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Document Title	INITIAL SUBMISSION: LTR FR EQUIVA SVCS TO USEPA W/RESLTS OF SUBCHRONIC TOXICITY TEST OF LOW-VISCOSITY PARAFFINIC WHITE OIL, DATED 081000 W/ ATTACHMENT		
Chemical Category	LOW-VISCOSITY PARAFFINIC WHITE OIL, 15 CST@40C		

**INITIAL
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Patrick W. Tomlinson
Director - Safety, Health and Environment

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By Certified Mail

August 10, 2000

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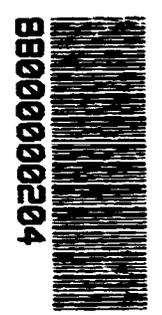
Dear Sir/Madam:

Equiva Services LLC (Equiva) provides Product Stewardship services to Equilon Enterprises LLC (Equilon). Equilon is participating in an industry consortium that is sponsoring subchronic toxicity testing of low-viscosity paraffinic white oil, 15 cSt @ 40C. The CAS# is 8042-47-5. Equiva has received preliminary results from this testing. We are submitting this letter on behalf of Equilon pursuant to TSCA Section 8(e), because these preliminary data include three findings that EPA may consider to be 8(e) reportable.

In Phase I of this study three groups of eight female Fischer F344 and Sprague-Dawley rats were fed 0%, 0.02% or 2% (F344) or 0%, 1% and 2% (SD) test article mixed into feed for 90 days and immune function was evaluated. A second phase was included which further evaluated immune response. Phase II group design was the same as Phase I, except the F344 rats were exposed for 120 days, followed by a 30-day nonexposed recovery period.

Four days prior to sacrifice, animals were exposed intravenously to sheep red blood cells as antigen challenge for subsequent assay. Following sacrifice, liver, spleen and lymph node weights were determined. Gross lesions, liver and mesenteric lymph node tissues along with adipose tissue adjacent to the lymph nodes were taken and processed for histopathological evaluation. Spleen IgM antibody-forming cell response to sheep red blood cells was determined at sacrifice, and serum IgG antibody titers were also measured in the recovery group.

The data received include the following findings, which were observed only in the high-dose F344 rats. First, an increased number of cells per spleen were noted. Second, granulomatous inflammation was observed in adipose tissue immediately adjacent to lymph nodes, whereas this inflammation had previously been described only in the lymph



nodes themselves. Third, rats had a decreased primary antibody response (IgM) when challenged with sheep red blood cells in a standard assay. This decrease is observed when the results are normalized per number of spleen cells, but not when normalized per spleen. The adipose tissue and antibody response changes were reversible, in that there was no longer a statistically significant difference from control 30 days post-exposure in parallel treatment groups. Serum antibody titers did not differ significantly from control. Otherwise, the data were comparable to those previously reported in the scientific literature for similar studies.

Copies of pertinent data tables and text from the draft laboratory reports are enclosed. EPA will be provided a copy of the complete study when it becomes available. If you require further information please contact Fred Reitman at (201) 874-4953, or by mail at this address.

Regards,



Patrick W. Tomlinson
Director - Safety, Health and Environment

Enclosures

EPL[®]

EXPERIMENTAL PATHOLOGY LABORATORIES, INC.

IMMUNOTOX, INC.
 STUDY NUMBER ITI 1298
 EPL PROJECT NUMBER 624-001

EFFECTS OF DIETARY MINERAL HYDROCARBONS ON 5-CELL
 DEPENDENT ANTIBODY PRODUCTION IN TWO STRAINS OF RATS

PATHOLOGY SUMMARY

Microscopic examinations were performed on selected tissues from two strains of rats. In Phase I, both rat strains were treated by dietary exposure. Approximately one month after the start of Phase I, Phase II was initiated. All Phase I rats were terminated after 90 days of exposure. As no immunologic effects were seen in the Phase I Sprague-Dawley rats, the Phase II Sprague-Dawley rats were also terminated after 90 days of exposure. Due to immunologic effects seen in the Fischer 344 rats in Phase I, the Fischer 344 rats in Phase II were exposed for 120 days and then allowed to recover for an additional 30 days. The purpose of this study was to evaluate the immunological parameters to further characterize the immune response to ingestion of mineral hydrocarbons (MHC) in two strains of rats, Fischer 344 [CDF[®](F-344)/CrBr] and Sprague Dawley [Cr:CD[®](SD)BR]. The experimental design for the study was as follows:

