CONTAINS NO CBI

8EHQ-0893-12242

OSi SPECIALTIES INCORPORATED

PRODUCT SAFETY
REGULATORY SERVICES

P. O. BOX 180
SISTERSVILLE, WV 26175
304-652-3211 FAX: 304-652-1175

A

August 27, 1993

8EHQ-93-12242
INIT 08/31/93

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Document Processing Center (TS-790)
Office of Pollution Prevention & Toxics
U.S. Environmental Protection Agency
401 M Street SW
Washington D.C. 20460

Attn: TSCA 8(e) Coordinator

Dear Sir or Madam:

OSi Specialties Incorporated (OSi) herewith submits the following information pursuant to TSCA Section 8(e), concerning preliminary unaudited information from a 14-day dietary feeding study on Poly(oxy-1,2-ethanediyl), alpha-methyl-omega-[3-[1,3,3,3-tetra-methyl-1-[trimethylsilyl)oxy]di-siloxanyl]propyl]- (SILWET L-77®, CASRN 27306-78-1), a surfactant. OSi received this information on August 11, 1993. The information is contained in the attachments and is summarized below.

The study was conducted in Fischer 344 rats with five groups of animals each fed a diet containing 0 (control), 1000, 8000, 15,000 and 20,000 ppm of SILWET L-77. These levels in the diet resulted in doses for males of 0 and approximately 100, 700, 1300 and 1600 mg/kg/day; and females of 0 and approximately 100, 800, 1400 and 1800 mg/kg/day (see Attachment 2, pages 1 and 2).

The preliminary unaudited findings from the study suggest that SILWET L-77 exerts an effect on Fischer 344 rats at high doses. These findings which will require further consideration are as follows:

1. <u>Hematology (Attachment 1, Pages 1-4)</u>

   a) Dosage-related decrease in platelet count at 8000, 15000 and 20000 ppm but not at 1000 ppm.

   b) Dosage-related decrease in reticulocyte count at 8000 ppm and above.

2. <u>Clinical Chemistry (Attachment 1, Pages 5-8)</u>

   a) Increased urea nitrogen at 15000 and 20000 ppm.

9-23-93

26 pgs.

b) Decreased serum alkaline phosphatase activity at 8000 ppm and above, with a more variable decrease in aspartate and alanine aminotrans-ferase activities.

3. Urine Chemistry (Attachment 1, Pages 9-10)

a) Increase N-acetyl-β-D-glucosaminidase activity at 8000 ppm and above in male rats.

4. Organ Weights (Attachment 1, Pages 15-18)

a) Increased liver weight, dosage-related, and expressed as either absolute or relative (to body and brain weight) statistically significant at 8000 ppm and above.

b) Dosage-related decrease in spleen weight, absolute and relative, in females at 8000 ppm and above.

c) Decreased testicular weight (absolute and relative) at 8000 ppm and above.

d) Decreased ovary weight (absolute and relative) at 8000 ppm and above.

e) Increased thyroid gland weight (absolute and relative) in males and females at 15000 and 20000 ppm.

Clarification of the pathophysiological significance, if any, of the above summarized hematology, clinical chemistry, and urine chemistry findings must await completion of other aspects of the study, notably histology. However, in view of the clear dosage-related decreases in testicular and ovarian weight, processing of these tissues from the high and control groups and a preliminary histological assessment was conducted. The tissues examined included the heart, liver, spleen and reproductive tissues from the control and high dose animals.

The histological assessment indicated an apparent uncoupling of spermiogenesis and dissociation of the primary and secondary spermatocytes in the seminiferous tubules of the testes in the high dose group rats with a reduction of mature spermatids in the epididymides. In addition, large numbers of spermatocytes were also present in the epididymal tubules of some high dose group rats whereas there were practically none found in the control rats.

The histological assessment also indicated that in the female rats, the high dose group showed fewer corpora lutea in the ovaries, and that these often had a number of vacuoles in the cyto-plasm of the luteal cells. The control female rats had a greater number of corpora lutea, without evidence of the vacuoles. The uteri of the high dose group females seemed to be small and uniformly inactive, whereas the uteri of the control females seemed to have a variety of cyclic changes typical of regularly cycling mature female rats.

A complete evaluation of the relevance of these preliminary unaudited findings must await completion of the study.

While no assertion of confidentiality is made, the Agency is advised that the publication rights to this information are the property of OSi.

A full copy of this report will be sent to the Agency promptly after it issues.

Please contact the undersigned with questions, if any, at 304-652-3211 (ext. 223).

C.R. Thrash

C.R. Thrash
Product Safety Manager

/bw
Attachments

UNION CARBIDE CHEMICALS AND PLASTICS COMPANY INC.
Product Safety/Regulatory Services 777 Old Saw Mill River Road
Specialty Chemicals Division Tarrytown, New York 10591-6799

FACSIMILE COVER LETTER

PLEASE DELIVER THE FOLLOWING DOCUMENT TO:

NAME: C.R. Pinsch

LOCATION: Sistersville

TELEPHONE: 304-652-1175

NOTE: Attachments for this L-77 8(e) letter

Jack

THIS DOCUMENT IS FROM:

NAME: J.J. Behen

LOCATION: Tarrytown - Silicones Building

TELEPHONE: 914-789-2103 (Internal Ext. 8-430-2103)

WE ARE TRANSMITTING 23 PAGES INCLUDING THIS COVER LETTER.

