SCREENING-LEVEL HAZARD CHARACTERIZATION OF HIGH PRODUCTION VOLUME CHEMICALS

CHEMICAL CATEGORY NAME Aromatic Extracts

SPONSORED CHEMICALS

SUBCATEGORY I: DISTILLATE AROMATIC EXTRACTS

Group 1: Paraffinic Distillate Aromatic Extracts

Heavy Paraffinic Distillate, Solvent ExtractCASRN 64742-04-7[9th CI Name: Extracts (Petroleum), Heavy Paraffinic Distillate Solvent]Light Paraffinic Distillate, Solvent Extract[9th CI Name: Extracts (Petroleum), Light Paraffinic Distillate Solvent]

Group 2: Naphthenic Distillate Aromatic Extracts

Heavy naphthenic distillate, solvent extractCASRN 64742-11-6[9th CI Name: Extracts (Petroleum), Heavy Naphthenic Distillate Solvent]Light naphthenic distillate, solvent extract[9th CI Name: Extracts (Petroleum), Light Naphthenic Distillate Solvent]

Subcategory II: Residual Aromatic Extracts

Residual Oil, Solvent ExtractCASRN 64742-10-5[9th CI Name: Extracts (Petroleum), Residual Oil Solvent]

The High Production Volume (HPV) Challenge Program¹ was conceived as a voluntary initiative aimed at developing and making publicly available screening-level health and environmental effects information on chemicals manufactured in or imported into the United States in quantities greater than one million pounds per year. In the Challenge Program, producers and importers of HPV chemicals voluntarily sponsored chemicals; sponsorship entailed the identification and initial assessment of the adequacy of existing toxicity data/information, conducting new testing if adequate data did not exist, and making both new and existing data and information available to the public. Each complete data submission contains data on 18 internationally agreed to "SIDS" (Screening Information Data Set²) endpoints that are screening-level indicators of potential hazards (toxicity) for humans or the environment.

The Environmental Protection Agency's Office of Pollution Prevention and Toxics (OPPT) is evaluating the data submitted in the HPV Challenge Program on approximately 1400 sponsored chemicals by developing hazard characterizations (HCs). These HCs consist of an evaluation of the quality and completeness of the data set provided in the Challenge Program submissions. They are not intended to be definitive statements regarding the possibility of unreasonable risk of injury to health or the environment.

The evaluation is performed according to established EPA guidance³ and is based primarily on hazard data provided by sponsors; however, in preparing the hazard characterization, EPA considered its own comments and public comments on the original submission as well as the sponsor's responses to comments and revisions made to the submission. In order to determine whether any new hazard information was developed since the time of the HPV submission, a search of the following databases was made from one year prior to the date of the HPV Challenge submission to the present: (ChemID to locate available data sources including Medline/PubMed, Toxline, HSDB, IRIS, NTP, ATSDR, IARC, EXTOXNET, EPA SRS, etc.), STN/CAS online databases (Registry file for locators, ChemAbs for toxicology data, RTECS, Merck, etc.) and Science Direct. OPPT's focus on these specific sources is based on their being of high quality, highly relevant to hazard characterization, and publicly available.

OPPT may not develop HCs for those HPV chemicals which have recently been assessed and published internationally through the HPV program of the Organization for Economic Cooperation and Development (OECD) and for which Screening Initial Data Set (SIDS) Initial Assessment Reports (SIAR) and SIDS Initial Assessment Profiles (SIAP) are available. These documents are presented in an international forum that involves review and endorsement by governmental authorities around the world. OPPT is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments. HCs may be created if new data suggest a need to update the case work where the OECD document will be used as key support documentation.

¹ U.S. EPA. High Production Volume (HPV) Challenge Program; <u>http://www.epa.gov/chemrtk/index.htm</u>.

² U.S. EPA. HPV Challenge Program – Information Sources; <u>http://www.epa.gov/chemrtk/pubs/general/guidocs.htm</u>.

³ U.S. EPA. Risk Assessment Guidelines; <u>http://cfpub.epa.gov/ncea/raf/rafguid.cfm</u>.

These hazard characterizations are technical documents intended to inform subsequent decisions and actions by OPPT. Accordingly, the documents are not written with the goal of informing the general public. However, they do provide a vehicle for public access to a concise assessment of the raw technical data on HPV chemicals and provide information previously not readily available to the public.

	Subcategory I		
	Sponsored Chemicals		
	Group 1		
	64742-04-7		
	64742-05-8		
Chemical Abstract Service Registry Number	Group 2		
(CASRN)	64742-11-6		
	64742-03-6		
	Subcategory II		
	Sponsored Chemical		
	64742-10-5		
	Subcategory I		
	Sponsored Chemicals		
	Group 1		
	Heavy Paraffinic Distillate,		
	Solvent Extract		
	Light Paraffinic Distillate,		
	Solvent Extract		
Chamical Abstract Index Name	Group 2		
Chemical Abstract muex Name	Heavy Naphthenic Distillate,		
	Solvent Extract		
	Light Naphthenic Distillate,		
	Solvent Extract		
	Subcategory II		
	Sponsored Chemical		
	Residual Oil, Solvent Extract		
Structural Formula	See Appendix		
	1		

Summary

The aromatic extracts consist of two sub-categories, the distillate aromatic extracts (DAEs) and the residual aromatic extracts (RAEs). The distillate aromatic extracts consist predominantly of aromatic hydrocarbons having carbon numbers in the C15 to C50 range and the residual aromatic extracts consist predominantly of aromatic hydrocarbons > C25. These complex mixtures are highly viscous to mobile liquids, which may be dark amber to black in color. The components of these mixtures possess low to negligible (estimated) and low to moderate (measured) water solubility and low to moderate (estimated) and moderate (measured) vapor pressure. They are expected to possess low mobility in soil. Volatilization is considered moderate based on estimated Henry's Law constant's for representative components of these mixtures; however, the strong tendency to adsorb to soil or sediment is likely to attenuate volatilization. The rate of hydrolysis is considered negligible for the components of these complex mixtures. The rate of atmospheric photooxidation is considered rapid to moderate; however, most mixture components are not expected to exist in the vapor phase in the ambient atmosphere. The representative components of the aromatic extracts category are expected to possess moderate (P2) to high (P3) persistence and low (B1) to high (B3) bioaccumulation potential.

Human Health Hazard

For assessing human health hazard, Subcategory I, distillate aromatic extracts is further divided into two subgroups based on paraffinic or naphthenic chemical characteristics of the distillate extracts.

Subcategory I: Distillate Aromatic Extracts

Group 1: Paraffinic Distillate Aromatic Extracts

The acute oral toxicity of CASRN 64742-05-8 to rats and acute dermal toxicity to rabbits is low. Following repeated oral exposure of CASRN 64742-04-7 to male rats for 13 weeks, decreased body weights and histopathological changes were seen in the liver, prostate and thymus at 125 mg/kg-day; the NOAEL for systemic toxicity is not established. A 13-week dermal exposure to CASRN 64742-04-7 resulted in a LOAEL of 30 mg/kg-day based on decreased body weight gain and histopathological changes; the NOAEL is not established. No data are available for reproductive or developmental toxicity. CASRN 64742-05-8 induced gene mutations in mammalian cells *in vitro* but CASRN 64742-04-7 did not induce chromosomal aberrations *in vivo*. CASRN 64742-05-8 was irritating to rabbit skin and eyes but was not sensitizing in guinea pigs. CASRNs 64742-04-7 and 64742-05-8 increased the incidence of skin tumors in mice.

The reproductive and developmental toxicity endpoints were identified as data gaps for Group 1, Subcategory I under the HPV Challenge Program.

Group 2: Naphthenic Distillate Aromatic Extracts

No data are available for acute, repeated-dose, reproductive and genetic toxicity endpoints. In a range finding prenatal developmental toxicity study with CASRN 64742-11-6 via the dermal route, maternal toxicity (decreased body weight gain) was observed at 500 mg/kg-day; the NOAEL for maternal toxicity is not established. The LOAEL for developmental toxicity is 2000

mg/kg-day based on increased fetal resorptions, decreased live implants and decreased litter weights; the NOAEL is 1000 mg/kg-day. No data are available for gene mutation and chromosomal aberrations endpoints. CASRN 64742-11-6 increased the incidence of tumors in mice.

Acute, repeated-dose, reproductive toxicity, gene mutation and chromosomal aberrations endpoints were identified as data gaps for Group 2, Subcategory I under the HPV Challenge Program.

Subcategory II: Residual Aromatic Extracts

No acute oral toxicity data are available. The acute dermal toxicity of CASRN 64742-10-5 is low in rats based on results obtained in a repeated-dose dermal toxicity study. In a repeated-dose dermal toxicity study with CASRN 64742-10-5 in rats, changes in several hematology and clinical chemistry parameters and significant increases in liver and spleen weights were observed at 2000 mg/kg-day; the NOAEL for systemic toxicity is 500 mg/kg-day. No reproductive toxicity data are available; however, an evaluation of reproductive organs in the dermal repeated-dose toxicity study with CASRN 64742-10-5 in rats via the dermal route showed no developmental toxicity study with CASRN 64742-10-5 in rats via the dermal route showed no developmental toxicity; the NOAEL is 2000 mg/kg-day (highest dose tested). No data for gene mutation are available; however, using a worst case scenario, the positive mutagenic response obtained for CASRN 64742-05-8 can be used to read across to this subcategory. CASRN 64742-10-5 did not induce chromosomal aberrations *in vivo*. CASRN 64742-10-5 increased the incidence of skin tumors in mice.

No data gaps were identified for Subcategory II under the HPV Challenge Program.

Hazard to the Environment

For ecotoxicity, the two subcategories are based on physical-chemical properties. Subcategory I contains light paraffinic and light naphthenic distillate, solvent extracts and Subcategory II contains heavy paraffinic and heavy naphthenic distillate, solvent extracts and residual oil, solvent extract.

Subcategory I

No adequate acute and chronic toxicity data are available for aquatic organism.

The acute toxicity to fish and aquatic invertebrates, toxicity to aquatic plants, and chronic toxicity to aquatic invertebrates are identified as data gaps for subcategory I under the HPV Challenge Program.