Group	Strain	Dietary Level	Animal Numbers		
			Phase I (91 days)	Phase II (91 days)	Phase II (151 days)
1 VHF	F344	0%	001-008		033-040
2 D1F	F344	0.02%	009-016		041-048
3 D2F	F344	2.0%	017-024		049-056
4 PCF	F344	CPS Positive Control ^b	025-032 ^a		057-064 ^a
5 VHS	SD	0%	101-108	133-140	
6 D1S	SD	1.0%	109-116	141-148	
7 D2S	SD	2.0%	117-124	149-156	
8 PCS	SD	CPS Positive Control ^b	125-132 ^a	157-164 ^a	

^aPositive control group had no tissues collected for histopathology.

^bCyclophosphamide 50 mg/kg

June 20, 2000 ORIGINAL 1,2/QA

Table

Spleen Antibody-Forming Cell Response to T-dependent Antigen Sheep Erythrocytes in Female Fischer 344 Rats Exposed to Dietary Mineral Hydrocarbon (P15) Daily for 90 Days

Day 4 Response

MHC-90-1R-FD Phase I

Treatment	Body Wgt (g)	Spleen Wgt (mg)	Spleen Cells ($\times 10^7$)	IgM AFC/ 10^6 Spleen Cells	IgM AFC/Spleen ($\times 10^3$)
Control Diet	175.1 \pm 1.7 (8)	426 \pm 11 (8)	24.95 \pm 0.75 (8)	602 \pm 65 (8)	151 \pm 17 (8)
P15 Mineral Oil Diet 0.02%	179.2 \pm 2.4 (8)	455 \pm 9 (8)	28.90 \pm 0.99 (8)	447 \pm 53 (8)	129 \pm 15 (8)
2%	183.7 \pm 1.5** (8)	602 \pm 16** (8)	36.11 \pm 1.80** (8)	362 \pm 43* (8)	128 \pm 13 (8)
Cyclophosphamide 50 mg/kg	172.6 \pm 3.4 (8)	259 \pm 8** (8)	10.16 \pm 0.67** (8)	89 \pm 85** (8)	9 \pm 8** (8)
H/NH	H	H	H	H	H
Trend Analysis	p < 0.01	p < 0.01	p < 0.01	p < 0.01	NS

Female Fischer 344 rats were administered control diet or P15 mineral oil containing diet daily for 90 days. The positive control, cyclophosphamide, was administered i.p. on days 87-90. On day 87, the rats were immunized (i.v.) with 2×10^8 sRBC. On day 91, spleen cells were prepared into single cell suspensions and the number of IgM sRBC antibody-forming cells was determined. Values represent the mean \pm SE derived from the number of animals indicated in parentheses. H = homogeneous data and NH = non-homogeneous data using the Bartlett's Test for homogeneity. Homogeneous data were evaluated using a parametric analysis of variance. When significant differences occurred, exposed groups were compared to the vehicle control group using the Dunnett's t Test. The positive control was compared to the vehicle control using the Student's t Test. Non-homogeneous data were evaluated using a non-parametric analysis of variance. When significant differences occurred, exposed groups were compared to the vehicle control group using the Wilcoxon Rank Test. Values significantly different from vehicle control at $p < 0.05$ are indicated by an asterisk, while those significant at $p < 0.01$ are noted by a double asterisk. The Jonckheere's Test was used to test for dose-related trends among the vehicle and exposed groups.