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# **Screening Assessment**

## **Base Oils**

**Environment and Climate Change Canada  
Health Canada**

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## Synopsis

Pursuant to section 68 or 74 of the *Canadian Environmental Protection Act, 1999* (CEPA), the Minister of the Environment and the Minister of Health have conducted a screening assessment of 39 base oils identified in Appendix A. Substances in this group were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA or were considered a priority on the basis of other human health concerns<sup>1</sup>.

Base oils are complex combinations of hydrocarbons produced by the vacuum distillation of residues originating from the atmospheric distillation of crude oil. They are considered to be of Unknown or Variable composition, Complex reaction products or Biological materials (UVCBs) and are related to the petroleum sector. Base oils are composed of normal- and branched alkanes (paraffins), cycloalkanes (naphthenes), and aromatics, primarily in the carbon range of C<sub>15</sub> to C<sub>50</sub>. Base oils are identified by Chemical Abstracts Service Registry Numbers (CAS RN<sup>2</sup>) which are based only on the last refining processing step undertaken to produce the base oil. The CAS RN does not describe the complete details of the refining process, such as the number and type of processing steps and the severity (or intensity) of each processing step, which determines the degree of removal of various components considered to be undesirable in the final product (e.g., aromatics, normal alkanes [i.e., waxes], heterocyclics, and sulphur). Thus, the composition of a specific CAS RN in terms of the proportion of aromatics, paraffins and naphthenes cannot be ascertained on the basis of the CAS RN alone; two base oils with the same CAS RN may vary significantly in their compositions with regard to the proportion of aliphatics and aromatics. On the basis of available safety data sheets, the aromatic content of base oils can range from less than 10 % by weight (wt%) to approximately 45 wt%, depending on the extent and severity of refinement.

Base oils may be consumed on-site at a refinery, blended into substances that leave the site with different CAS RNs, or be transported by truck or train to other petroleum or non-petroleum sector facilities for use as feedstocks or to be blended with other feedstocks, resulting in a new CAS RN. Twenty-seven of the 39 base oils identified as priorities for assessment were identified as being used industrially or present in products available to consumers, including in lubricants, transformer oils, automotive care products, processing aids (including extender oils for rubber-based products), printing inks, fuels and solvents, paints and coatings, soaps and detergents, adhesives and

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<sup>1</sup> The substance bearing CAS RN 68782-97-8 was not identified under subsection 73(1) of CEPA but was included in this assessment as it was considered a priority on the basis of other human health concerns.

<sup>2</sup> The Chemical Abstracts Service Registry Number (CAS RN) is the property of the American Chemical Society, and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

sealants, household cleaning products, lawn and garden care products, and building products.

As the aromatic content of the base oils used in many industrial applications is unknown, aromatic contents ranging from 10 to 45 % by weight were considered in the ecological assessment. Empirical toxicity data for base oils of unspecified aromatic content indicate low hazard; however, modelled toxicity values for high aromatic base oils suggest they may be hazardous to aquatic organisms.

Four industrial uses of base oils were identified as having the highest potential for release to the environment: manufacture of lubricants; use in the treatment of wastewater; use in the pulp and paper industry; and deinking operations (release from inks). Environmental concentrations in the aquatic environment following wastewater treatment associated with releases from these uses were estimated and compared to modelled predicted no effect concentrations on the basis of the predicted composition of base oil in the effluent. In addition, the concentration of base oils in soils following the application of biosolids from wastewater treatment facilities to soil were compared to predicted no effect concentrations for soil organisms. On the basis of these comparisons, base oils are expected to pose a low risk of harm to aquatic and soil organisms. Sediment studies on aliphatic petroleum substances support a determination of low toxicity to sediment organisms for low aromatic base oils; however, it is uncertain how applicable the base oil toxicity test results are to high aromatic base oils.