IF THERE ARE ANY PROBLEMS PLEASE CONTACT:

NAME: Sandra Lee Morris

TELEPHONE: 914-789-2185 (Internal Ext. 8-430-2185)

TO SEND A FACSIMILE TO THE PRODUCT SAFETY AND REGULATORY GROUP USE THE FOLLOWING

NAME: Ms Sandra Lee Morris

TELEPHONE: 914-789-2282 (Internal Ext. 8-430-2282)

ATTACHMENT 1, p.1

DRAFT

SILWET® SURFACTANT L-77™: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF HEMATOLOGY
WEEK 2

MALES

GROUP: PPM	0	1000	8000	15000	20000
ERYTHROCYTES ($10^6/\mu l$)					
MEAN	8.64	8.71	8.56	8.68	8.52
S.D.	0.246	0.296	0.322	0.249	0.269
N	10	10	10	10	10
HEMOGLOBIN (g/dl)					
MEAN	16.9	16.9	16.6	16.6	16.4
S.D.	0.30	0.45	0.50	0.44	0.52
N	10	10	10	10	10
HEMATOCRIT (%)					
MEAN	47.4	47.8	46.9	47.0	46.4
S.D.	1.10	1.48	1.51	1.49	1.37
N	10	10	10	10	10
MEAN CORPUSCULAR VOLUME (μm^3)					
MEAN	55.	55.	55.	54.**	55.
S.D.	0.5	0.8	0.6	0.5	0.5
N	10	10	10	10	10
MEAN CORPUSCULAR HEMOGLOBIN (pg)					
MEAN	19.6	19.4	19.4	19.1	19.3
S.D.	0.37	0.43	0.53	0.27	0.43
N	10	10	10	10	10
MEAN CORPUSCULAR HEMOGLOBIN CONCENTRATION (g/dl)					
MEAN	35.6	35.3	35.3	35.4	35.3
S.D.	0.64	0.81	0.93	0.77	0.54
N	10	10	10	10	10
PLATELETS ($10^3/\mu l$)					
MEAN	720.	743.	681.	649.**	634.**
S.D.	49.1	47.8	68.3	53.4	58.5
N	10	10	10	10	9
LEUKOCYTES ($10^3/\mu l$)					
MEAN	7.6	6.7	6.5	7.0	6.9
S.D.	0.89	0.88	1.09	1.04	0.61
N	10	10	10	10	10
SEGMENTED NEUTROPHILS ($10^3/\mu l$)					
MEAN	0.96	0.91	0.80	0.89	0.92
S.D.	0.342	0.129	0.208	0.221	0.200
N	10	10	10	10	10
LYMPHOCYTES ($10^3/\mu l$)					
MEAN	6.28	5.81	5.32	5.80	5.65
S.D.	0.884	0.848	0.918	0.887	0.581
N	10	10	10	10	10
MONOCYTES ($10^3/\mu l$)					
MEAN	0.22	0.21	0.22	0.20	0.21
S.D.	0.091	0.114	0.117	0.062	0.056
N	10	10	10	10	10

** significantly different from control group ($p < .01$)

ATTACHMENT 1, p.4

DRAFT

SILWET® SURFACTANT L-77™: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF HEMATOLOGY
WEEK 2

MALES

GROUP: PPM	0	1000	8000	15000	20000
BASOPHILS (10^3/µl)					
MEAN	0.03	0.03	0.02	0.03	0.03
S.D.	0.013	0.019	0.014	0.010	0.012
N	10	10	10	10	10
EOSINOPHILS (10^3/µl)					
MEAN	0.06	0.06	0.07	0.07	0.06
S.D.	0.015	0.016	0.015	0.021	0.023
N	10	10	10	10	10
RETICULOCYTES (% of RBCs)					
MEAN	3.4	3.4	2.9*	2.6**	2.2**
S.D.	0.40	0.52	0.45	0.37	0.38
N	10	10	10	10	10

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

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ATTACHMENT 1, p3

DRAFT

SILWET® SURFACTANT L-77™: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF HEMATOLOGY
WEEK 2

FEMALES

GROUP: PPM	0	1000	8000	15000	20000
ERYTHROCYTES ($10^6/\mu l$)					
MEAN	8.65	8.65	8.80	8.67	8.76
S.D.	0.210	0.316	0.300	0.239	0.161
N	10	10	10	10	10
HEMOGLOBIN (g/dl)					
MEAN	17.4	17.4	17.5	17.2	17.2
S.D.	0.47	0.40	0.41	0.42	0.12
N	10	10	10	10	10
HEMATOCRIT (%)					
MEAN	48.1	48.1	48.5	47.5	48.0
S.D.	1.25	1.73	1.14	1.47	1.15
N	10	10	10	10	10
MEAN CORPUSCULAR VOLUME (μm^3)					
MEAN	56.	56.	55.	55.*	55.*
S.D.	0.7	0.7	0.9	0.6	0.8
N	10	10	10	10	10
MEAN CORPUSCULAR HEMOGLOBIN (pg)					
MEAN	20.1	20.1	19.8	19.9	19.6
S.D.	0.30	0.52	0.48	0.37	0.38
N	10	10	10	10	10
MEAN CORPUSCULAR HEMOGLOBIN CONCENTRATION (g/dl)					
MEAN	36.2	36.3	36.0	36.3	35.8
S.D.	0.65	0.96	0.62	0.81	0.94
N	10	10	10	10	10
PLATELETS ($10^3/\mu l$)					
MEAN	699.	687.	623.*	581.**	583.**
S.D.	47.8	104.8	43.6	51.6	48.3
N	9	10	10	10	10
LEUKOCYTES ($10^3/\mu l$)					
MEAN	7.2	6.5	6.7	6.3	7.2
S.D.	1.58	0.63	0.92	0.97	0.97
N	10	10	10	10	10
SEGMENTED NEUTROPHILS ($10^3/\mu l$)					
MEAN	0.72	0.65	0.75	0.66	0.71
S.D.	0.199	0.106	0.111	0.118	0.100
N	10	10	10	10	10
LYMPHOCYTES ($10^3/\mu l$)					
MEAN	6.22	5.60	5.70	5.41	6.22
S.D.	1.331	0.525	0.889	0.828	0.872
N	10	10	10	10	10
MONOCYTES ($10^3/\mu l$)					
MEAN	0.17	0.18	0.17	0.15	0.17
S.D.	0.102	0.067	0.091	0.040	0.054
N	10	10	10	10	10

