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SUPPORT: DEVELOPMENTAL TOXICITY STUDY OF REFINERY STREAMS SUSPECTED OF CONTAINING CARBAZOLES (VDF AND STRAIGHT RUN DIESEL) DERMALLY APPLIED TO RATS W/COVER LETTER DATED 102292		
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SUPP

OFFICE OF TOXIC SUBSTANCES

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Contains No CBI

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Document Control Officer (TS-790)
Attention: 8(e) Coordinator
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Subject: TSCA Section 8(e) Notice on Refinery Streams Suspected of Containing Varying Levels of Carbazoles that are Contained in Carbon Black Oil (CAS 64741-62-4; 8EHQ-1185-0576)

Dear Sir/Madam:

In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act, the Atlantic Richfield Company (ARCO) is submitting information on the preliminary results of two studies in experimental animals to assess the developmental toxicity of refinery streams suspected of containing carbazoles. This information supplements a previous TSCA submittal on such materials.

This is one of several follow-up studies initiated by ARCO in response to previous reports by Mobil and ARCO (8EHQ-1185-0576) of adverse effects on rat fetuses after dermal exposure to carbon black oil (CBO) a material which contains carbazoles. The objective of the ARCO studies being reported in this letter was to determine the maternal and fetal toxicity of selected refinery streams that, like CBO, may contain carbazoles.

The materials that were examined in the current studies are VDF Diesel and Straight Run Diesel which were dermally administered to groups of pregnant rats. Animals received doses of 0, 125 or 250 mg/kg/day once daily during days 0 through 20 of gestation. An additional group was administered a dose of 1000 mg/kg/day during days 5 through 9 of gestation. Pups were examined daily for external abnormalities and were weighed on Day 0 and Day 4 of lactation.

18 pgs.

The data indicate that administration of VDF Diesel (CAS #68410-00-4) at 125, 250 and 1000 mg/kg caused a decrease in mean pup body weights. Signs of maternal toxicity considered related to the administration of VDF Diesel included decreased body weights, body weight changes and food consumption at doses of 250 and 1000 mg/kg.

The data for Straight Run Diesel (CAS #68410-00-4) indicate similar effects. Decreases in pup body weights were observed at a dose level of 250 mg/kg. Signs of maternal toxicity considered related to the administration of this material included decreased body weights, body weight changes and food consumption at doses of 250 and 1000 mg/kg.

The data from these studies have received only a preliminary review. Additional statistical analysis and historic controls comparisons will be performed for the final reports. This additional analysis may change the preliminary summary of adverse effects listed above.

Our current MSD Sheets on the refinery streams tested in these studies are being reviewed with these results in mind.

We are attaching the preliminary information on these studies which were contained in a review of the draft summary data compiled by the testing laboratory. EPA will be sent a copy of the final reports once they are received by ARCO.

Sincerely yours,

William D. Leake

William D. Leake

WDL/FJK/isc

Attachment

DRAFT SUMMARY

The objective of this study was to determine the developmental toxicity of F-195 following dermal administration to female Sprague-Dawley rats daily for Days 0 through 20 of gestation.

Two groups of 15 or 14 presumed pregnant female Sprague-Dawley rats were administered F-195 topically at a dose of 125.0 or 250.0 mg/kg/day, respectively, once daily during Days 0 through 20 of gestation. A third group of 15 presumed pregnant female Sprague-Dawley rats were administered F-195 topically at a dose of 1,000.0 mg/kg/day, once daily during Days 5 through 9 of gestation. A fourth group of 19 presumed pregnant female Sprague-Dawley rats served as a sham control group; with the exception of test article application these animals underwent the same procedures as the 125.0 and 250.0 mg/kg dose groups.

Each female was observed twice daily for viability and once daily for signs of toxicity. Body weights were recorded for each female at receipt; near the end of the quarantine period; on Days 0, 4, 8, 12, 16, and 20 of gestation; and on Days 0 and 4 of lactation. Food consumption was measured for Days 0 to 4, 4 to 8, 8 to 12, 12 to 16, and 16 to 20 of gestation; and Days 0 to 4 of lactation. On Day 4 of lactation or on Gestation Day 25 for females that did not deliver a litter, each female was sacrificed and subjected to a gross necropsy. The ovaries and uterine horns of each female that delivered a litter were examined to determine the number of corpora lutea and implantation sites, respectively.

Pups were examined daily for external abnormalities. On Days 0 and 4 of lactation, each pup was weighed and its sex was determined. On Day 4 of lactation, all surviving pups were sacrificed and discarded.

Signs of maternal toxicity considered to be related to administration of F-195 included decreased body weights, and body weight changes, and food consumption at doses of 250.0, and 1,000.0 mg/kg.

Dermal irritation related to administration of F-195 was observed in all of the dose groups treated with F-195.

Signs of developmental toxicity considered to be related to administration of F-195 included decreased pup body weights on Lactation Days 0 and 4 at a dose of 250.0 mg/kg.

Based on the results of this study, the no-observable-effect level for maternal and developmental toxicity was 125.0 mg/kg (dosing duration Gestation Days 0 to 20). Administration of the test article at a higher dose level (1,000.0 mg/kg), but for a shorter dosing period (Gestation Days 5 to 9), produced signs of maternal toxicity without any evidence of developmental toxicity.

UBTL Study No.: 66355
Protocol No.: ATX-91-0129

Summary of Female Body Weight Data (g)

	Gestation						Lactation	
	Day 0	Day 4	Day 8	Day 12	Day 16	Day 20	Day 0	Day 4
Dose: Sham Control								
Mean	273.5	297.3	314.1	332.0	366.6	424.7	331.3	341.0
Std Dev	13.0	8.1	12.5	17.8	19.6	27.2	21.1	19.0
N	15	14	14	15	15	15	15	15
Dose: 125 mg F-195/kg								
Mean	277.3	300.3	314.2	336.0	364.3	423.8	322.4	328.4
Std Dev	17.4	17.2	12.8	17.2	13.8	19.5	13.3	14.0
N	12	12	12	12	12	12	12	12
Dose: 250 mg F-195/kg								
Mean	272.3	288.4	301.4	320.0	345.5	401.3	305.1	318.3
Std Dev	15.6	14.0	18.3	21.0	22.4	22.9	26.7	29.3
N	10	10	10	10	10	10	10	10
Dose: 1000 mg F-195/kg								
Mean	277.6	301.5	298.9	301.6	332.9	388.6	310.2	324.0
Std Dev	16.5	13.8	13.5	16.2	20.9	40.2	23.7	25.2
N	14	14	14	14	14	14	13	13

* = Significantly different from control group at $p<0.05$
** = Significantly different from control group at $p<0.01$

Table 1