Subcategory II

No adequate acute and chronic toxicity data are available for aquatic organism. However, based on the physical-chemical properties of the category members [log K_{ow} (8.0 to 19.6) and water

solubility ($<1x10^{-6}$ to 0.002 mg/L)], acute and chronic aquatic toxicity to aquatic organisms is not expected.

The sponsor, the American Petroleum Institute Petroleum HPV Testing Group, submitted a Test Plan and Robust Summaries to EPA for the aromatic extracts category dated December 15, 2003. EPA posted the submission on the ChemRTK HPV Challenge website on January 20, 2004 (http://www.epa.gov/chemrtk/pubs/summaries/aroexcat/c14900tc.htm). EPA comments on the original submission were posted to the website on June 25, 2004. Public comments were also received and posted to the website. The sponsor submitted updated/revised documents on January 14, 2009, which were posted to the ChemRTK website on March 11, 2009.

Category Justification

The aromatic extracts category members are by-products of the extraction process for lubricating oil base stocks and waxes. Specifically, the category members are solvent extracts of vacuum distillates or vacuum residua of crude oil that has undergone atmospheric distillation.

The aromatic extracts category was divided into two subcategories (distillate aromatic extracts [DAEs] and residual aromatic extracts [RAEs]) based on the vacuum tower fraction from which they were derived. EPA agrees with this grouping; however, no information was provided to show that testing on paraffinic DAEs would be representative of napthenic DAEs; thus EPA recommends that testing be completed on both groups when there are data gaps. For this reason, the DAE subcategory was divided into two groups. Untreated DAEs are composed of $\sim 60 -$ 78% aromatic hydrocarbons (~ 28 - 35% of which are one- or two-ring aromatic hydrocarbons and ~ 17 - 23% of which are three- to five-ring aromatic hydrocarbons) and ~ 22 - 40%naphthenic and isoparaffinic hydrocarbons. Untreated RAEs are composed of $\sim 81 - 92\%$ aromatic hydrocarbons (\sim 37 – 40% of which are one- or two-ring aromatic hydrocarbons and 20 - 23% of which are three- to five-ring aromatic hydrocarbons). RAEs generally have molecular weights greater than DAEs and long alkyl or naphthene side chains. There are three overlapping carbon ranges within the category: a low of C15 - C30, a middle of C20 - C50 and a high range of > C25. The physical-chemical properties of the substances are directly related to their carbon range, and to a lesser extent, the paraffinic or naphthenic character of the feedstock from which they were extracted. The carbon range influences the volatility, water solubility and viscosity of these substances, and can therefore impact the environmental fate, ecotoxicity and potential bioavailability of toxic components.

The sponsor grouped the chemicals into a single category based on the following rationale: (1) the refinery process (solvent extraction) is similar for each of the category members, yielding substances that have high aromatic content and (2) the toxicity of the category members is proportional to the concentration of dimethyl sulfoxide (DMSO)-extractable three- to seven-ring polycyclic aromatic compounds (PACs). Although the Sponsor asserts that mammalian toxicity is related to the ring class profile of DMSO-extractable PACs, the lower viscosity of light paraffinic DAEs could result in increased bioavailability. For this reason, the sponsor has agreed to provide additional test data for the light paraffinic and light napthenic DAEs. The original test plan also implied that PAC content could be used to predict the toxicity of untested substances.

This claim is based on a publication by Feuston et al. (1994) which examined the correlation between the weight percentage of various chemical classes represented in thirteen refinery streams and the magnitude of effects seen in rats following dermal treatment with these substances in repeated-dose and developmental toxicity studies. Since the underlying data used to correlate PAC content with mammalian toxicity were limited, a more sophisticated and robust analysis was needed. A report has since been issued describing the results of such an evaluation (of the association between PAC content and toxicity), and the development of predictive models for eleven (selected) endpoints for dermal repeated-dose and developmental toxicity in the rat (API, 2008).

The PAC modeling approach was reviewed by a Toxicology Excellence for Risk Assessment (TERA) Peer Consultation Panel, which issued a report on January 28, 2008 (http://www.tera.org/peer/API/PAC%20MEETING%20REPORT%20Final.pdf, accessed 05/23/2011). The Panelists raised a number of questions, strongly suggesting that more work and broader input were needed. The revised submission (July 2, 2009) does not indicate that the Sponsor has performed additional work to address comments made in the Peer Consultation Panel report. The EPA believes that without additional information or documentation of their performance, these models cannot be evaluated for predictive power. Therefore, at this time the modeling approach is not adequately supported.

The Sponsor is in the process of investigating the relationship between PAC content and the potential genetic and reproductive toxicities of petroleum substances, and whether predictive models can or should be developed for these two endpoints. The results of these investigations will be reported separately.

For ecotoxicity, there are two subcategories based on their physical-chemical properties:

Subcategory I:

CASRN 64742-05-8
CASRN 64742-03-6
CASRN 64742-04-7
CASRN 64742-11-6
CASRN 64742-10-5

1. <u>Chemical Identity</u>

1.1 Identification and Purity

The following description is taken from the Sponsor's 2003 Test Plan and Robust Summary. Untreated DAEs are generally composed of approximately 60-78% aromatics with 1-2 ring aromatic hydrocarbons (PAHs) representing 28-35% and 3-5 ring PAHs representing 17-23% of the aromatic fraction. The remaining balance of material consists of naphthenic and iso-paraffinic hydrocarbons. Untreated RAEs are generally composed of approximately 81-92% aromatics with 1-2 ring PAHs representing 37-40% and 3-5 ring PAHs representing 20-23% of the aromatic fraction. Aromatic concentration (in DAEs or RAEs) is largely dependent upon the source and type of crude from which the extract is processed.

1.2 <u>Physical-Chemical Properties</u>

The physical-chemical properties of the aromatic extracts category members are provided in Table 1. Representative structures for individual components of the aromatic extracts are provided in the Appendix.

The aromatic extracts consist of two subcategories, the distillate aromatic extracts (DAE) and the residual aromatic extracts (RAE). The distillate aromatic extracts consist predominantly of aromatic hydrocarbons having carbon numbers in the range approximately C15 to C50 and the residual aromatic extracts consist predominantly of aromatic hydrocarbons having carbon numbers >C25. These complex mixtures are highly viscous to mobile liquids, which may be dark amber to black in color. The components of these mixtures possess low to negligible water solubility and low to negligible vapor pressure. The components of these mixtures possess low to negligible (estimated) and low to moderate (measured) water solubility and low to moderate (measured) water solubility and low to moderate (measured) and moderate (measured) vapor pressure.

Table 1. Physical-Chemical Properties of Aromatic Extracts ¹					
	Sul	ocategory I: Distillate	Aromatic Extracts (DA	AEs)	Subcategory II:
	Group 1: Pa	raffinic DAEs	Group 2: Nap	hthenic DAEs	Residual Aromatic Extracts
Property	Extracts (Petroleum), Heavy Paraffinic Distillate Solvent	Extracts (Petroleum), Light Paraffinic Distillate Solvent	Extracts (Petroleum), Heavy Naphthenic Distillate Solvent	Extracts (Petroleum), Light Naphthenic Distillate Solvent	Extracts (Petroleum), Residual Oil Solvent
CASRN	64742-04-7	64742-05-8	64742-11-6	64742-03-6	64742-10-5
Molecular Weight	Complex mixture	Complex mixture	Complex mixture	Complex mixture	Complex mixture
Physical State		Н	ighly viscous to mobile li	quids	
Melting Point	-6 to 36°C (measured pour point)	-6 to 36°C (measured pour point)	-6 to 36°C (measured pour point)	-6 to 36°C (measured pour point)	>20°C (measured pour point)
Boiling Point	250–680°C (measured)	250–680°C (measured)	250–680°C (measured)	250–680°C (measured)	>380°C (measured)
Vapor Pressure	<0.075 mm Hg at 25°C (measured); 0.038 to $<1\times10^{-7}$ mm Hg at 25°C (estimated) ²	<0.075 mm Hg at 25°C (measured); 0.038 to $<1\times10^{-7}$ mm Hg at 25°C (estimated) ²	<0.075 mm Hg at 25°C (measured); 0.038 to $<1\times10^{-7}$ mm Hg at 25°C (estimated) ²	<0.075 mm Hg at 25°C (measured); 0.038 to $<1\times10^{-7}$ mm Hg at 25°C (estimated) ²	$<0.075 \text{ mm Hg at } 25^{\circ}\text{C}$ (measured); $<1.4 \times 10^{-5} \text{ mm Hg at } 25^{\circ}\text{C}$ (estimated) ²
Dissociation Constant pK _a)			Not applicable		
Henry's Law Constant	3.4×10^{-5} to 0.012 atm- m ³ /mol (estimated) ^{3,4}	0.003 to 0.009 atm- m^{3} /mol (estimated) ^{3,4}	3.4×10^{-5} to 0.012 atm- m ³ /mol (estimated) ^{3,4}	0.003 to 0.009 atm- m^{3} /mol (estimated) ^{3,4}	1.3×10^{-4} to 101 atm- m ³ /mol (estimated) ^{3,4}
Water Solubility	$\begin{array}{c} \hline 1.4-5.8 \text{ mg/L} \\ (\text{measured})^{1.5}; \\ <1\times10^{-6} \text{ to } 0.002 \text{ mg/L} \\ (\text{estimated})^{3.4} \end{array}$	1.4-5.8 mg/L (measured) ^{1,5} ; <1×10 ⁻⁶ to 0.7 mg/L (estimated) ^{3,4}	$\begin{array}{c c}\hline 1.4-5.8 \text{ mg/L} \\ (\text{measured})^{1.5}; \\ <1\times10^{-10} \text{ to } 0.002 \text{ mg/L} \\ (\text{estimated})^{3.4} \end{array}$	$1.4-5.8 \text{ mg/L} (measured)^{1,5}; <1\times10^{-6} to 0.7 mg/L (estimated)^{3,4}$	Sparingly soluble; 2×10^{-6} mg/L(estimated) ^{3,4}
Log K _{ow}	8.0-19.6 (estimated) ^{3,4}	5.6–12.0 (estimated) ^{3,4}	8.0-19.6 (estimated) ^{3,4}	4.4-7.2 (measured)	9.8–14.4 (estimated) ^{3,4}

¹ American Petroleum Institute Petroleum HPV Testing Group. 2009. Revised Test Plan and Robust Summary for Aromatic Extracts. Available online at <u>http://www.epa.gov/chemrtk/pubs/summaries/aroexcat/c14900tc.htm</u> as of December 7, 2010.