Considering all available lines of evidence presented in this screening assessment, there is low risk of harm to the environment from base oils. It is concluded that the 39 base oils do not meet the criteria under paragraphs 64(a) or (b) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

A critical health effect for the initial categorization of base oils was carcinogenicity, based primarily on classifications by international agencies. On the basis of the likelihood of base oils to contain polycyclic aromatic hydrocarbons (PAHs), the European Commission classifies the 38 of the 39 base oil CAS RNs addressed in this assessment as either Category 1A (“known to have carcinogenic potential for humans”; 9 substances) or 1B (“Substances presumed to have carcinogenic potential for humans”; 29 substances). However, the European Commission considers the Category 1B substances not carcinogenic if they are refined to contain less than 3% dimethylsulfoxide (DMSO) extract. The International Agency for Research on Cancer concluded there is no evidence for the carcinogenicity in laboratory animals for base oils that meet this standard. this

Base oils used as ingredients in products available to consumers are typically refined to contain a low level of PAHs. On the basis of Canadian base oil product testing, only

residual to low levels (low parts per billion to low parts per million) of PAHs were found. Converting all 16 standard PAHs into benzo[a]pyrene (B[a]P) equivalents resulted in an equivalent B[a]P level which was lower than the European Union individual PAH limits for rubber and soft plastic toys and children's articles (0.5 ppm) and also lower than allowed as residuals in food grade petrolatum (1 ppm). Therefore, the base oils used to formulate products available to consumers examined in this assessment are not considered to be a concern for human health.

Refined base oils exhibit low toxicity, even at high doses in studies of acute and repeated dermal dosing, and short-term oral dosing in laboratory studies; therefore, non-cancer risk to human health from intermittent, oral and dermal exposure to products available to consumers containing base oils is considered to be low. Due to their high viscosity and low volatility, inhalation exposure to base oils is not expected. Exposures to base oils via environmental media are not expected.

On the basis of the information presented in this screening assessment, it is concluded that the 39 base oils do not meet the criteria under paragraph 64(c) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Therefore, it is concluded that the 39 base oils listed in Appendix A do not meet any of the criteria set out in section 64 of CEPA.

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## 1. Introduction

Pursuant to sections 68 or 74 of the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999), the Minister of the Environment and the Minister of Health have conducted a screening assessment on a group of 39 petroleum base oils to determine whether these substances present or may present a risk to the environment or to human health. During categorization, these 39 base oils were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA or were considered a priority on the basis of other human health concerns (ECCC, HC [modified 2017a]). The Chemical Abstracts Service Registry Numbers (CAS RN<sup>3</sup>) and *Domestic Substances List* (DSL) names of these 39 substances are listed in Table A.1 in Appendix A; descriptions of each CAS RN as reported on the DSL are provided in ECCC (2018a). Compositional variability within and between base oils can lead to the interchangeable use of CAS RNs in products if they meet product use specifications.

This screening assessment includes consideration of information on chemical properties, environmental fate, hazards, uses and exposures, including additional information submitted by stakeholders. Relevant data were identified up April 2018. Empirical data from key studies as well as results from models were used to reach conclusions. When available and relevant, information presented in assessments from other jurisdictions and agencies including the European Union (EU) and International Agency for Research on Cancer (IARC) was considered.

This screening assessment was prepared by staff in the CEPA Risk Assessment Program at Health Canada and Environment and Climate Change Canada (ECCC) and incorporates input from other programs within these departments. The ecological and human health portions of this assessment have undergone external peer review and/or consultation. Comments on the technical portions relevant to the environment were received from Geoff Granville (GCGranville Consulting Corp) and Dr. Connie Gaudet. Comments on the technical portions relevant to human health were received from Dr. Glenn Talaska (University of Cincinnati, USA) and Dr. Susan Griffin (US EPA). Additionally, the draft of this screening assessment (published October 6, 2018) was subject to a 60-day public comment period. While external comments were taken into consideration, the final content and outcome of the screening assessment remain the responsibility of Health Canada and Environment and Climate Change Canada.

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<sup>3</sup> The Chemical Abstracts Service Registry Number (CAS RN) is the property of the American Chemical Society, and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.



This screening assessment focuses on information critical to determining whether substances meet the criteria as set out in section 64 of CEPA by examining scientific information and incorporating a weight of evidence approach and precaution.<sup>4</sup> This screening assessment presents the critical information and considerations on which the conclusion is based.

