0	1	0	0	0	1	0	0
		23	0	1	0	0	0	1/S	0	0
		24	0	2	0	0	0	2/S	0	0
		25	0	2	0	0	0	2/S	0	0
26		0	2	0	0	0	1/S	0	0	
27	0	2	0	0	0	1	0	0		
28	0	1	0	0	0	1/S	0	0		
29	0	2	0	0	0	1/S	0	0		
30	0	2	0	0	0	1/S	0	0		

LF = left flank

RF = right flank

S = dryness of the skin



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

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

APR 19 1994

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 this 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

12711 A

CHEMICAL TRIAGE TRACKING: DBASE ENTRY FORM

CHEM DATA: Submission # 8EHO-0993-12711 SEQ A

INFORMATION REQUESTED: FLWP DATE: _____

- 0501 NO INFO REQUESTED
 - 0502 INFO REQUESTED (TECH)
 - 0503 INFO REQUESTED (VOL ACTIONS)
 - 0504 INFO REQUESTED (REPORTING RATIONALE)
- DISPOSITION:
 0639 REFER TO CHEMICAL SCREENING
 0678 CAP NOTICE

- VOLUNTARY ACTIONS:**
- NO ACTION REPORTED
 - 0402 STUDIES PLANNED/UNDERWAY
 - 0403 NOTIFICATION OF WORKER/THIRDS
 - 0404 LABELMSDS CHANGES
 - 0405 PROCESS/HANDLING CHANGES
 - 0406 APP/USE DISCONTINUED
 - 0407 PRODUCTION DISCONTINUED
 - 0408 CONFIDENTIAL

TYPE: (INT) SUPP FLWP
 SUBMITTER NAME: Atcherson North America, Inc.

SUB. DATE: 09/28/93 OTS DATE: 09/29/93 CSRAD DATE: 10/25/93

CHEMICAL NAME: _____
 CAS# 68937-96-2

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL. TRANS (IN VITRO)	01 02 04	HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/ITERATO (HUMAN)	01 02 04	ENV. OCC/REL/FATE	01 02 04	0246 CLAS TO (HUMAN)	01 02 04
0207 REPRO/ITERATO (ANIMAL)	01 02 04	EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	RESPONSE REQUEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHIR. TOX. (HUMAN)	01 02 04	CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	METAB/PHARMACO (HUMAN)	01 02 04		

TRIAJE DATA: NON-CBI INVENTORY YES (CONTINUE)
 ONGOING REVIEW: YES (DROP/REFER) NO (CONTINUE) REFER:
 SPECIES: GP
 TOXICOLOGICAL CONCERN: LOW
 USE: MED Dermal sensitization
 PRODUCTION: Market development prod. - presubfiling agent

COMMENTS: Non-Tox

8(e)-12711A

MODERATE--Dermal sensitization

A positive reaction was seen in 9/20 (45%) guinea pigs using the Magnusson and Kligman method of dermal application.