² NOMO5. 1987. Programs to Enhance PC-Gems Estimates of Physical Properties for Organic Compounds. The Mitre Corp.

³ Data range is based upon the representative structures; see Appendix for detailed information on the structures.

⁴ U.S. EPA. 2010. Estimation Programs Interface Suite[™] for Microsoft[®] Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <u>http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm</u> as of December 7, 2010. Representative structures were used in theEPI Suite program to generate estimates. Smiles notations for the representative structures are provided in the appendix.

⁵ Values reported for an unspecified distillate aromatic extract sample.

2. <u>General Information on Exposure</u>

2.1 Production Volume and Use Pattern

Available information is provided on the following sponsored chemicals of the Aromatic extract Category: CASRN 64742-04-7; 64740-05-8; 64742-11-6; 64742-03-6; 64742-10-5

The Distillate Aromatic Extracts category chemicals had an aggregated production and/or import volume in the United States greater than 3 billion 100 million pounds in calendar year 2005.

- CASRN 64742-04-7: 1 billion pounds and greater;
- CASRN 64740-05-8: 1 billion pounds and greater;
- CASRN 64742-11-6: 100 million to < 500 million pounds;
- CASRN 64742-10-5: 1 billion pounds and greater;

CASRN 64742-03-6 was not reported in the 2006 IUR.

CASRN 64740-05-8, 64742-11-6 and 64742-10-5:

No industrial processing and uses, and commercial and consumer uses were reported for these chemicals.

CASRN 64742-04-7:

Non-confidential information in the IUR indicated that the industrial processing and uses for the chemical include other rubber product manufacturing as intermediates; and tire manufacturing as processing aid not otherwise listed. Non-confidential commercial and consumer uses of this chemical include rubber and plastic products.

2.2 Environmental Exposure and Fate

The environmental fate properties of the aromatic extracts category members are provided in Table 2.

The components of the aromatic extracts are expected to possess low mobility in soil. Extracts (petroleum), light naphthenic distillate solvent (CASRN 64742-03-6) was not readily biodegradable (0% theoretical CO₂ evolution after 28 days) using a method equivalent to the modified Strum test (OECD 301B). This mixture was not degraded over 28 days using a closed bottle (OECD 301D) test. Some of the lower molecular weight components of these mixtures may be inherently biodegradable after an adaptation period; however, the majority of these substances are considered persistent in the environment. Volatilization is considered moderate based on estimated Henry's Law constants for representative components of these mixtures; however, the strong tendency to adsorb to soil or sediment is likely to attenuate volatilization. The rate of hydrolysis is considered negligible for the components of these complex mixtures since they do not contain functional groups that hydrolyze under environmental conditions. The components of the aromatic extracts category are expected to possess moderate (P2) to high (P3) persistence and low (B1) to high (B3) bioaccumulation potential.

Table 2. Environmental Fate Properties of Aromatic Extracts ¹					
		Subcategory II:			
	Group 1: Paraffinic Exti	acts	Group 2: Naphtheni Exti	c Distillate Aromatic	Residual Aromatic Extracts
Property	Extracts (Petroleum), Heavy Paraffinic Distillate Solvent	Extracts (Petroleum), Light Paraffinic Distillate Solvent	Extracts (Petroleum), Heavy Naphthenic Distillate Solvent	Extracts (Petroleum), Light Naphthenic Distillate Solvent	Extracts (Petroleum), Residual Oil Solvent
CASRN	64742-04-7	64742-05-8	64742-11-6	64742-03-6	64742-10-5
Photodegradation Half- life	0.6–1.7 hours $(estimated)^{2,3}$	0.9–2.2 hours (estimated) ^{2,3}	0.6–1.7 hours $(estimated)^{2,3}$	2.2–3.2 hours (estimated) ^{2,3}	1.5–2.7 hours (estimated) ^{2,3}
Hydrolysis Half-life			Stable		·
Biodegradation	No data	No data	No data	0% in 28 days (not readily biodegradable)	No data
Bioaccumulation Factor	$1.0-2.6 \times 10^{5}$ (estimated) ^{2,3}	369–7,560 (estimated) ^{2,3}	$1.0-2.6 \times 10^{5}$ (estimated) ^{2,3}	369–7,560 (estimated) ^{2,3}	$10-2.1 \times 10^4$ (estimated) ^{2,3}
Log K _{oc}	5.6–13	4.4-8.1	5.6–13	4.4-8.1	6.9–8.3
Fugacity (Level III Model) Air (%) Water (%) Soil (%) Sediment (%)	<0.1-0.3 6.3-15.4 58.2-93.7 <0.1-26.2	<0.1-0.3 8.1-12.9 80.6-84.6 2.4-11.0	<0.1-0.3 6.3-15.4 58.2-93.7 <0.1-26.2	0.2–0.3 8.0–20.1 65.5–80.1 <0.1–21.6	0.1–0.3 9.7–20.1 56.8–79.6 0.1–33.4
Persistence	P2 (moderate) to P3 (high)	P2 (moderate) to P3 (high)	P2 (moderate) to P3 (high)	P2 (moderate) to P3 (high)	P2 (moderate) to P3 (high)
Bioaccumulation	B1 (low) to B3 (high)	B1 (low) to B3 (high)	B1 (low) to B3 (high)	B1 (low) to B3 (high)	B1 (low) to B3 (high)

¹ American Petroleum Institute Petroleum HPV Testing Group. 2009. Revised Test Plan and Robust Summary for Aromatic Extracts. Available online at <u>http://www.epa.gov/chemrtk/pubs/summaries/aroexcat/c14900tc.htm</u> as of December 7, 2010.
 ²Data range is based upon the representative structures; see Appendix for detailed information on the structures.
 ³U.S. EPA. 2010. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available

online at http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm as of December 7, 2010.

Conclusion: The aromatic extracts consist of two sub-categories, the distillate aromatic extracts (DAE) and the residual aromatic extracts (RAE). The distillate aromatic extracts consist predominantly of aromatic hydrocarbons having carbon numbers in the range approximately C15 to C50 and the residual aromatic extracts consist predominantly of aromatic hydrocarbons having carbon numbers >C25. These complex mixtures are highly viscous to mobile liquids, which may be dark amber to black in color. The components of these mixtures possess low to negligible (estimated) and low to moderate (measured) water solubility and low to moderate (estimated) and moderate (measured) vapor pressure. They are expected to possess low mobility in soil. Volatilization of is considered moderate based on estimated Henry's Law constant's for the representative components of these mixtures; however, the strong tendency to adsorb to soil or sediment is likely to attenuate volatilization. The rate of hydrolysis is considered negligible for the components of these complex mixtures. The rate of atmospheric photooxidation is considered rapid to moderate; however, most of the components of these mixtures are not expected to exist in the vapor phase in the ambient atmosphere. The components of the aromatic extracts category are expected to possess moderate (P2) to high (P3) persistence and low (B1) to high (B3) bioaccumulation potential.

3. <u>Human Health Hazard</u>

A summary of health effects data submitted for SIDS endpoints is provided in Table 3. The table also indicates where data for tested category members are read-across (RA) to untested members of the category as appropriate.

Acute Oral Toxicity

Subcategory I: Distillate Aromatic Extracts

Group 1: Paraffinic Distillate Aromatic Extracts

Light paraffinic distillate, solvent extract (CASRN 64742-05-8)

Sprague-Dawley rats (5/sex/dose) were administered CASRN 64742-05-8 via gavage at 5000 mg/kg and observed for 14 days following dosing. No mortalities were observed. Additional details are from TSCATS (OTS0000901D9; OTS0000371-5). $LD_{50} > 5000 \text{ mg/kg}$

Acute Dermal Toxicity

Subcategory I: Distillate Aromatic Extracts

Group 1: Paraffinic Distillate Aromatic Extracts

Light paraffinic distillate, solvent extract (CASRN 64742-05-8)

New Zealand White rabbits (2/sex/dose) were administered CASRN 64742-05-8 dermally at 2000 or 3000 mg/kg-bw to intact or abraded skin for 24 hours under occlusive conditions, and observed for 14 days. One low-dose female in the intact skin group died during the study. No

other mortalities were observed at the high-dose level. Additional details are from TSCATS (OTS0000901D9; OTS0000371-5). $LD_{50} > 3000 \text{ mg/kg}$

Repeated-Dose Toxicity

Subcategory I: Distillate Aromatic Extracts

Group 1: Paraffinic Distillate Aromatic Extracts

Heavy paraffinic distillate, solvent extract (CASRN 64742-04-7)

(1) In a 13-week study, Sprague-Dawley rats (10 males/group) were orally administered CASRN 64742-04-7 (purity not specified) via gavage at doses of 0, 125 or 500 mg/kg-day, 5 days/week. Histopathological evaluations of the male reproductive organs (gonads, epididymides, prostates and seminal vesicles) were conducted on animals from the 500 mg/kg- day group. At 500 mg/kgday, four of the males were terminated prior to scheduled sacrifice. All other rats survived until the scheduled necropsy. Treatment-related clinical signs (pallor and decreased body temperature) were observed at 500 mg/kg-day. Body weight was statistically significantly decreased at 500 mg/kg-day compared to control animals. Hematological parameters that were affected included statistically significant decreases in red blood cell (RBC) count and hemoglobin at both doses and decreased platelet count, mean corpuscular hemoglobin concentration (MCHC), hematocrit and white blood cell count (WBC) at 500 mg/kg-day. With the exception of significantly increased sorbitol dehydrogenase activity, effects seen on serum chemistry parameters at week 5 diminished by week 13. Effects on male reproductive parameters (decreased size of testes and prostates and abnormal sperm heads) were observed in males treated at 500 mg/kg-day. Increases in absolute and relative liver weights and decreases in absolute and relative thymus weights were seen at 125 and 500 mg/kg-day. Decreases in the absolute and/or relative weights of the epididymides, prostate and seminal vesicle were observed in treated males. Treatment-related histopathological changes were most prominent in the adrenals (cortical vacuolation, hyperplasia of zona glomerulosa), bone marrow (decreased cellularity, fibrosis), brain (hemorrhage), kidneys (dilation of cortical tubules), liver (hepatocyte hypertrophy, centrilobular necrosis, periportal hepatocellular vacuolation), lymph nodes (reddened), stomach (congestion of glandular mucosa) and thymus (atrophy), testes, prostate and seminal vesicle(s) (atrophy). At 500 mg/kg-day, small focal hemorrhages were seen by gross and microscopic examinations in several organs including the brain, spinal cord, heart, lung, liver, thymus, testes and bone marrow. Additional details are from TSCATS (OTS0509763-7). LOAEL = 125 mg/kg-day (based on decreased body weight and histopathological changes in liver, prostate and thymus) **NOAEL** = Not established