## 2. Identity of substances

Base oils are petroleum substances with a boiling point range of approximately 300 to 600°C (570 to 1,110°F). Distillate base oils are derived from the vacuum distillation of residues originating from the atmospheric distillation of crude oil. Residual base oils are derived from the residuum of vacuum distillation following deasphalting.<sup>5</sup> Base oils are mainly composed of normal- and branched alkanes (paraffins), cycloalkanes (naphthenes), and aromatics (substances containing at least one benzene ring) having carbon numbers ranging from approximately C<sub>15</sub> to C<sub>50</sub> (API 2011a, Kramer et al. 1999). Light base oils generally contain components ranging from C<sub>15</sub> to C<sub>30</sub>, while the carbon range of heavy base oils is generally C<sub>20</sub> to C<sub>50</sub>. Industrial nomenclature practises may refer to base oils as 'base oil stocks' or 'lubricating oil base stocks' or other such terminology (CONCAWE 2014).

Foots oils are oils sweated from the wax removed from base oils during refining, and are thus similar in composition to base oils; therefore, they are considered to be part of the base oil group (API 2011a) and are included within this assessment.

Base oils are UVCB substances that are complex combinations of hydrocarbon molecules that originate in nature or are the result of chemical reactions and processes that take place during processing and blending of petroleum. Given their complex and variable compositions, base oils cannot practicably be synthesized by simply combining individual constituents.

Base oils can be described in a variety of ways. They may be described as paraffinic or naphthenic, depending upon the predominant hydrocarbon type of the crude oil from which they were derived (Stipanovic 2003, Rizvi 2009). Paraffinic oils that have undergone mild solvent extraction and are used as process oils may be referred to as mild extract solvate (MES), while similarly refined naphthenic process oils are simply referred to as naphthenic oils (Tonkonogov et al. 2013).

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<sup>4</sup>A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products available to consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazardous Products Regulations*, which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other acts.

<sup>5</sup> A representative diagram describing the refining process for base oils is given in API (2011a).

Base oils that have not undergone further processing or refinement following distillation (or deasphalting in the case of residual base oils) are considered to be unrefined. Unrefined base oils may undergo further refining (i.e., solvent extraction, dewaxing, hydrocracking, hydrofinishing or clay treatment) to improve their performance characteristics by removing undesirable components (e.g., aromatics, normal alkanes [i.e., waxes], heterocyclics, and sulphur) and improve viscosity and stability characteristics (Stipanovic 2003, Rizvi 2009, API 2011a). One or more refining processes may be used, depending on the specifications for the final base oil, with each additional step of processing decreasing the amount of undesirable components (API 2011a). In addition, the severity (or intensity) of each process determines the extent of this removal, with more severe processing resulting in greater removal (API 2011a). Therefore, the final composition of the base oil, depends on the type and number of refining processes used and the severity of these processes (Rizvi 2009, Hall 2010, NYNAS 2001). Generally, unrefined or mildly-refined base oils have hydrocarbon compositions that resemble the feedstock and have larger proportions of aromatics (CONCAWE 1997). However, with increasing number and/or severity of refining processes, the compositional variation due to the crude oil source is reduced (CONCAWE 1997). As the CAS RN name describes only the last refining step undertaken on the base oil (API 2011a), the degree of refining and thus composition of a specific CAS RN in terms of the proportion of aromatics, paraffins and naphthenes cannot be ascertained based solely on the CAS RN resulting in base oils with the same CAS RN having a range of possible aromatic contents.