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

ATTACHMENT 1, p.4

DRAFT

SILWET® SURFACTANT L-77®: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF HEMATOLOGY
WEEK 2

FEMALES

GROUP: PPM	0	1000	8000	15000	20000
BASOPHILS ($10^3/\mu l$)					
MEAN	0.03	0.02	0.03	0.02	0.02
S.D.	0.011	0.009	0.030	0.008	0.010
N	10	10	10	10	10
EOSINOPHILS ($10^3/\mu l$)					
MEAN	0.05	0.05	0.06	0.07	0.06
S.D.	0.013	0.013	0.015	0.014	0.028
N	10	10	10	10	10
RETICULOCYTES (% of RBCs)					
MEAN	2.2	2.2	1.9*	1.8**	1.9**
S.D.	0.23	0.27	0.35	0.30	0.19
N	10	10	10	10	10

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

ATTACHMENT 1, p-5

DRAFT

SILWET® SURFACTANT L-77™: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF CLINICAL CHEMISTRY
WEEK 2

MALES

GROUP: PPM	0	1000	8000	15000	20000
GLUCOSE (g/l)					
MEAN	1.16	1.16	1.15	1.10	1.15
S.D.	0.114	0.142	0.147	0.086	0.128
N	10	10	10	10	10
UREA NITROGEN (mg/l)					
MEAN	152.	149.	160.	179.**	194.**
S.D.	12.9	13.2	23.6	19.8	8.7
N	10	10	10	10	10
CREATININE (mg/l)					
MEAN	6.	6.	6.	6.	6.
S.D.	1.1	1.2	0.6	0.6	0.7
N	10	10	10	10	10
TOTAL PROTEIN (g/l)					
MEAN	62.	62.	61.	61.	60.
S.D.	2.4	1.8	2.7	2.3	2.9
N	10	10	10	10	10
TOTAL BILIRUBIN (mg/l)					
MEAN	1.	1.	1.	1.	1.
S.D.	0.0	0.0	0.0	0.0	0.0
N	10	10	10	10	10
DIRECT BILIRUBIN (mg/l)					
MEAN	1.	1.	1.	1.	1.
S.D.	0.0	0.0	0.0	0.0	0.0
N	10	10	10	10	10
INDIRECT BILIRUBIN (mg/l)					
MEAN	0.	0.	0.	0.	0.
S.D.	0.0	0.0	0.0	0.0	0.0
N	10	10	10	10	10
CALCIUM (mg/l)					
MEAN	101.	101.	102.	101.	100.
S.D.	3.1	2.9	2.1	2.9	2.4
N	10	10	10	10	10
INORGANIC PHOSPHORUS (mg/l)					
MEAN	88.	84.	83.	78.**	77.**
S.D.	9.5	7.7	5.7	5.5	4.9
N	10	10	10	10	10
SODIUM (mmol/l)					
MEAN	146.	147.	147.	147.	147.
S.D.	2.0	2.4	1.5	2.1	1.9
N	10	10	10	10	10
POTASSIUM (mmol/l)					
MEAN	5.4	5.2	4.9*	4.7**	4.8**
S.D.	0.62	0.50	0.25	0.29	0.30
N	10	10	10	10	10
CHLORIDE (mmol/l)					
MEAN	111.	112.	112.	113.	113.
S.D.	1.2	1.3	1.7	1.6	1.6
N	10	10	10	10	10
ASPARTATE AMINOTRANSFERASE (IU/l)					
MEAN	77.	69.	66.	61.*	61.*
S.D.	17.2	12.9	9.4	3.7	6.8
N	10	10	10	10	10
ALANINE AMINOTRANSFERASE (IU/l)					
MEAN	34.	33.	29.**	29.**	29.**
S.D.	5.3	5.2	2.0	4.0	2.6
N	10	10	10	10	10