(2) In a 13-week study, conducted simultaneously with the study above (1), separate groups of Sprague-Dawley rats (10/sex/group) were administered CASRN 64742-04-7 (purity not specified) via the dermal route to clipped, intact skin at 0 (untreated control), 30, 125, 500 or 1250 mg/kg-day without occlusion, 5 days/week. All rats were fitted with Elizabethan collars to prevent oral ingestion of the test substance. All animals treated at 1250 mg/kg-day, were terminated prior to scheduled sacrifice. At 500 mg/kg-day, all males and three females were

terminated prior to scheduled sacrifice. All other rats survived until the scheduled necropsy. Histopathological evaluations of the male and female reproductive organs (gonads, epididymis, prostate and seminal vesicles) were conducted on animals at the highest nonfatal dose, 125 mg/kg-day. Treatment-related clinical signs (pallor and decreased body temperature) were observed at 500 and 1250 mg/kg-day; males appeared to be more affected than females. Skin irritation was apparent in a few males and females at \geq 30 mg/kg-day. The body weight gain was significantly decreased in males exposed to $\geq 500 \text{ mg/kg-day}$ and females exposed to ≥ 30 mg/kg-day compared to the control animals. Affected hematological parameters included statistically significant (p< 0.05) decreases in RBC count, hemoglobin, hematocrit and platelet counts in males and females at ≥ 125 mg/kg-day. A greater number of serum chemistry parameters were affected in males than females. At week five, affected serum chemistry parameters in males treated at 1250 mg/kg-day included significant decreases in uric acid, glucose and inorganic phosphorus concentrations and alanine amino transferase (ALT) and alkaline phosphatase (ALP) activities, and increases in urea nitrogen, and concentrations and aspartate, amino transferase (AST) and sorbitol dehydrogenase (SDH) activity. Significant decreases in uric acid and potassium and increases in urea nitrogen, cholesterol and SDH were observed in females treated 1250 mg/kg-day. Urinalysis showed no treatment-related effects. Increases in absolute and relative liver weights and decreases in absolute and relative thymus weights were seen in males at 125 or 500 mg/kg-day. Females showed significantly decreased absolute thymus weight at 125 and 500 mg/kg-day and significant increases in absolute heart, kidney and liver weights at 125 and 500 mg/kg-day. Treatment-related histopathological changes were most prominent in the adrenals (males at all doses-slight to moderate diffuse cortical vacuolization and at a lower incidence and severity, cortical necrosis), bone marrow (fibrosis and decreased cellularity at \geq 125 mg/kg-day), kidneys (epithelial necrosis in the cortical tubules at \geq 500 mg/kg-day), liver (hypertrophy, centrilobular necrosis at \geq 500 mg/kg-day and increased hepatic vacuolation at >125 mg/kg-day), treated skin (epidermal hyperplasia and hyperkeratosis, minimal to slight hyperplasia of the sebaceous glands and minimal infiltration by mononuclear inflammatory cells), stomach (congestion of glandular mucosa, hyperplasia and hyperkertosis of squamous mucosa) and thymus (marked atrophy at ≥ 125 mg/kg-day). No effects were seen during histopathological evaluation of the reproductive organs at 125 mg/kg-day, the nonfatal dose. In treated animals, small focal hemorrhages were seen by gross and microscopic examinations in several organs including the brain, spinal cord, heart, lung, testes and bone marrow. Additional details are from TSCATS (OTS0509763-7). **LOAEL = 30 mg/kg-day** (based on decreased body weight gain and histopathological changes) **NOAEL** = Not established

Light paraffinic distillate, solvent extract (CASRN 64742-05-8)

(3) In a 28-day study, New Zealand white rabbits (5/sex/dose) were administered undiluted CASRN 64742-05-8 dermally, 6 hours/day, 3 times/week, under occlusive conditions, at 0, 250, 500 or 1000 mg/kg-day until 13 applications had been made. There were no treatment-related effects on clinical observations, body weight, clinical pathology measurements or necropsy findings. Skin irritation was observed in all treatment groups and was scored according to the Draize scale; the mean irritation scores were 0, 1.0, 2.3, and 3.2 for 0, 250, 500 and 1000 mg/kg-day, respectively. Other treatment-related dermal effects included dry, scaly, fissured and/or rough skin and thickened dermis. Although increased absolute (28% at

250 mg/kg-day) and relative (21% at 500 and 19.5% at 1000 mg/kg-day) liver weights (level of statistical significance not provided) were observed in females, and increased relative liver weight (27% at 1000 mg/kg-day) was observed in males, there was no supporting clinical pathology or histopathology. Microscopic findings were limited to the skin—slight to moderately severe proliferative changes in all animals at 1000 mg/kg-day. No other treatment-related effects were observed in any tissue examined.

LOAEL (local effects) = 250 mg/kg-day (based on skin irritation) NOAEL (local effects) = Not established

NOAEL (systemic effects) = 1000 mg/kg-day

Subcategory II: Residual Aromatic Extracts

Residual oil, solvent extract (CASRN 64742-10-5)

In a 13-week study, Sprague-Dawley rats (10/sex/dose) were administered two samples of CASRN 64742-10-5 via the dermal route to clipped, intact skin at doses of 0 (untreated control), 500 (Mobilsol 40) or 2000 mg/kg-day (BSE-Australia and Mobilsol 40) without occlusion, 5 days/week. Additionally, one group of 10 males and one group of 10 females were each administered a residual oil solvent extract sample (BSE-Ninian and BSE-Satfjord, respectively) at a dose of 2000 mg/kg-day. All animals were fitted with Elizabethan collars to minimize ingestion of the test substance. No treatment-related clinical signs or evidence of skin irritation were observed. During week 5, administration of BSE-Australia resulted in decreased mean corpuscular hemoglobin and lymphocyte counts in males and increased white blood cell counts in females. Decreased white blood cell counts were noted in BSE-Satfjord treated females (2000 mg/kg-day). At week 13, decreased red blood cell counts and hematocrit were observed in females treated with Mobilsol 40, BSE-Australia or BSE-Satfjord at 2000 mg/kg-day, and decreased hemoglobin was noted in females treated with BSE-Australia and BSE-Statfjord. Clinical chemistry effects observed in animals exposed to Mobilsol 40 included decreased glucose in high-dose males and females, decreased albumin in high- and low-dose males and increased calcium in high-dose females. Clinical chemistry effects related to BSE-Australian exposure included decreased glucose, creatinine, total bilirubin, and chloride in females; decreased albumin, albumin/globulin ratio, creatinine and total protein in males; increased cholesterol in females; and increased sorbitol dehydrogenase (SDH) in both sexes. Exposure to BSE-Statfjord resulted in increased SDH and alkaline phosphatase levels and decreased calcium in females at 2000 mg/kg-day. BSE-Ninian exposure caused decreases in albumin, calcium, chloride, uric acid and inorganic phosphorous and increased SDH. Urinalysis showed no treatment-related effects. Significantly increased relative liver weights were observed in highdose males exposed to Mobilsol 40. BSE-Australia exposure caused significantly increased absolute and relative liver and spleen weights in males and increased relative liver weights in females. No treatment-related effects were observed on reproductive organs (ovaries, uteri, testes, epididymides or prostates); evaluations of epididymal spermatozoa (morphology and count) and the testicular spermatid count showed no differences among the various treatment groups as compared to controls. There were no treatment-related histopathological findings. LOAEL = 2000 mg/kg-day (based on changes in hematological and clinical chemistry parameters and increases in liver and spleen weight) NOAEL = 500 mg/kg-day

Reproductive Toxicity

Subcategory I: Distillate Aromatic Extracts

Group 1: Paraffinic Distillate Aromatic Extracts

Heavy paraffinic distillate, solvent extract (CASRN 64742-04-7)

(1) In the 13-week oral repeated-dose toxicity study CASRN 64742-04-7 in rats described previously, sperm evaluation showed a slight increase in the frequency of sperm with abnormal heads in rats dosed at 500 mg/kg-day. Decreases in the absolute and/or relative weights of the epididymis, prostate and seminal vesicle were observed in treated males.

(2) In the 13-week dermal repeated-dose toxicity study on CASRN 64742-04-7 in rats described previously, no effects were seen during histopathological evaluation of the reproductive organs at 125 mg/kg-day, the nonfatal dose.

Light paraffinic distillate, solvent extract (CASRN 64742-05-8)

In the 24-months toxicity/carcinogenicity study in male C_3H/HeJ mice, described below, dermal application of 50 μ L of CASRN 64742-05-8 resulted in decreased absolute and relative testicular weights compared to controls at 24 months. Data are from TSCATS (OTS0000426-9).

Subcategory II: Residual Aromatic Extracts

Residual oil, solvent extract (CASRN 64742-10-5)

In the 13-week dermal repeated-dose toxicity study in rats with four CASRN 64742-10-5 samples, described previously, no treatment-related effects were observed following examination of reproductive organs (ovaries, uteri, testes, epididymides or prostates). Epididymal spermatozoa morphology and count, and testicular spermatic counts were unaffected by treatment.

