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NON-CONFIDENTIAL INFORMATION
March 2, 2012

Document Processing Center (Mail Code 7407M)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue
Washington, DC 20460-0001



Re: TSCA 8(e) Submission of Findings on Extracts (petroleum), light paraffinic distillate solvent (CAS# 64742-05-8) from a Developmental Toxicity Test in Rats

Dear Madam or Sir:

The American Petroleum Institute (API), on behalf of the Petroleum HPV Testing Group, is submitting this notice pursuant to Section 8(e) of the Toxic Substances Control Act for the substance, "Extracts (petroleum), light paraffinic distillate solvent" (CAS# 64742-05-8). The Testing Group is an unincorporated group of petroleum substance manufacturers and importers affiliated by contractual obligation to establish and fund a voluntary data disclosure and testing program, in response to EPA's HPV Chemical Challenge Program. The Testing Group program is administered by API (membership list attached).

The Testing Group has received an audited draft report from a study titled "A Dermal Prenatal Developmental Toxicity Study of Extract, Light Paraffinic Distillate Solvent in Rats." This study was conducted in general accordance with the EPA Health Effects Test Guideline OPPTS 870.3700, Prenatal Developmental Toxicity Study, August, 1998 and the OECD Guidelines for Testing of Chemicals Guideline 414, Prenatal Developmental Toxicity Study, 22 January 2001. Developmental effects as evidenced by increased postimplantation loss (primarily early resorptions), lower mean fetal body weights, and test substance-related fetal developmental variations were reported. Therefore, in accordance with EPA's published TSCA Section 8(e) guidance we are submitting the test findings for your review.

Extracts (petroleum), light paraffinic distillate solvent is a Class 2 substance (UVCB) defined as "A complex combination of hydrocarbons obtained as the extract from a solvent extraction process. It consists predominantly of aromatic hydrocarbons having carbon numbers predominantly in the range of C15 through C30. This stream is likely to contain 5 wt. % or more of 4- to 6- membered condensed ring aromatic hydrocarbons."

The test substance in the vehicle (acetone) was administered by dermal application to the dorsal scapular area (approximately 10% of total body surface area) of 4 groups (Groups 3-6) of 25 bred female Crl:CD(SD) rats once daily from gestation days 0 through 19; animals were exposed to the test substance for 6 hours each day. Exposure levels were 5, 25, 150, and 450 mg/kg/day administered at a dosage volume of 1.5 mL/kg. A concurrent vehicle control group (Group 2) composed of 25 bred females

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received the vehicle on a comparable regimen. A concurrent sham control group (Group 1) was subjected to the same procedures (*i.e.* shaving, collaring, sham dosing with a glass rod, and removal of residual test substance) as Groups 2-6; however, no vehicle or test substance was applied to these animals.

Maternal toxicity was evident in the 25, 150, and 450 mg/kg/day groups with adverse clinical and/or macroscopic findings and a higher incidence of dermal observations at these exposure levels. Additionally, mean body weight losses and/or lower mean body weight gains with corresponding lower mean food consumption was noted generally throughout the treatment period in the 150 and 450 mg/kg/day groups. These effects resulted in moribundity at 150 and 450 mg/kg/day. Mean thymus weights (absolute and relative to brain) were noted in the 25, 150, and 450 mg/kg/day groups. No evidence of maternal toxicity was noted at 5 mg/kg/day. Developmental effects were noted in the 150 and 450 mg/kg/day groups as evidenced by increased mean litter proportions of postimplantation loss (primarily early resorptions) with a corresponding decrease in the mean numbers and litter proportions of viable fetuses. In addition, lower mean male, female, and combined fetal weights were noted in the 25 and 150 mg/kg/day groups. Lower fetal weights were also noted for the single surviving litter in the 450 mg/kg/day group. Test substance-related fetal developmental variations (sternebra(e) nos. 5 and/or 6 unossified, reduced ossification of the skull, reduced ossification of the vertebral arches, sternebra(e) nos. 1, 2, 3, and/or 4 unossified, and cervical centrum no.1 ossified) were noted in the 150 mg/kg/day group and for surviving fetuses in the 450 mg/kg/day group and were considered secondary to lower fetal weights. Intrauterine growth and survival at 5 mg/kg/day and skeletal fetal morphology at 5 and 25 mg/kg/day were unaffected by test substance administration.