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

ATTACHMENT 1, p. 0

DRAFT

SILWET® SURFACTANT L-77™: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF CLINICAL CHEMISTRY
WEEK 2

MALES

GROUP: PPM	0	1000	8000	15000	20000
γ-GLUTAMYL TRANSFERASE (IU/L)					
MEAN	4.	4.	4.	5.	5.**
S.D.	0.5	0.5	0.5	0.5	0.8
N	10	10	10	10	10
CREATINE KINASE (IU/L)					
MEAN	342.	297.	284.	153.	203.
S.D.	261.5	348.3	307.7	65.4	142.2
N	10	10	10	10	10
LACTATE DEHYDROGENASE (IU/L)					
MEAN	266.	153.*	170.	153.	159.
S.D.	145.9	73.9	51.8	83.0	73.9
N	10	10	10	10	10
SORBITOL DEHYDROGENASE (IU/L)					
MEAN	8.	8.	8.	9.	10.
S.D.	2.4	3.5	0.9	1.3	1.5
N	10	10	10	10	10
ALKALINE PHOSPHATASE (IU/L)					
MEAN	224.	217.	170.**	149.**	134.**
S.D.	10.8	18.1	15.3	7.3	9.6
N	10	10	10	10	10

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

ATTACHMENT I, p. 1

DRAFT

SILWET® SURFACTANT L-77®: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF CLINICAL CHEMISTRY
WEEK 2

FEMALES

GROUP: PPM	0	1000	8000	15000	20000
GLUCOSE (g/l)					
MEAN	0.92	0.95	1.00	1.10**	1.05*
S.D.	0.130	0.184	0.083	0.098	0.079
N	7	10	10	10	9
UREA NITROGEN (mg/l)					
MEAN	162.	161.	164.	174.	188.**
S.D.	8.3	12.3	12.1	12.1	11.3
N	7	10	10	10	9
CREATININE (mg/l)					
MEAN	6.	6.	6.	6.	5.
S.D.	0.5	0.7	0.5	0.7	0.5
N	7	10	10	10	9
TOTAL PROTEIN (g/l)					
MEAN	58.	58.	59.	60.	60.
S.D.	1.7	2.1	1.8	1.5	1.5
N	7	10	10	10	9
TOTAL BILIRUBIN (mg/l)					
MEAN	1.	1.	1.	1.	1.
S.D.	0.0	0.0	0.0	0.3	0.0
N	7	10	10	10	9
DIRECT BILIRUBIN (mg/l)					
MEAN	1.	1.	1.	1.	1.
S.D.	0.0	0.0	0.0	0.3	0.0
N	7	10	10	10	9
INDIRECT BILIRUBIN (mg/l)					
MEAN	0.	0.	0.	0.	0.
S.D.	0.0	0.0	0.0	0.0	0.0
N	7	10	10	10	9
CALCIUM (mg/l)					
MEAN	100.	101.	100.	101.	102.
S.D.	2.5	1.1	1.1	2.0	1.8
N	7	10	10	10	9
INORGANIC PHOSPHORUS (mg/l)					
MEAN	95.	86.*	82.**	84.**	81.**
S.D.	11.2	4.5	6.4	9.8	10.8
N	7	10	10	10	9
SODIUM (mmol/l)					
MEAN	145.	145.	146.*	146.	146.*
S.D.	1.1	1.0	1.2	1.8	1.4
N	7	10	10	10	9
POTASSIUM (mmol/l)					
MEAN	5.7	5.3	5.2	5.5	5.3
S.D.	0.82	0.55	0.44	0.48	0.33
N	7	10	10	10	9
CHLORIDE (mmol/l)					
MEAN	114.	113.	114.	115.	115.
S.D.	1.5	1.3	1.6	2.7	1.7
N	7	10	10	10	9
ASPARTATE AMINOTRANSFERASE (IU/l)					
MEAN	74.	74.	71.	67.	60.
S.D.	9.7	17.2	17.2	11.9	12.6
N	7	10	10	10	9
ALANINE AMINOTRANSFERASE (IU/l)					
MEAN	27.	31.	28.	29.	27.
S.D.	5.0	12.7	2.4	3.5	2.0
N	7	10	10	10	9

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

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ATTACHMENT 1, p. 8

DRAFT

SILWET® SURFACTANT L-77™: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF CLINICAL CHEMISTRY
WEEK 2

FEMALES

GROUP: PPM	0	1000	8000	15000	20000
γ-GLUTAMYL TRANSFERASE (IU/l)					
MEAN	6.	5.	6.	8.*	8.**
S.D.	1.5	1.6	1.7	1.3	1.7
N	7	10	10	10	9
CREATINE KINASE (IU/l)					
MEAN	386.	374.	463.	338.	233.
S.D.	230.1	330.2	514.1	228.4	205.3
N	7	10	10	10	9
LACTATE DEHYDROGENASE (IU/l)					
MEAN	250.	270.	235.	188.	167.*
S.D.	48.9	81.1	73.7	66.0	55.4
N	7	10	10	10	9
SORBITOL DEHYDROGENASE (IU/l)					
MEAN	10.	11.	9.	9.	8.
S.D.	2.4	5.0	1.2	1.6	1.3
N	7	10	10	10	9
ALKALINE PHOSPHATASE (IU/l)					
MEAN	182.	169.	131.**	111.**	104.**
S.D.	18.4	9.5	12.6	8.1	8.0
N	7	10	10	10	9

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

ATTACHMENT 1, p 7

DRAFT

SILWET® SURFACTANT L-77™: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF URINE CHEMISTRY
WEEK 2

MALES

GROUP: PPM	0	1000	8000	15000	20000
URINE TOTAL PROTEIN (g/l)					
MEAN	4.47	4.22	4.63	4.22	4.08
S.D.	0.551	0.689	0.798	0.468	0.495
N	10	10	10	10	10
URINE CREATININE (mg/l)					
MEAN	973.	852.*	882.	723.**	658.**
S.D.	96.4	147.6	94.4	115.1	82.0
N	10	10	10	10	10
N-ACETYL-B-D-GLUCOSAMINIDASE (IU/L)					
MEAN	8.08	7.62	9.85*	11.01**	11.34**
S.D.	0.718	1.267	1.408	2.276	1.769
N	10	10	10	10	10