Developmental Toxicity

Subcategory I: Distillate Aromatic Extracts

Group 1: Paraffinic Distillate Aromatic Extracts

Heavy paraffinic distillate, solvent extract (CASRN 64742-04-7)

Pregnant Sprague-Dawley rats (11/group) were administered CASRN 64742-04-7 (318 isthmus furfural extract) via gavage at 2000 mg/kg-bw during one of the gestation days (GD) 11 - 15. To determine dose response, additional groups were administered the test substance on GD 12 at 125, 500 or 2000 mg/kg-bw. Control animals were administered tap water on GDs 11 - 15. Dams were monitored daily for clinical signs of toxicity and body weights were recorded on days 0, 6, 11-16 and 20 of gestation. At necropsy on GD 20, thoracic and abdominal cavities were exposed and reproductive organs were examined grossly for evidence of pathology. The liver, thymus, uterus and ovaries were weighed and the number of corpora lutea, implantation sites, early/late resorptions and live/dead pups were determined. Offspring were evaluated for

pup body weight, gender and developmental malformations. Half of the offspring from each litter were randomly distributed for soft tissue or skeletal evaluations. Signs of maternal toxicity included transient, but significant (p < 0.05) weight loss 1 or 2 days following administration at dose levels \geq 125 mg/kg-bw and an overall net decrease in mean body weight gain in association with decreased food consumption at 2000 mg/kg-bw. Absolute/relative thymus weight and gravid uterine weight were significantly reduced at >500 mg/kg-bw/day. Reproductive parameters were also affected (e.g., decreased litter size and increased resorptions) following treatment at 2000 mg/kg-bw/day on GD 11-12. Signs of developmental toxicity included significant decreases in fetal body weights (p <0.01) and an increased incidence of fetal malformations involving the mouth (cleft palate), hindlimbs (brachydactyly, adactyly), tail (fleshy tab at the tip of the tail and shortened tail) and viscera (heart anomalies, small lungs, hernia, right sided esophagus, small spleen, distended ureters, dilatation of renal pelvis) in offspring born to dams treated at 2000 mg/kg-bw on GD 13 - 14. Skeletal malformations (incomplete ossification of skull and thoracic vertebrae, misshapen cervical transverse process and costa cartilage, and absent or misshapen/fused hind-paw phalanges) were observed following treatment at >500 mg/kg-bw/day. (The study director noted that restriction of the period of exposure to a single oral dose provided a better means by which to gauge teratogenic potential). Data are from TSCATS (OTS0509763-8).

LOAEL (maternal toxicity) = 2000 mg/kg-bw (based on decreased body weight gain and decreased thymus weight)

NOAEL (maternal toxicity) = 500 mg/kg-bw

LOAEL (developmental toxicity) = 500 mg/kg-bw (based on skeletal malformations) NOAEL (developmental toxicity) = 125 mg/kg-bw

(2) Pregnant Sprague-Dawley rats (15/dose) were administered CASRN 64742-04-7 via the dermal route without occlusion at doses of 0 (untreated control), 8, 30 and 125 mg/kg-day on GDs 0 - 19 and at 500 and 1000 mg/kg-day on GD 0 - 16 and 10 - 12, respectively. Dams were sacrificed on GD 20 (prenatal groups). Additional dams from the control and 125 mg/kg-day groups (10/group) were sacrificed on postpartum day 4 (postpartum observation groups). Three additional dams were administered the test substance containing ³H-B(a)P and ¹⁴C-carbazole via the dermal route in a protective device at 1000 mg/kg-day on GDs 10-12 (bioavailability group). Urine and feces were collected from the dams from the bioavailability group, which were housed in a metabolism cage until they were sacrificed on GD 13. All rats were fitted with Elizabethan collars to prevent ingestion of the test substance. There were no mortalities, Effects observed at 125 and 500 mg/kg-day included vaginal bleeding, paleness, decreased stool, decreased body weights and food consumption, reduced gravid uterine weights and carcass weights and net maternal weight gain during gestation. At necropsy, a statistically significant reduction in thymus weight and significantly increased relative liver weight was observed at \geq 125 mg/kg-day; absolute liver weights were increased in animals treated at 1000 mg/kgbw/day. Mean litter size was decreased and the number of resorptions was increased at 125 and 500 mg/kg-day. White blood cell counts increased at 125 and 500 mg/kg-bw/day and platelets decreased at 500 mg/kg-bw/day. Most clinical chemistry parameters were affected at 125 and/or 500 mg/kg-day. There was a statistically significant reduction in fetal weights at \geq 125 mg/kg-day. One fetus at 125 mg/kg-day and two at 1000 mg/kg-day, were edematous. Three additional fetuses from the 1000 mg/kg-day group exhibited various abnormalities including shortened limbs, shortened and missing digits, shortened trunk, cleft palate and kinked

tail. No treatment-related gross abnormalities were noted in the control, 8 or 30 mg/kg-day groups. Treatment-related skeletal abnormalities observed at 1000 mg/kg-day included increased rib malformations (costal cartilage misshapen). In the postpartum observation group, three females were not pregnant, five resorbed their entire litters and one dam had only two pups, which she subsequently cannibalized. Because there was only one viable litter in this group, evaluation of postpartum effects was not performed. Evaluation of the bioaccumulation group revealed that dermal absorption of both labeled compound s was minimal and was less for H³-B(a)P than for 14C¹⁴-carbazole. From the limited data, there was no evidence of either compounds accumulating in the embryo. Similarly, due to study limitations, a definitive assessment of the dose and route of exposure is not possible.

Group 2: Naphthenic Distillate Aromatic Extracts

Heavy naphthenic distillate, solvent extract (CASRN 64742-11-6)

In the dose-range finding study, pregnant Fischer 344 rats (5/dose) were administered CASRN 64742-11-6 (Process 65, purity not specified) in mineral oil via the dermal route at doses of 0 (vehicle control), 500, 1000 or 2000 mg/kg-day (equivalent concentrations of 0, 24.4, 48.7 and 97.5% [undiluted], respectively) without occlusion for 6 hours on GDs 7 - 16 (a total of 10 treatments). Rats were fitted with Elizabethan collars to prevent oral ingestion of the test substance. Dams were sacrificed on GD 20 for necropsy. All fetuses were examined externally for developmental abnormalities, and were sexed and weighed. All animals survived until scheduled sacrifice. Food consumption was reduced in a dose-related manner at all treatment levels. All dosed groups lost weight after the first day of treatment. For the low- and mid-dose groups, consistent increases in body weight were not detected until GD 9 and 14, respectively. After treatment termination, all dosed groups exhibited increases in body weight. Yellow anogenital staining occurred in one of the control animals and one of the 2000 mg/kg-day animals. Sporadic vaginal discharge was observed in 1/5, 2/5, 2/5 and 4/5 animals in the control, 500, 1000 and 2000 mg/kg-/day dose groups, respectively. Nasal and ocular discharges were observed in all of the dose-level groups during treatment. Other incidental changes included closed eyelids, dilation of the left pupil and rales. The pregnancy rates and ratios of implantations to corpora lutea were not affected by treatment at 500 or 1000 mg/kg-day. At 2000 mg/kg-day, resorptions were increased substantially with a corresponding decrease in live implants. Fetal sex-distribution was comparable for all of the dose groups. Group mean litter weights were reduced in a dose-related manner at all doses when compared to the control group. [Based on maternal and fetal toxicity, dose levels of 200, 400 and 800 mg/kg-day were selected for full dermal developmental toxicity study.]Data are from TSCATS (OTS0540342). LOAEL (maternal toxicity) = 500 mg/kg-day (based on decreases in body weight gains, matted fur, and nasal, ocular and vaginal discharge) **NOAEL** (maternal toxicity) = Not established

LOAEL (developmental toxicity) = 2000 mg/kg-day (based on increased resorptions, a corresponding decrease in live implants and reduced fetal and mean litter weights) NOAEL (developmental toxicity) = 1000 mg/kg-day

Subcategory II: Residual Aromatic Extracts

Residual oil, solvent extract (CASRN 64742-10-5)

Pregnant Sprague-Dawley rats (15/dose) were administered CASRN 64742-10-5 (Mobilsol 40; purity not specified) via the dermal route at dose s of 0 (untreated control), 500 or 2000 mg/kg-day under unoccluded conditions once daily on GDs 0 - 19 (prenatal group). An additional control and high-dose postnatal group (10 dams/group) were treated in a similar manner except that dams and pups were sacrificed on postpartum day 4 (postnatal observation group). All dams were fitted with Elizabethan collars to prevent oral ingestion of the test substance. Slight skin irritation consisting of erythema, flaking and scabbing was observed in all treated groups. The body weight gains over the gestation period of the prenatal animals treated at 2000 mg/kg-day were less than the controls, but the postnatal animals were similar to the corresponding controls. During days 3-6 of gestation, the 2000 mg/kg-day prenatal groups consumed less food than the corresponding controls. The 2000 mg/kg-day postnatal animals also consumed less food than their corresponding controls during the first 3 days of gestation, but ate significantly more during the latter part of gestation. Uterine weights and net body weights of the prenatal animals were significantly lower than controls following treatment at 2000 mg/kg-day. Necropsy revealed no treatment-related gross pathological findings. There were no treatment-related effects on the number of corpora lutea, implantation sites, viable fetuses, resorptions, preimplantation loss or litter size. There was an increase in aspartate amino transferase (AST) activity in the 2000 mg/kg-day animals; however, there were no supporting histopathological findings. Fetal body weight, sex and number were not affected at any level of treatment. External, skeletal and visceral examination revealed no treatment-related abnormalities.

NOAEL (maternal/developmental toxicity) = 2000 mg/kg-day (highest dose tested)

Genetic Toxicity – Gene Mutation

In vitro

Subcategory I: Distillate Aromatic Extracts

Group 1: Paraffinic Distillate Aromatic Extracts

Light paraffinic distillate, solvent extract (CASRN 64742-05-8)

L5178Y mouse lymphoma cells were exposed to CASRN 64742-05-8 in ethanol at concentrations of 0 (solvent control), 25, 50, 75, 100, 150 or 200 µL/mL without metabolic activation and at 0 (solvent control), 12.5, 25, 50, 75, 100 or 150 µL/mL with metabolic activation for 4 hours. Positive controls were tested and elicited appropriate responses. Insoluble test substance was observed at $\geq 100 \ \mu$ L/mL with and without metabolic activation. The robust summary indicated that the highest test substance concentration both with and without metabolic activation was highly toxic. Mutagenic responses were elicited at 150 and 200 μ L/mL without metabolic activation and at 25, 50, 75, 100 and 150 μ L/mL with metabolic activation. A dose-response relationship was apparent with activation only. Additional details are from TSCATS (OTS0000285-5).