The aromatic fraction of base oils includes all components that contain an aromatic (i.e., benzene) ring within the structure, and includes parent monoaromatic hydrocarbons (MAHs), polycyclic aromatic hydrocarbons (PAHs) and their alkylated derivatives (i.e., MAHs and PAHs containing normal, branched or cyclic alkyl groups), as well as oxygen-, nitrogen- and sulphur-containing aromatics. The PAHs and oxygen-, nitrogen- and sulphur-containing polycyclic aromatics are collectively referred to as polycyclic aromatic compounds (PACs). The type of refining process and/or its severity may preferentially remove larger PAHs including those associated with carcinogenicity (e.g., certain non-alkylated and mono-alkylated PAHs) from a base oil while leaving a significant amount of smaller, non-carcinogenic aromatic components which are desirable for solvency in some base oil applications (Casserly and Rasco 2011). Therefore, a base oil can meet the requirements to be called not carcinogenic (i.e., have an aromatic extract of <3 % by weight (wt%) according to method IP 346 (IP 1985, 1993)) yet still have high total aromaticity (see Tables B1 and B2 in Appendix B). The total aromatic content (wt%) of base oils is of importance to the ecological assessment, as aromatics in general are the main contributors to the ecotoxicity of base oils (Verbruggen et al. 2008, Cermak et al. 2013), and thus this measurement is considered in the ecological assessment.

The composition of a base oil will be dependent on the specifications for its use. Paraffinic base oils used in automotive engine oils range from very low aromatics (i.e., less than 1 wt% (Mansfield 2000)) to greater than 10 wt% (API 2016), though the use of very low aromatic base oils is becoming more common in the automotive industry

(Bergstra 2009). Base oils used as process oils in rubber compounding have a higher aromatic content than many automotive oils, with aromatic contents of up to 34 wt% for paraffinic base oils and 29 wt% or greater for naphthenic base oils (Rizvi 2009). Reported aromatic contents for various naphthenic and paraffinic base oils can range up to approximately 45 wt% (Tables B.1 and B.2, Appendix B). Base oils are subject to oxidation in many applications (e.g., lubricants, hydraulic fluids, transmission oil, transformer oil) which leads to the formation of oxidation products such as acids, ketones and phenols (Nynas 2001, Hall 2010). Used base oils may also become contaminated by fuel combustion products when used in engines, or metals when used as lubricants (CH2M Hill Engineering Ltd. 1992, in Environment Canada, Health Canada 1994). These changes in composition of the oil occur such that the “used” oil is no longer captured by the physical and chemical definition of base oils as considered in this assessment. The conclusions herein therefore apply to unused base oils and to base oils that are not physically or chemically altered by the nature of their intended use.

### 3. Physical and chemical properties

The physical and chemical properties of base oils are shown in Table 3.1. Some values presented are derived from representative structures in the carbon range of the base oil substances, or from (Material) Safety Data Sheet (MSDS). When MSDS were used to obtain physical and chemical data for base oils, only those listing the base oil at greater than 95% purity were considered.

**Table 3.1. Physical and chemical properties of base oils**

Property	Value	Reference
Pour Point (°C) <sup>a</sup>	-60 to 15.5	CONCAWE 1997; API 2011a
Boiling Point (°C)	> 250 to 604	MSDS 2012; API 2011a
Density (kg/m <sup>3</sup> )	810 to 980	MSDS 2018, 2017a, CONCAWE 1997; API 2011a; MSDS 2016b,c; MSDS 2016a;
Vapour Pressure (Pa) <sup>b</sup>	4.9×10 <sup>-16</sup> to 6.4	ECCC 2018a
Octanol-water Partition Coefficient (Log K <sub>ow</sub> ) <sup>c</sup>	4.9 to 25	ECCC 2018a
Water Solubility (mg/L) <sup>b</sup>	Insoluble	MSDS 2017b
	6×10 <sup>-21</sup> to 0.9	ECCC 2018a

<sup>a</sup> Defined as the lowest temperature at which movement of the test specimen is observed.

<sup>b</sup> on the basis of modelled (EPI Suite 2008) values for a range of C<sub>15</sub> to C<sub>50</sub> representative structures

<sup>c</sup> on the basis of modelled Log K<sub>ow</sub> (EPI Suite 2008) for a range of C<sub>15</sub> to C<sub>50</sub> representative structures. Note that log K<sub>ow</sub> values above 8.27 are outside of the training set of the model.