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

ATTACHMENT 3, P 10

DRAFT

SILWET® SURFACTANT L-77™: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF URINE CHEMISTRY
WEEK 2

FEMALES

GROUP: PPM	0	1000	8000	15000	20000
URINE TOTAL PROTEIN (g/l)					
MEAN	2.86	2.81	2.88	3.10	3.22
S.D.	0.502	0.506	0.392	0.558	0.347
N	10	10	10	10	10
URINE CREATININE (mg/l)					
MEAN	898.	802.	771.	788.	766.
S.D.	153.8	122.6	82.9	101.8	75.3
N	10	10	10	10	10
N-ACETYL-B-D-GLUCOSAMINIDASE (IU/L)					
MEAN	6.78	8.43	6.68	6.91	7.01
S.D.	1.291	1.505	0.782	1.233	1.119
N	10	10	10	10	10

None significantly different from control group

ATTACHMENT 1, p. 11

DRAFT

SILWET® SURFACTANT L-77™: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF URINALYSIS
WEEK 2

MALES

GROUP: PPM	0	1000	8000	15000	20000
TOTAL VOLUME (ml)					
MEAN	7.3	5.3	7.2	8.6	8.8*
S.D.	1.25	2.70	1.21	2.80	1.14
N	10	10	10	10	10
SPECIFIC GRAVITY					
MEAN	1.058	1.052	1.056	1.055	1.051
S.D.	0.0054	0.0078	0.0060	0.0085	0.0052
N	10	10	10	10	10
pH					
MEAN	7.0	7.0	7.1	7.0	6.8
S.D.	0.00	0.33	0.77	0.24	0.26
N	10	10	10	10	10
PROTEIN (mg/dl)					
30	0	4	0	2	4
100	10	6	10	8	6
GLUCOSE (mg/dl)					
NEGATIVE	10	10	10	10	10
KETONES (mg/dl)					
NEGATIVE	3	5	9	9	10
TRACE	7	5	1	1	0
BILIRUBIN					
NEGATIVE	4	6	7	9	10
SMALL	6	4	3	1	0
OCCULT BLOOD					
NEGATIVE	10	10	10	10	9
TRACE	0	0	0	0	1
UROBILINOGEN (EHRLICH UNITS/dl)					
0.2	9	10	10	10	10
1.0	1	0	0	0	0
COLOR					
YELLOW	10	10	10	10	10
TURBIDITY					
SL CLOUDY	10	9	4	7	7
MOD CLOUDY	0	1	6	2	3
VERY CLOUDY	0	0	0	1	0

* Significantly different from control group ($p < .05$)
Statistics performed on total volume, specific gravity and pH only.

ATTACHMENT 1, p. 12

DRAFT

SILWET® SURFACTANT L-77™: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF URINALYSIS
WEEK 2

MALES

GROUP: PPM	0	1000	5000	15000	20000
CELLS (CELLS/HPF)					
RBC					
NONE	10	10	10	10	10
WBC					
NONE	10	10	10	10	10
EPC					
NONE	10	9	10	10	10
<5	0	1	0	0	0
CRYSTALS (NUMBER/HPF)					
TRIPLE PHOSPHATE					
NONE	2	2	2	4	1
FEW	8	8	8	6	9
CALCIUM OXALATE					
NONE	10	10	10	10	10
URIC ACID					
NONE	10	10	10	10	10
AMORPHOUS PHOSPHATE					
NONE	5	3	3	3	5
FEW	4	7	7	7	4
MODERATE	1	0	0	0	1
MISCELLANEOUS					
SPERM (NUMBER/HPF)					
NONE	5	7	8	7	9
FEW	5	3	2	3	1
CASTS (NUMBER/HPF)					
NONE	10	10	10	10	10
BACTERIA (NUMBER/HPF)					
NONE	10	10	10	10	10
DEBRIS (NUMBER/HPF).					
FEW	9	10	6	4	1
MODERATE	1	0	4	5	9
MANY	0	0	0	1	0

None significantly different from control group
Statistics performed on total volume, specific gravity and pH only.
Number/HPF = Number/High Power Field.

ATTACHMENT 1, p. 15

DRAFT

SILWET® SURFACTANT L-77™: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF URINALYSIS
WEEK 2

FEMALES

GROUP: PPM	0	1000	8000	15000	20000
TOTAL VOLUME (ml)					
MEAN	5.7	6.2	5.9	5.2	5.4
S.D.	0.94	1.49	0.80	1.72	0.97
N	10	10	10	10	10
SPECIFIC GRAVITY					
MEAN	1.062	1.058	1.060	1.066	1.068
S.D.	0.0079	0.0063	0.0078	0.0078	0.0086
N	10	10	10	10	10
pH					
MEAN	6.9	7.0	7.1	6.8	6.7
S.D.	0.28	0.00	0.21	0.24	0.26
N	10	10	10	10	10
PROTEIN (mg/dl)					
30	7	10	10	8	10
100	3	0	0	2	0
GLUCOSE (mg/dl)					
NEGATIVE	10	10	10	10	10
KETONES (mg/dl)					
NEGATIVE	6	9	10	10	9
TRACE	4	1	0	0	1
BILIRUBIN					
NEGATIVE	5	5	4	3	2
SMALL	5	5	6	7	8
OCCULT BLOOD					
NEGATIVE	10	9	10	10	10
TRACE	0	1	0	0	0
UROBILINOGEN (EHRLICH UNITS/dl)					
0.2	7	7	9	10	9
1.0	3	3	1	0	1
COLOR					
YELLOW	10	10	10	10	10
TURBIDITY					
CLEAR	0	0	0	0	1
SL CLOUDY	10	9	10	10	8
MOD CLOUDY	0	1	0	0	1

None significantly different from control group
Statistics performed on total volume, specific gravity and pH only.