CASRN 64742-05-8 was mutagenic in this assay.

Group 2: Naphthenic Distillate Aromatic Extracts

No data.

Subcategory II: Residual Aromatic Extracts

No data.

Genetic Toxicity – Chromosomal Aberrations

In vivo

Subcategory I: Distillate Aromatic Extracts

Group 1: Paraffinic Distillate Aromatic Extracts

Heavy paraffinic distillate, solvent extract (CASRN 64742-04-7)

In the 13-week dermal and oral repeated-dose toxicity study in rats described previously, *in vivo* micronucleus evaluations were performed on bone marrow harvested at study termination. No treatment-related increase in micronuclei was observed. No cytotoxicity was reported. **CASRN 64742-04-7 did not induce chromosomal aberrations in this assay.**

Group 2: Naphthenic Distillate Aromatic Extracts

No data.

Subcategory II: Residual Aromatic Extracts

Residual oil, solvent extract (CASRN 64742-10-5)

In the 13-week dermal repeated-dose toxicity study in rats described previously, *in vivo* micronucleus evaluations were performed on bone marrow harvested at study termination. No treatment-related increase in micronuclei was observed. No cytotoxicity was reported. **CASRN 64742-10-5 did not induce chromosomal aberrations in this assay.**

Additional Information

Skin Irritation

Subcategory I: Distillate Aromatic Extracts

Group 1: Paraffinic Distillate Aromatic Extracts

Light paraffinic distillate, solvent extract (CASRN 64742-05-8)

Six New Zealand White albino rabbits were administered CASRN 64742-05-8 (0.5 mL) dermally to abraded and intact sites on each animal under occluded conditions for 24 hours. Rabbits were observed for 14 days following treatment. Total irritation scores for erythema and edema using the Draize method at 1, 3, 4, 7 and 14 days were 5.7, 5.1, 3.3, 0.5 and 0,

respectively, and the primary dermal irritation index was 5.4. Additional details are from TSCATS (OTS0000901D9; OTS0000371-5).

CASRN 64742-05-8 was irritating to rabbit skin in this study.

Eye Irritation

Subcategory I: Distillate Aromatic Extracts

Group 1: Paraffinic Distillate Aromatic Extracts

Light paraffinic distillate, solvent extract (CASRN 64742-05-8)

Nine New Zealand White Albino rabbits were administered undiluted light paraffinic distillate, solvent extract (0.1 mL) into one eye. After approximately 30 seconds, the treated eyes of three rabbits were rinsed with water. All rabbits were observed for 7 days following exposure. One animal was found dead on day 5. No pain response was noted and no corneal or iridial irritation was observed. Blanching of the cornea was seen in one animal at 2 hours.

Scoring of ocular lesions was carried out according to the Draize technique. Mean irritation scores at 1 hour and 1, 2, 3 and 7 days were 3.7, 1.3, 0, 0 and 0 for the six unwashed eyes and 3.3, 0, 0, 0 and 0 for the three washed eyes, respectively. Additional details are from TSCATS (OTS0000901D9; OTS0000371-5).

CASRN 64742-05-8 was irritating to the rabbit eyes in this study.

Sensitization

Subcategory I: Distillate Aromatic Extracts

Group 1: Paraffinic Distillate Aromatic Extracts

Light paraffinic distillate, solvent extract (CASRN 64742-05-8)

Hartley guinea pigs (10 males/dose) were induced with CASRN 64742-05-8 in paraffin oil dermally (0.4 mL) at concentrations of 0 (control) or 50% (v/v) to clipped, intact skin for 6 hours/week for 3 weeks under occlusive conditions and observed for 48 hours following exposure. A positive control group received 2, 4-dinitrochlorobenzene (DNCB) as a 30% solution in ethanol. Two weeks after the third induction application, animals were dermally challenged with the test substance in paraffin oil at a concentration of 1% (v/v). Additional naïve vehicle control animals were challenged in the same manner and additional naïve positive control animals were challenged with DNCB. Vehicle and positive control groups received similar treatments for both the induction and challenge phases. Moderate to severe irritation occurred in positive control animals; therefore, the application site for the third dose was different. Very slight erythema was observed in 8/10, 9/10, 3/10 and 4/19 animals in the treated, naïve control, vehicle control and naïve positive control group, respectively. All positive control animals exhibited slight to severe irritation. Additional details are from TSCATS (OTS0000901D9; OTS0000371-5).

CASRN 64742-05-8 was not sensitizing to the skin of guinea pigs in this study.

Carcinogenicity

Subcategory I: Distillate Aromatic Extracts

Group 1: Paraffinic Distillate Aromatic Extracts

Heavy paraffinic distillate, solvent extract (CASRN 64742-04-7)

CD1 mice (25/sex/group) were administered 20 mg of CASRN 64742-04-7 (five samples with varying viscosity) via dermal application twice weekly for 78 weeks. A control group (50 - 15 mice/sex) was administered mineral oil in a similar manner. Animals were observed for 6 months following the 18-month exposure period. Male and female survival rates ranged from 76 to 96% and from 68 to 100%, respectively. The time to first observable tumor varied from 3 to 6 months in males and from 3 to 12 months in females. The percentage of mice that had an observable mass on their skin varied from 4 to 48% in males and from 18 to 48% in females. Histopathological classifications of observable masses (i.e., squamous cell carcinoma, benign epithelial papilloma, hyperkeratosis, acanthosis and conditions of irritation having mononuclear cell invasion of tissue) were not performed. It was estimated (from later studies) that \geq 80% of observable masses would be classified as tumors (benign or malignant) with a large majority being benign epithelial papillomas. Data are from TSCATS (OTS0200438). **CASRN 64742-04-7 increased incidence of skin tumors in mice in this study.**

Light paraffinic distillate, solvent extract (CASRN 64742-05-8)

Male C₃H/HeJ mice (50/group) were administered 50 µL of light paraffinic distillate, solvent extract via dermal application to the clipped region of the back twice per week for 3 or 12 months (chronic toxicity screening study) or 104 weeks (carcinogenicity study). An additional vehicle control, sham control and two positive control groups were also tested. Group mean organ weights and ratios were compared in animals surviving to week 104. Percent survivability was decreased compared to untreated and toluene controls (66, 16 and 2% at 12, 18 and 24 months, respectively). Mice had slightly decreased body weights when compared to controls. These slightly decreased weights were seen during weeks 52 - 72 and 84 - 104. There were no treatment-related systemic toxic effects. Extensive dermal lesions were observed and virtually 100% of mice developed mild to moderate desquamation, irritation and alopecia. Observations included minimal to moderate dermal inflammation (58%), hyperkeratosis (32%), acanthosis (100%), epidermal crusting (82%), dermal pigmentation (58%), dermal fibrosis (94%), ulceration (32%), dermal vascularization (20%), epidermal erosion (6%) and dermal neoplasms (benign and malignant tumors at the treated skin site; 62%). Absolute and relative kidney and testes weights were reduced when compared to controls at 24 months. Benign and malignant primary liver neoplasms were noted in 4 and 14% of the mice, respectively. The percentages of mice developing histologically confirmed benign and malignant dermal neoplasms were 2 and 88%, respectively. Multiple tumors were observed in 32% of all of the mice (average of 1.28 tumors per mouse). Six percent of the mice had metastases. The mean time from initiation of dosing to appearance of first tumor (mean latency) was 72 weeks. Data are from TSCATS (OTS0000426-9).

CASRN 64742-05-8 increased incidence of skin tumors in mice in this study.

Group 2: Naphthenic Distillate Aromatic Extracts

Heavy naphthenic distillate, solvent extract (CASRN 64742-11-6)

C3H mice (50/sex/dose) were administered CASRN 64742-11-6 via the dermal route at 100 (undiluted) or 50% (in paraffin oil) to shaved intact skin 3 times/week for 13 weeks. Negative control animals were either untreated (85 males and 100 females) or treated with the vehicle alone (100/sex). A low- and high-dose positive control group (100/sex/group) received benzo[a]pyrene (B[a]P) in acetone at 0.05 or 0.1%, respectively. No treatment-related effects on mortality, body weight or clinical observations were reported. One male in the undiluted test group was observed with paralysis and a laceration and dependent swelling of the paws/feet/tail, which was considered to be caused by a traumatic injury of the hind foot. This animal died 8 days after the injury was first observed. As other animals in the group survived and had no overt signs of toxicity, the death was regarded to be "spontaneous" or possibly secondary to the traumatic injury. Observations such as "emaciation" and "lethargy" were commonly made for animals at or near death. As mortality data did not indicate any test substance or control substance effect on survival, such signs were considered to be associated with weak or dving animals and not with toxicity of the heavy naphthenic distillate, solvent extract. In the 50% dilution group, no tumors were observed. Temporary hair loss was observed in 60% (30/50) of the males after treatment week 3 and in 14% (7/50) of the males after treatment week 4. No other treatment-related gross changes in the skin were reported. In the undiluted treatment group, two tumors were observed on one male and one tumor was observed on one female. In addition, dry skin, temporary hair loss and desquamation were noted for both males and females. The first tumor in the male was observed 83 days after treatment initiation. The second tumor in the same male was first observed on the day of sacrifice. The tumor on the female was first observed 98 days after treatment initiation. Tissue specimens of the tumors were taken at sacrifice (100 and 98 days after treatment initiation for the male and female, respectively) and histological examination revealed two squamous cell carcinomas for the male and a benign papilloma for the female. Hair loss was first observed in 77% (33/34) of the males at the end of treatment week 2 and increased to include 92% (35/38) of the males at the end of treatment week 4. During treatment week 5, hair grew back on male mice and only one male had hair loss. Hair loss was first observed in 52% (26/50) of the females by the end of treatment week 2 and increased to 68% (34/50) by treatment week 3. Hair grew back on all females by the end of treatment week 4. Desquamation was first observed on one male at the end of treatment week 4. Desquamation was noted in 3, 0, 0, 0, 24, 34, 45 and 47% of males at the end of treatment weeks 6 - 13. Desquamation was observed on one female at the end of treatment week 11 and another female at the end of treatment week 13. Dry skin was noted sporadically on a single male at the end of weeks 3, 5, 12 and 13 and once each on three females at the end of treatment weeks 3 or 4. Other epithelial changes, including acanthosis and hyperkeratosis, were present on the skin of male test animals. No tumors were noted for untreated controls, vehicle controls or low-dose positive controls. Data are from TSCATS (OTS0509702; OTS0546325). CASRN 64742-11-6 increased incidence of tumors in to mice in this study.