Based on these results, an exposure level of 5 mg/kg/day was considered to be the no-observed-adverse-effect level (NOAEL) for maternal toxicity and embryo/fetal development when Extract, light paraffinic distillate solvent was administered by dermal application to bred Crl:CD(SD) rats.

Adverse developmental effects have been reported on a similar test substance, Extract (petroleum), heavy paraffinic distillate solvent (CAS# 64742-04-7) by Feuston et al., 1996. Both the light (current study) and heavy (Feuston et al. 1996) paraffinic aromatic extracts contain significant concentrations of polycyclic aromatic compounds (PAC). Other petroleum substances with significant PAC content have been shown to cause similar developmental toxicity when applied dermally (Feuston et al., 1994), so the results reported in the current study are not surprising. The relationship between the aromatic ring-class profile and the developmental toxicity of high-boiling petroleum substances has been developed into a model for predicting the dose-response (API, 2008). The current study will assist in the validation and continued refinement of that model.

When the final report of the study is complete, the results will be submitted to EPA as part of the Testing Group's submissions under EPA's HPV Challenge Program. If you have any questions or require further information regarding this submission please don't hesitate to contact me.

Sincerely,



Howard J. Feldman

References:

Feuston, M.H., Low, L.K., Hamilton, C.E., and Mackerer. 1994. Correlation of systemic and developmental toxicities with chemical component classes of refinery streams. *Fund. Appl. Toxicol.* 22:622-630.

Feuston, M.H., Hamilton, C.E., and Mackerer, C.R. 1996. Systemic and developmental toxicity of dermally applied distillate aromatic extract in rats. *Fund. Appl. Toxicol.* 30:276-284.

API (American Petroleum Institute) PAC Analysis Task Group. 2008. "The relationship between the aromatic ring class content and selected endpoints of repeat-dose and developmental toxicity of high-boiling petroleum substances." <http://www.petroleumhpv.org/pages/pac.html>, accessed 27 Feb 2012

Attachments: Petroleum HPV Testing Group Membership List

cc. Oscar Hernandez, USEPA
Diane Sheridan, USEPA
Mark Townsend, USEPA



**Member Companies of the Petroleum HPV Testing Group
March 2012**

1. Alcoa Inc. (LA)
2. Alcoa, Inc. (VA)
3. Big West Oil LLC
4. BP
5. Calcasieu Refining Company
6. Chevron Corporation
7. CHS Inc.
8. CITGO Asphalt Refining Company
9. CITGO Petroleum Corp.
10. Coffeyville Resources, Refining and Marketing, LLC
11. ConocoPhillips Company
12. Countrymark Refinery
13. Cross Oil Refining & Marketing, Inc.
14. Dakota Gasification Company
15. Delek Refining, LTD
16. Dynegy Liquids MKTG & Trade
17. Edgington Oil Company
18. Elkhorn Operating Company
19. Equilon Enterprises LLC/Motiva Enterprises LLC
20. Ergon Refining, Inc.
21. Ergon West Virginia Inc
22. ExxonMobil Americas Refining and Supply Company
23. Flint Hills Resources, LP
24. Formosa Hydrocarbons Co., Inc.
25. Giant Industries, Inc.
26. Hess Corporation
27. Holly Corp/Navajo Refining Co
28. Houston Refining LP
29. Hovensa, LLC
30. Hunt Refining Co.
31. Kern Oil & Refining Company
32. Lion Oil Company
33. Marathon Oil Company LLC
34. Merichem Chemicals & Refinery Serv LLC
35. Murphy Oil Corporation
36. National Cooperative Refinery Association
37. Neville Chemical Company
38. Pasadena Refining System, Inc.
39. PDV Midwest Refining, LLC
40. Placid Refining Company LLC
41. Safety-Kleen Oil Recovery
42. Sasol North America Inc.
43. Shell Oil Company
44. Sid Richardson Gasoline Co.
45. Silver Eagle Refining, Inc. (UT)
46. Silver Eagle Refining, Inc. (WY)
47. Sinclair Oil Corporation
48. South Hampton Refining Company
49. Sunoco Inc (R+M)
50. Tesoro Petroleum Corporation
51. The Goodyear Tire & Rubber Company
52. The Premcor Refining Group Inc.
53. Total Petrochemicals USA, Inc.
54. Tricor Refining, LLC
55. True Oil Co/88 Oil Co/Equit. Oil Purch. Co
56. US Oil & Refining Co.
57. Valero Energy Corp
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