ATTACHMENT 1, p. 14

DRAFT

SILWET® SURFACTANT L-77™: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF URINALYSIS
WEEK 2

FEMALES

GROUP: PPM	0	1000	8000	15000	20000
CELLS (CELLS/HPF)					
RBC					
NONE	10	10	10	10	10
WBC					
NONE	10	10	10	10	10
EPC					
NONE	10	10	10	10	10
CRYSTALS (NUMBER/HPF)					
TRIPLE PHOSPHATE					
NONE	5	3	4	5	2
FEW	5	7	6	5	8
CALCIUM OXALATE					
NONE	10	10	10	10	10
URIC ACID					
NONE	10	10	10	10	10
AMORPHOUS PHOSPHATE					
NONE	2	1	5	5	8
FEW	8	7	5	5	2
MODERATE	0	2	0	0	0
MISCELLANEOUS					
CASTS (NUMBER/HPF)					
NONE	10	10	10	10	10
BACTERIA (NUMBER/HPF)					
NONE	10	10	10	10	10
DEBRIS (NUMBER/HPF)					
NONE	0	1	0	0	0
FEW	10	9	10	10	10

None significantly different from control group
Statistics performed on total volume, specific gravity and pH only.
Number/HPF = Number/ High Power Field.

ATTACHMENT 1, p 15

DRAFT

SILWET L-77®: FOURTEEN-DAY DIETARY STUDY IN FISCHER 344 RATS
SUMMARY OF ORGAN WEIGHTS AS % OF FINAL BODY WEIGHT
ANIMALS SACRIFICED AT WEEK 2

MALES

GROUP: PPM	0	1000	8000	15000	20000
LIVER					
MEAN	3.155	3.215	3.619**	3.586**	4.341**
S.D.	0.1122	0.0768	0.1141	0.1675	0.1982
N	10	10	10	10	10
KIDNEYS					
MEAN	0.799	0.789	0.826	0.861**	0.878**
S.D.	0.0306	0.0145	0.0384	0.0242	0.0324
N	10	10	10	10	10
HEART					
MEAN	0.416	0.389*	0.388*	0.399	0.395
S.D.	0.0290	0.0269	0.0211	0.0272	0.0313
N	10	10	10	10	10
SPLEEN					
MEAN	0.241	0.238	0.242	0.253	0.245
S.D.	0.0148	0.0164	0.0127	0.0137	0.0130
N	10	10	10	10	10
BRAIN					
MEAN	1.042	1.029	1.107	1.121*	1.135*
S.D.	0.0597	0.0802	0.1111	0.0775	0.0444
N	10	10	10	10	10
ADRENAL GL					
MEAN	0.023	0.021	0.022	0.023	0.023
S.D.	0.0027	0.0031	0.0020	0.0009	0.0009
N	10	10	10	10	10
TESTES					
MEAN	1.348	1.315	1.093*	0.898**	0.882**
S.D.	0.1535	0.1074	0.3211	0.3080	0.2631
N	10	10	10	10	10
THYROID GL					
MEAN	0.006	0.006	0.005	0.008**	0.009**
S.D.	0.0007	0.0011	0.0015	0.0010	0.0021
N	10	9	10	10	10

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

ATTACHMENT 1, p 16

DRAFT

SILNEX L-77®: FOURTEEN-DAY DIETARY STUDY IN FISCHER 344 RATS
SUMMARY OF ORGAN WEIGHTS (GRAMS)
ANIMALS SACRIFICED AT WEEK 2

MALES

GROUP: PPM	0	1000	8000	15000	20000
FINAL BODY WEIGHT					
MEAN	161.0	165.7	153.7	148.4*	143.3**
S.D.	12.30	16.02	18.40	11.03	7.20
N	10	10	10	10	10
LIVER					
MEAN	5.089	5.327	5.555*	5.908**	6.222**
S.D.	0.5278	0.5194	0.6223	0.3923	0.4211
N	10	10	10	10	10
KIDNEYS					
MEAN	1.286	1.306	1.266	1.277	1.258
S.D.	0.1018	0.1185	0.1576	0.0935	0.0702
N	10	10	10	10	10
HEART					
MEAN	0.670	0.642	0.595**	0.590**	0.566**
S.D.	0.0777	0.0439	0.0682	0.0465	0.0478
N	10	10	10	10	10
SPLEEN					
MEAN	0.387	0.394	0.374	0.376	0.352
S.D.	0.0268	0.0488	0.0624	0.0385	0.0294
N	10	10	10	10	10
BRAIN					
MEAN	1.674	1.692	1.684	1.656	1.627
S.D.	0.0521	0.0366	0.0573	0.0519	0.0850
N	10	10	10	10	10
ADRENAL GL					
MEAN	0.035	0.035	0.034	0.034	0.033
S.D.	0.0026	0.0038	0.0045	0.0026	0.0019
N	10	10	10	10	10
TESTES					
MEAN	2.175	2.189	1.706*	1.347**	1.265**
S.D.	0.3236	0.3480	0.5835	0.4882	0.4050
N	10	10	10	10	10
THYROID GL					
MEAN	0.009	0.010	0.008	0.012**	0.012*
S.D.	0.0012	0.0022	0.0029	0.0016	0.0031
N	10	9	10	10	10