Subcategory II: Residual Aromatic Extracts

Residual oil, solvent extract (CASRN 64742-10-5)

(1) Fifty female CF1 mice were administered 0.2 mL of 50% CASRN 64742-10-5 in solvent refined mineral oil to clipped, intact skin twice a week for 78 weeks under non-occlusive conditions. A group of 100 untreated control female mice was included in the study. Treated mice were generally smaller and more lethargic compared to controls (body weights were not recorded). Percent survival for treated and control mice were 78 and 70%, respectively. Chronic renal disease was responsible for the deaths of 5/22 controls and 9/15 treated mice. No treatment-related skin lesions or changes in epidermal thickness were observed. A single squamous cell carcinoma was observed in the control group. Increased incidences of renal pallor and pitting and severe glomerulosclerosis were observed in treated mice. Systemic tumors were identified in 59 and 58% of control and treated mice, respectively, and tumors of the lungs, hematopoietic tissue and ovaries were the most frequently recorded. Although there were no differences in incidences for the various tumor types, there were increased incidences of ovarian tumors in the control group.

CASRN 64742-10-5 did not increase tumor incidence in mice in this study.

(2) Female CF1 mice (50/group) were administered CASRN 64742-10-5 (0.1 mL) dermally to clipped, intact skin 3 times/week for 104 weeks. Untreated mice were the negative controls and positive control mice were administered an oil (N1, unspecified CAS number) that had been shown in previous studies to be a skin carcinogen 1 time/week for 22 weeks and then once every 2 weeks for a total of 78 weeks. Additional female mice (5/group) were treated in a similar manner, but were sacrificed after 22 or 52 weeks. Minimal skin irritation was observed following treatment. There were no treatment-related effects on mortality, body weight gain or gross pathology. Histopathological examination revealed minimal evidence of acanthosis at the treatment site. No skin tumors were observed in negative control mice. Six treated mice exhibited eight tumors of epidermal origin, two of which were malignant (squamous cell carcinomas). Positive controls exhibited redness, scabbing, cracking, flaking, chronic inflammation, acanthosis, hyperkeratosis, ulcers, parakeratosis, and abrasions and ulcerations during the first 22 weeks of treatment. Histopathological examination of positive controls revealed 56 tumors of epidermal origin in 23 mice, 17 of which were malignant (squamous cell carcinomas and one single malignant basal cell tumor). Only 24% of the positive controls survived the study duration; all others were sacrificed in extremis.

CASRN 64742-10-5 increased tumor incidence in mice in this study.

Conclusion:

Subcategory I: Distillate Aromatic Extracts

Group 1: Paraffinic Distillate Aromatic Extracts

The acute oral toxicity of CASRN 64742-05-8 to rats and acute dermal toxicity to rabbits is low. Following repeated oral exposure of CASRN 64742-04-7 to male rats for 13 weeks, decreased body weights and histopathology changes were seen in the liver, prostate and thymus at 125 mg/kg-day; the NOAEL for systemic toxicity is not established. A 13-week dermal exposure to CASRN 64742-04-7 resulted in a LOAEL of 30 mg/kg-day based on decreased body weight gain and histopathology changes; the NOAEL is not established. No data are available for reproductive or developmental toxicity. CASRN 64742-05-8 induced gene mutations in mammalian cells *in vitro* but CASRN 64742-04-7 did not induce chromosomal aberrations *in*

vivo. CASRN 64742-05-8 was irritating to rabbit skin and eyes but was not sensitizing in guinea pigs. CASRNs 64742-04-7 and 64742-05-8 increased the incidence of skin tumors in mice.

Group 2: Naphthenic Distillate Aromatic Extracts

No data are available for acute, repeated-dose, reproductive and genetic toxicity endpoints. In a range finding prenatal developmental toxicity study with CASRN 64742-11-6 via the dermal route, maternal toxicity (decreased body weight gain) was observed at 500 mg/kg-day; the NOAEL for maternal toxicity is not established. The LOAEL for developmental toxicity is 2000 mg/kg-day based on increased fetal resorptions, decreased live implants and decreased litter weights; the NOAEL is 1000 mg/kg-day. No data are available for gene mutation and chromosomal aberrations endpoints. CASRN 64742-11-6 increased the incidence of tumors in mice.

Subcategory II: Residual Aromatic Extracts

No acute oral toxicity data are available. The acute dermal toxicity of CASRN 64742-10-5 is low in rats based on results obtained in a repeated-dose dermal toxicity study. In a repeated-dose dermal toxicity study with CASRN 64742-10-5 in rats, changes in several hematology and clinical chemistry parameters and significant increases in liver and spleen weights were observed at 2000 mg/kg-day; the NOAEL for systemic toxicity is 500 mg/kg-day. No reproductive toxicity data are available; however, an evaluation of reproductive organs in the dermal repeateddose toxicity study described above revealed no treatment-related effects. A prenatal developmental toxicity study with CASRN 64742-10-5 in rats via the dermal route showed no developmental or maternal toxicity; the NOAEL is 2000 mg/kg-day (highest dose tested). No data for gene mutation are available; however, using a worst case scenario, the positive mutagenic response obtained for CASRN 64742-05-8 can be used to read across to this subcategory. CASRN 64742-10-5 did not induce chromosomal aberrations *in vivo*. CASRN 64742-10-5 increased the incidence of skin tumors in mice.

Table 3. Summary of Human Health Data					
	Subcategory I: Distillate Aromatic Extracts (DAEs)Group 1: Paraffinic DAEsGroup 2: Naphthenic DAEs			ts (DAEs) hthenic DAEs	Subcategory II: Residual Aromatic Extracts
Endpoints	Light paraffinic distillate, solvent extract (64742-05-8)	Heavy paraffinic distillate, solvent extract (64742-04-7)	Light naphthenic distillate, solvent extract (64724-03-6)	Heavy naphthenic distillate, solvent extract (64742-11-6)	Residual oil, solvent extract (64742-10-5)
Acute Oral Toxicity LD ₅₀ (mg/kg-bw)	> 5000	No Data > 5000 (RA)	No Data	No Data	No Data > 5000 (RA)
Acute Dermal Toxicity LD ₅₀ (mg/kg-bw)	> 3000	No Data > 3000 (RA)	_	—	No Data > 3000 (RA)
Repeated-Dose Toxicity NOAEL/LOAEL Oral (mg/kg-bw/day)	_	NOAEL = NE LOAEL = 125	_	—	No Data NOAEL = NE LOAEL = 125 (RA)
Repeated-Dose Toxicity NOAEL/LOAEL Dermal (mg/kg-bw/day)	NOAEL = 1000 (hdt)	NOAEL = NE LOAEL = 30	No Data	No Data	NOAEL = 500 LOAEL = 2000
Reproductive Toxicity NOAEL/LOAEL Oral (mg/kg-bw/day)	_	(13-week repeated-dose toxicity study indicated effects on sperm)	_	_	_
Reproductive Toxicity NOAEL/LOAEL Dermal (mg/kg-bw/day)	No adequate data	No effects on reproductive organs of rats after 13 wks of repeated dermal exposure.	No Data ^a	No Data ^a	No effects on reproductive organs of rats after 13 wks of repeated dermal exposure.

Table 3. Summary of Human Health Data					
	Subcategor Group 1: Par	ry I: Distillate A affinic DAEs	romatic Extract Group 2: Nap	Subcategory II: Residual Aromatic Extracts	
Endpoints	Light paraffinic distillate, solvent extract (64742-05-8)	Heavy paraffinic distillate, solvent extract (64742-04-7)	Light naphthenic distillate, solvent extract (64724-03-6)	Heavy naphthenic distillate, solvent extract (64742-11-6)	Residual oil, solvent extract (64742-10-5)
Developmental Toxicity NOAEL/LOAEL Oral (mg/kg-bw) Maternal Toxicity	No Data	NOAEL = 500 LOAEL = 2000	_	_	No Data NOAEL $= 500$ LOAEL $= 2000$
Developmental Toxicity		NOAEL = 125 $LOAEL = 500$			NOAEL = 125 $LOAEL = 500$ (RA)
Developmental Toxicity NOAEL/LOAEL Dermal (mg/kg-bw/day) Maternal Toxicity	No Data	No Data	No Data	NOAEL = NE	NOAEL = 2000 (bdt)
Developmental Toxicity				NOAEL=1000 LOAEL=2000	NOAEL = 2000 (hdt)
Genetic Toxicity – Gene Mutation <i>In vitro</i>	Positive	No Data Positive (RA)	No Data	No Data	No Data Positive (RA)
Genetic Toxicity – Chromosomal Aberrations <i>In vivo</i>	No Data	Negative	No Data	No Data	Negative
Additional Information Skin Irritation Eye Irritation Sensitization	irritating irritating Non-sensitizing				
Carcinogenicity	Positive	Positive	_	Positive	Positive

Measured data in bold text; (RA) = Read Across; – indicates that endpoint not addressed for this chemical; hdt = highest dose tested; NE = Not established

^aEPA does not agree with the sponsor's proposal to use read across from light paraffinic distillate, solvent extract information.

4. <u>Environmental Effects – Aquatic Toxicity</u>

A summary of aquatic toxicity data submitted for SIDS endpoints is provided in Table 4. The submitted studies were all conducted using water accommodated fractions (WAFs) without reporting measured concentrations for the test solutions. Initially, EPA accepted the studies that the sponsor submitted. Upon further review, EPA decided to use them as weight of evidence to support EPA's conclusions. They are included in the appendix of this document; however, there is not enough detailed information included in these studies for consideration as critical studies.

- 1. For subcategory I, EPA could not estimate the toxicity of the category members based on the physical-chemical properties (since estimated log K_{ow} values are between 4.4 and 12.0).
- 2. For Subcategory II, based on the physical-chemical properties [estimated high log K_{ow} (8.0 to 19.6) and low water solubility (<1x10⁻⁶ to 0.002 mg/L)] of the category members, EPA determined that the category members have no effect at saturation (NES) for both acute and chronic aquatic toxicity.