To predict the physical/chemical properties and ecological fate of complex petroleum substances such as base oils, representative structures were chosen from each chemical class found in the substance. As the composition of base oils is variable and not well defined, representative structures for alkanes, isoalkanes, cycloalkanes, one-

ring to six-ring aromatics, and cycloalkane mono- and diaromatics ranging from C<sub>15</sub> to C<sub>50</sub> were selected based solely on carbon numbers for each hydrocarbon class. Physical and chemical data were assembled from scientific literature and from the EPI Suite (2008) group of environmental models. A summary of empirical and modelled physical and chemical property data for the representative hydrocarbon structures of base oils is provided in ECCO (2018a).

Water solubilities for components of base oils are generally very low ( $6 \times 10^{-21}$  to 0.9 mg/L), and octanol-water partition coefficient ( $\log K_{ow}$ ) estimations range between 4.9 and 25, indicating high sorption potential. The considerable variability in  $\log K_{ow}$  values results from the complex nature of these mixtures and their different carbon ranges. Representative structures of base oils have low to moderate vapour pressures ( $4.9 \times 10^{-16}$  to 6.4 Pa).

It should be noted that the physical and chemical behaviour of the representative structures will differ if these representative structures are present in a complex substance, such as base oils. The vapour pressures of components of a mixture will be lower than their individual vapour pressures according to Raoult's Law (i.e., the total vapour pressure of an ideal mixture is proportional to the sum of the vapour pressures of the mole fractions of each individual component). Similar to Raoult's Law, the water solubilities of components in a mixture are lower than when they are present individually (Banerjee 1984; Di Toro et al. 2007). Concurrently, however, when an individual petroleum hydrocarbon chemical that is normally solid under environmental conditions is part of a petroleum mixture (or UVCB), it may be found in a liquid state due to the lowering of its melting point when in a mixture (Di Toro et al. 2007). Presence of a hydrocarbon that is normally solid in a mixture thus results in an increase in its vapour pressure and water solubility, as determined by the subcooled vapour pressure (Staikova et al. 2005) and subcooled solubility (Di Toro et al. 2007). ). The subcooled vapour pressure or solubility is used to determine the contribution of a normally solid component to the overall vapour pressure or solubility of a petroleum substance.

## 4. Sources and uses

Information on the 39 base oils have been collected under various surveys conducted pursuant to section 71 of CEPA. Twenty-two of these CAS RNs were surveyed (Canada 2008; 2009; 2011) under the Petroleum Sector Stream Approach to obtain information on manufacture, transport, and uses and included data on quantities. A survey issued pursuant to section 71 of CEPA for the remaining 17 base oils (Canada 2015) was restricted to uses only and thus did not collect quantity data. The quantity data available for the initial 22 base oils surveyed were considered to be sufficient for the assessment, as it provided an order of magnitude estimate of the quantities of base oils that could be used within a given application.

## 4.1 Manufacture and import of base oils

According to information submitted (Environment Canada 2012) pursuant to a CEPA section 71 survey (Canada 2011), in 2010 the total quantities for 20 base oil CAS RNs surveyed for manufacture or import were greater than 1 billion kilograms and greater than 100 million kilograms, respectively.<sup>6</sup>

## 4.2 Uses

According to information submitted pursuant to CEPA section 71 surveys (Environment Canada 2008, 2009, 2012; ECCC 2016a), searches of on-line databases and a search of material safety data sheets, base oils may be intermediates in the refining process at a petroleum facility or be blended with other feedstocks resulting in a new CAS RN. They can be transported by truck or train to other petroleum or non-petroleum sector facilities for use as feedstocks or blending components or to be formulated into a product. Base oils are ingredients in industrial products as well as certain products available to consumers. In 2010, greater than 100 million kilograms of 20 base oil CAS RNs were used in Canada (Environment Canada 2012).

Use information on the base oils was submitted pursuant to CEPA section 71 surveys (20 CAS RNs; Environment Canada 2012, ECCC 2016a), a voluntary data gathering initiative (14 CAS RNs; ECCC 2016b), and searches of on-line databases, and contractor reports. Of the 39 base oils considered within this assessment, thirteen<sup>7</sup> were identified as not having any industrial or consumer use. The remaining 26 CAS RNs were identified as having industrial or consumer uses as or in lubricants, transformer oils, automotive care products, processing aids (including extender oils), printing inks, fuels and solvents, paints and coatings, soaps and detergents, adhesives and sealants, household cleaning products, lawn and garden care products, building products, and other miscellaneous products.