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

ATTACHMENT 1, p.17

DRAFT

SIGMET L-77*: FOURTEEN-DAY DIETARY STUDY IN FISCHER 344 RATS
SUMMARY OF ORGAN WEIGHTS AS % OF BRAIN WEIGHT
ANIMALS SACRIFICED AT WEEK 2

MALES

GROUP: PPM	0	1000	5000	15000	20000
LIVER					
MEAN	303.594	314.442	329.340*	356.923**	383.125**
S.D.	25.4241	24.8874	28.8800	25.2899	27.3047
N	10	10	10	10	10
KIDNEYS					
MEAN	76.736	77.121	75.019	77.069	77.373
S.D.	4.6505	5.8440	6.9182	4.2250	3.5377
N	10	10	10	10	10
HEART					
MEAN	40.014	37.945	35.287**	35.667**	34.836**
S.D.	4.0658	1.9569	3.1553	2.9249	2.7305
N	10	10	10	10	10
SPLEEN					
MEAN	23.140	23.269	22.135	22.676	21.609
S.D.	1.5174	2.5637	1.1245	2.1704	1.2012
N	10	10	10	10	10
ADRENAL GL					
MEAN	2.098	2.064	2.036	2.059	1.999
S.D.	0.1678	0.2323	0.2603	0.1563	0.0870
N	10	10	10	10	10
TESTES					
MEAN	129.694	129.184	101.059*	81.403**	77.853**
S.D.	17.2773	18.7984	33.7813	29.6380	23.2389
N	10	10	10	10	10
THYROID GL					
MEAN	0.550	0.611	0.467	0.737**	0.756**
S.D.	0.0733	0.1296	0.1600	0.0976	0.1816
N	10	9	10	10	10

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

ATTACHMENT 1, p. 18

DRAFT

SILVEX S-77®: FOURTEEN-DAY DIETARY STUDY IN FISCHER 344 RATS
SUMMARY OF ORGAN WEIGHTS (GRAMS)
ANIMALS SACRIFICED AT WEEK 2

FEMALES

GROUP: PPM	0	1000	5000	15000	20000
FINAL BODY WEIGHT					
MEAN	117.6	119.7	112.8	114.1	112.1*
S.D.	7.50	5.84	5.86	3.58	5.04
N	10	10	10	10	10
LIVER					
MEAN	3.636	3.757	3.960*	4.355**	4.689**
S.D.	0.3731	0.3001	0.2007	0.1862	0.3702
N	10	10	10	10	10
KIDNEYS					
MEAN	1.026	1.027	0.985	0.988	0.965
S.D.	0.0889	0.0574	0.0565	0.0298	0.0524
N	10	10	10	10	10
HEART					
MEAN	0.482	0.518*	0.463	0.458	0.484
S.D.	0.0230	0.0452	0.0423	0.0270	0.0451
N	10	10	10	10	10
SPLEEN					
MEAN	0.315	0.316	0.277*	0.278**	0.272**
S.D.	0.0907	0.0279	0.0347	0.0217	0.0230
N	10	10	10	10	10
BRAIN					
MEAN	1.600	1.607	1.593	1.571	1.568
S.D.	0.0544	0.0356	0.0434	0.0473	0.0429
N	10	10	10	10	10
ADRENAL GL					
MEAN	0.041	0.040	0.039	0.035**	0.036**
S.D.	0.0020	0.0027	0.0030	0.0038	0.0022
N	10	10	10	10	10
OVARIES					
MEAN	0.070	0.069	0.056*	0.053**	0.052**
S.D.	0.0072	0.0170	0.0124	0.0096	0.0072
N	10	10	10	10	10
THYROID GL					
MEAN	0.007	0.008	0.009	0.009**	0.010**
S.D.	0.0011	0.0015	0.0015	0.0019	0.0023
N	9	10	10	10	10

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

ATTACHMENT 1, p.19

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TABLE 14

SILMET L-77®: FOURTEEN-DAY DIETARY STUDY IN FISCHER 344 RATS
SUMMARY OF ORGAN WEIGHTS AS % OF FINAL BODY WEIGHT
ANIMALS SACRIFICED AT WEEK 2