Conclusion:

Subcategory I

No adequate acute and chronic toxicity data are available for aquatic organism.

The acute toxicity to fish and aquatic invertebrates, toxicity to aquatic plants, and chronic toxicity to aquatic invertebrates are identified as data gaps for subcategory I under the HPV Challenge Program.

Subcategory II

No adequate acute and chronic toxicity data are available for aquatic organism. However, based on the physical-chemical properties of the category members [log K_{ow} (8.0 to 19.6) and water solubility (<1x10⁻⁶ to 0.002 mg/L)], acute and chronic aquatic toxicity to aquatic organisms is not expected.

Table 4. Summary of Environmental Effects – Aquatic Toxicity Data						
	Subcat	egory I	Subcategory II			
Endpoints	Light paraffinic distillate, solvent extract	Light naphthenic distillate, solvent extract	Heavy paraffinic distillate, solvent extract	Heavy naphthenic distillate, solvent extract	Residual oil, solvent extract	
	(64742-05-8)	(64742-03-6)	(64742-04-7)	(64742-11-6)	(64742-10-5)	
Fish 96-h LC ₅₀ (mg/L)	No Adequate Data	No Adequate Data	No Adequate Data NES	No Adequate Data NES	No Adequate Data NES	
Aquatic Invertebrates 48-h EC ₅₀ (mg/L)	No Adequate Data	No Adequate Data	No Adequate Data NES	No Adequate Data NES	No Adequate Data NES	
Aquatic Plants 72-h EC ₅₀ (mg/L)	No Adequate Data	No Adequate Data	No Adequate Data NES	No Adequate Data NES	No Adequate Data NES	
Chronic Toxicity to Invertebrates 21-d EC ₅₀ (mg/L)	No Adequate Data	No Adequate Data	No Adequate Data NES	No Adequate Data NES	No Adequate Data NES	

NES = no effects at saturation (water solubility limit)

APPENDIX

The following pages contain:

- 1. Diagram of s Simplified processing plan for a Petroleum Refinery
- 2. Description of Category Chemicals of the Aromatic Extracts Category
- 3. Representative structures of chemicals in the Aromatic Extracts category
- 4. Environmental Effects Aquatic Toxicity Data (considered inadequate by EPA)



Fig. 1. Simplified processing plan for a petroleum refinery

Description of Category Chemicals of the Aromatic Extracts Category

Materials in the Aromatic Extracts Category are grouped into two subcategories according to the class of lubricating base stock refinery stream from which they are derived. "Distillate" aromatic extracts (DAE) are formed as a byproduct during the extraction of distillate lubricating oil base stocks; "residual" aromatic extracts (RAE) are derived from the extraction of residual lubricating oil base stocks. Chemical structures were not explicitly provided for members of the Aromatic Extracts Category. These substances are complex and variable mixtures that primarily consist of aromatic compounds (1–7 ring; 60–80%) and lesser amounts of non-aromatic substances (e.g., iso-paraffins and naphthenes; 20–40%). Hydrocarbon compounds found in distillate and residual aromatic extracts typically have 15–50 and >25 carbon atoms, respectively.

CASDN	Hydrocarbon Chain Longth	Total	1-2 Ring	3-5 Ring
CASKIN	Chain Length	Aromatics	Aromatics	Aromatics
Distillates (DAE)				
64742-04-7	C20–C50	60–78%	28–35%	17–23
64742-05-8	C15–C30	60–78%	28–35%	17–23
64742-11-6	C20–C50	60–78%	28–35%	17–23
64742-03-6	C15–C30	60–78%	28-35%	17–23
Distillates (RAE)				
64742-10-5	C25+	81–92%	37–40%	20-23%

The aromatic concentration in DAEs and RAEs depends upon the source and type of crude oil from which extracts are obtained. The remaining substances are identified as naphthenic and iso-paraffinic hydrocarbons.

Process Streams, CASRN, Structures and Description of the Aromatic Extracts Category		
Name	CASRN	TSCA Description
		Distillate Aromatic Extracts
Extracts (Petroleum), Heavy Paraffinic Distillate Solvent	64742-04-7	H ₃ C ₄ C _{H3} (+++)C ₄ C ₄ C _{H3} (+++)C ₄ C ₄

Process Streams, CASRN, Structures and Description of the Aromatic Extracts Category			
Name	CASRN	TSCA Description	
Extracts (Petroleum), Light Paraffinic Distillate Solvent	64742-05-8	$\begin{array}{c} H_{3}C_{+}CH_{3} \\ (CH_{3} \\ (CH_{3} \\ CH_{3} \\ (CH_{3} \\ H_{3}C_{-}CH_{3} \\ \end{array}$ A complex combination of hydrocarbons obtained as the extract from a solvent extraction process. It consists predominantly of aromatic hydrocarbons having carbon numbers 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.	
Extracts (Petroleum), Heavy Naphthenic Distillate Solvent	64742-11-6	$\begin{array}{c} H_{3}C_{+}CH_{3}\\ (+) + H_{3}C_{+}CH_{3}\\ (+) +$	

Process Stre	ams, CASRN,	Structures and Description of the Aromatic Extracts Category
Name	CASRN	TSCA Description
Extracts (Petroleum), Light Naphthenic Distillate Solvent	64742-03-6	H ₃ C ₊ CH ₃ (+)CH ₃ (
		4- to 6-membered condensed ring aromatic hydrocarbons.
		Residual Aromatic Extracts
Extracts (Petroleum), Residual Oil Solvent	64742-10-5	CH ₃ CH ₃ C

Environmental Effects – Aquatic Toxicity (considered inadequate by EPA)

Acute Toxicity to Fish

Subcategory I:

No data are available for this endpoint.

Subcategory II:

Heavy paraffinic distillate, solvent extract (CASRN 64742-04-7)

Rainbow trout (*Oncorhynchus mykiss*) were exposed to CASRN 64742-04-7 as the water accommodated fractions (WAFs) under semi-static conditions for 96 hours. The loading rates were 0 (control) or 1000 mg/L. No effects were noted at either of the WAF loading rates. Analysis was performed based on Total Organic Carbon (TOC). **No effects at saturation.**

Residual oil, solvent extract (CASRN 64742-10-5)

Rainbow trout (*Oncorhynchus mykiss*) were exposed to CASRN 64742-10-5 as the water accommodated fractions (WAFs) under semi-static conditions for 96 hours. The loading rates were 0 (control) or 1000 mg/L. No effects were noted at either of the WAF loading rates. Analysis was performed based on TOC.

No effects at saturation.

Acute Toxicity to Aquatic Invertebrates

Subcategory I:

Light paraffinic distillate, solvent extract (CASRN 64742-05-8)

Water fleas (*Daphnia magna*) were exposed to CASRN 64742-05-8 as the water accommodated fractions (WAFs) under static conditions for 48 hours. The loading rates were 0 (control), 0.1, 1.0, 100 or 1000 mg/L. The test chambers were closed with screw top PTFE-lined caps to minimize evaporation and volatilization. The SPME Biomimetic Extract analysis detected hydrocarbon compounds in all WAFs at 0.5 mg/L and above. The final concentrations remained at least 54 % of the initial concentrations. 40 % immobilization was observed at 10 mg/L (loading rate), and 55 % immobilization was observed at 100 mg/L (loading rate). **48-h EL**₅₀ = **35.9 mg/L**

Subcategory II:

Heavy paraffinic distillate, solvent extract (CASRN 64742-04-7)

Water fleas (*Daphnia magna*) were exposed to CASRN 64742-04-7 as the water accommodated fractions (WAFs) under static conditions for 48 hours. The loading rates were 0 (control) or 1000 mg/L. No effects were noted at either of the WAF loading rates. Analysis was performed based on TOC.

No effects at saturation.

Residual oil, solvent extract (CASRN 64742-10-5)

Water fleas (*Daphnia magna*) were exposed to CASRN 64742-10-5 as the water accommodated fractions (WAFs) under static conditions for 48 hours. The loading rates were 0 (control) or 1000 mg/L. No effects were noted at either of the WAF loading rates. Analysis was performed based on TOC.

No effects at saturation.

Toxicity to Aquatic Plants

Subcategory I:

Light paraffinic distillate, solvent extract (CASRN 64742-05-8)

Green algae (*Scendesmus subspicatus*) were exposed to CASRN 64742-05-8 as the water accommodated fractions (WAFs) under static conditions for 72 hours. The loading rates were 0 (control), 0.1, 1.0, 10, 100 or 1000 mg/L. The test chambers were closed with screw top and completely filled with WAF solutions (no headspace). The SPME Biomimetic Extract analysis detected hydrocarbon compounds in all WAFs. The final concentrations remained at least 73 % of the initial concentrations. 24, 50, 61 and 81 % growth inhibition was observed at 1.0, 10, 100 and 1000 mg/L (loading rate), respectively.

72-h EL₅₀ (growth rate) = 18.8 mg/L

Subcategory II:

Residual oil, solvent extract (CASRN 64742-10-5)

Green algae (*Scendesmus subspicatus*) were exposed to CASRN 64742-10-5 as the water accommodated fractions (WAFs) under static conditions for 72 hours. The loading rates were 0 (control) or 1000 mg/L. No effects were noted at either of the WAF loading rates. Analysis was performed based on TOC.

No effects at saturation.

Chronic Toxicity to Aquatic Invertebrates

Subcategory I:

No data are available for this endpoint.

Subcategory II:

Heavy paraffinic distillate, solvent extract (CASRN 64742-04-7)

Water fleas (*Daphnia magna*) were exposed to CASRN 64742-04-7 as the water accommodated fractions (WAFs) under semi-static conditions for 21 days. The loading rates were 0 (control), 10 or 1000 mg/L. No effects were noted at any of the WAF loading rates. Analysis was performed based on TOC.

No effects at saturation.

Residual oil, solvent extract (CASRN 64742-10-5)

Water fleas (*Daphnia magna*) were exposed to CASRN 64742-10-5 as the water accommodated fractions (WAFs) under semi-static conditions for 21 days. The loading rates were 0, 10 or 1000 mg/L. No effects were noted at any WAF loading rate. Analysis performed based on TOC. **No effects at saturation.**