FEMALES

GROUP: PPM	0	1000	8000	15000	20000
LIVER					
MEAN	3.090	3.137	3.512**	3.820**	4.192**
S.D.	0.1977	0.1397	0.1024	0.1508	0.2205
N	10	10	10	10	10
KIDNEYS					
MEAN	0.874	0.859	0.873	0.866	0.861
S.D.	0.0573	0.0322	0.0259	0.0241	0.0255
N	10	10	10	10	10
HEART					
MEAN	0.412	0.433	0.410	0.399	0.431
S.D.	0.0221	0.0221	0.0185	0.0262	0.0331
N	10	10	10	10	10
SPLEEN					
MEAN	0.267	0.264	0.245*	0.241**	0.242**
S.D.	0.0281	0.0136	0.0234	0.0147	0.0121
N	10	10	10	10	10
BRAIN					
MEAN	1.364	1.345	1.415*	1.378	1.400
S.D.	0.0593	0.0466	0.0557	0.0342	0.0342
N	10	10	10	10	10
ADRENAL GL					
MEAN	0.035	0.034	0.034	0.031**	0.032*
S.D.	0.0027	0.0021	0.0023	0.0032	0.0019
N	10	10	10	10	10
OVARIES					
MEAN	0.059	0.057	0.050*	0.046**	0.046**
S.D.	0.0047	0.0120	0.0093	0.0085	0.0048
N	10	10	10	10	10
THYROID GL					
MEAN	0.006	0.007	0.008	0.008**	0.009**
S.D.	0.0008	0.0012	0.0014	0.0017	0.0019
N	9	10	10	10	10

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

ATTACHMENT 1, p.20

DRAFT

SILNET L-77®: FOURTEEN-DAY DIETARY STUDY IN FISCHER 344 RATS
SUMMARY OF ORGAN WEIGHTS AS % OF BRAIN WEIGHT
ANIMALS SACRIFICED AT WEEK 2

FEMALES

GROUP: PPM	0	1000	8000	15000	20000
LIVER					
MEAN	227.033	233.571	248.390**	277.441**	296.906**
S.D.	18.6996	14.9190	7.9167	14.3897	19.6976
N	10	10	10	10	10
KIDNEYS					
MEAN	64.138	63.894	61.764	62.892	61.540
S.D.	4.6969	2.7229	2.6892	2.0897	2.4100
N	10	10	10	10	10
HEART					
MEAN	30.195	32.217*	29.029	28.969	30.826
S.D.	1.5475	2.3412	2.0723	1.9707	2.3420
N	10	10	10	10	10
SPLEEN					
MEAN	19.653	19.650	17.334**	17.488**	17.297**
S.D.	2.6888	1.3879	1.8840	1.4171	1.0430
N	10	10	10	10	10
ADRENAL GL					
MEAN	2.554	2.507	2.423	2.239**	2.277**
S.D.	0.1726	0.1448	0.1890	0.2068	0.1311
N	10	10	10	10	10
OVARIES					
MEAN	4.341	4.257	3.517**	3.381**	3.275**
S.D.	0.3771	0.9820	0.7103	0.6557	0.3778
N	10	10	10	10	10
THYROID GL					
MEAN	0.455	0.503	0.540	0.579**	0.630**
S.D.	0.0653	0.0899	0.0946	0.1173	0.1385
N	9	10	10	10	10

* Significantly different from control group ($p < .05$)
** Significantly different from control group ($p < .01$)

ATTACHMENT 2, P.1

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TABLE 11

SILWET® SURFACTANT L-77®: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF TEST SUBSTANCE CONSUMPTION (MG/KG/DAY)

MALES

GROUP: PPM	0	1000	8000	15000	20000
DAY 0 TO 2					
MEAN		105.6	721.8	1153.6	1174.9
S.D.		6.26	66.73	96.69	168.34
N		10	10	10	15
DAY 2 TO 4					
MEAN		102.1	752.0	1352.4	1690.6
S.D.		4.99	62.87	78.17	162.60
N		10	10	10	15
DAY 4 TO 7					
MEAN		95.8	723.7	1328.8	1739.4
S.D.		4.53	41.71	55.38	195.29
N		10	10	10	15
DAY 7 TO 10					
MEAN		91.3	660.9	1233.0	1648.4
S.D.		5.56	22.54	48.90	116.18
N		10	10	10	15
DAY 10 TO 14					
MEAN		94.6	674.7	1243.4	1619.5
S.D.		21.06	33.57	47.28	116.38
N		10	10	10	15
GRAND MEAN					
MEAN		97.9	706.6	1262.3	1574.5
S.D.		5.84	37.71	79.96	227.93
N		5	5	5	5

Data not included for animals removed from food consumption

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ATTACHMENT 2, P.2

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TABLE 12

SILWET® SURFACTANT L-77™: FOURTEEN-DAY DIETARY STUDY
IN FISCHER 344 RATS
SUMMARY OF TEST SUBSTANCE CONSUMPTION (MG/KG/DAY)

FEMALES:

GROUP: PPM	0	1000	6000	15000	20000
DAY 0 TO 2					
MEAN		102.2	734.7	1145.9	1609.8
S.D.		6.31	37.97	158.37	1145.81
N		10	10	10	15
DAY 2 TO 4					
MEAN		102.1	789.1	1589.2	1927.1
S.D.		5.69	87.61	297.04	173.50
N		10	10	10	15
DAY 4 TO 7					
MEAN		101.1	758.0	1446.0	1963.3
S.D.		6.36	53.92	126.61	122.33
N		10	10	10	15
DAY 7 TO 10					
MEAN		97.3	732.0	1387.2	1902.4
S.D.		3.83	31.00	117.35	119.56
N		10	10	10	15
DAY 10 TO 14					
MEAN		91.4	744.5	1256.0	1851.0
S.D.		4.67	58.54	70.55	106.81
N		10	10	10	15
GRAND MEAN					
MEAN		98.8	751.6	1384.9	1850.7
S.D.		4.59	23.28	160.83	140.73
N		5	5	5	5

Data not included for animals removed from food consumption