Five CAS RNs (ECCC 2018a) were identified as being used in the oil and gas industry as a component in hydraulic fracturing fluids (US House of Representatives 2011).

For the 39 base oils considered within this assessment, none are listed in the Drug Products Database or the Therapeutic Products Directorate's internal Non-Medicinal Ingredient Database as medicinal or non-medicinal ingredients present in final pharmaceutical products or veterinary drugs in Canada (DPD 2010, Personal

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<sup>6</sup> Values reflect quantities reported in response to the survey conducted under section 71 of CEPA (Canada 2011). See survey for specific inclusions and exclusions (schedules 2 and 3).

<sup>7</sup> CAS RNs 64741-51-1, 64742-19-4, 64742-21-8, 64742-35-4, 64742-36-5, 64742-44-5, 64742-64-9, 64742-67-2, 64742-68-3, 64742-76-3, 68782-97-8, 74869-22-0, and 93763-38-3

communication, from Health Canada Therapeutic Products Directorate to Health Canada Risk Management Bureau, dated March 2010; unreferenced). CAS RN 64741-76-0, as C15-23 Alkane as opposed to distillates (petroleum), heavy hydrocracked, is listed in the Natural Health Products Ingredients Database with a non-medicinal role for topical use only as solvent, as well as listed in the Licensed Natural Health Products Database as being present as such, a non-medicinal ingredient, in a currently licensed topical natural health product (LNHPD [modified 2018]; NHPID [modified 2019]). CAS RNs 64741-76-0 and 64742-55-8 were initially identified as being used in cosmetic products in Canada. However, the International Nomenclature of Cosmetic Ingredients (INCI) provides multiple ingredient names under the heading of the CAS RN for these substances. For example, under CAS RN 64741-76-0 the following ingredient names are listed as being present in cosmetics: C14-17 Alkane, C14-19 Alkane, C15-19 Alkane, C15-23 Alkane, and C18-21 Alkane. Under CAS RN 64742-55-8 the following ingredient names are used: C16-23 Alkane, C18-29 Alkane, and C21-28 Alkane [Nikitakis and Lange 2015, EU CosIng 2018a, b). Follow-up with the Consumer Product Safety Directorate (personal communication, email from the Consumer Product Safety Directorate, Health Canada (HC) to the Existing Substances Risk Assessment Bureau (HC), dated Dec. 1, 2017) indicated that the suppliers are producing materials with more specific ranges, and that a generic CAS has been assigned to them. These generic descriptions are considered to describe substances which are different in composition from those substances when they are described by their standard DSL CAS RN names. On the basis of the different compositions of the substances in cosmetic and natural health product uses, they are not considered further in this assessment.

Eleven of the 39 base oils<sup>8</sup> are identified as being used in food packaging materials and/or incidental additive applications, in particular as lubricants in machinery used for processing food. However, none of these substances were stated to have potential for direct food contact [Personal communication, from Health Canada Food Directorate to Health Canada Risk Management Bureau, dated August 2017; unreferenced]. In addition, 14 of the 39 base oils<sup>9</sup> are considered List 2 formulants by Health Canada's Pest Management Regulatory Agency (PMRA 2017).

## 5. Releases to the environment

Base oils may be released to the environment from activities in industrial facilities associated with production, transportation, storage, and disposal, as well as during industrial, commercial and consumer use.

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<sup>8</sup> CAS RNs 64741-88-4, 64741-89-5, 64741-95-3, 64741-96-4, 64741-97-5, 64742-01-4, 64742-18-3, 64742-52-5, 64742-54-7, 72623-86-0, and 93924-32-4

<sup>9</sup> CAS RNs 64741-88-4, 64741-89-5, 64741-96-4, 64742-01-4, 64742-52-5, 64742-53-6, 64742-54-7, 64742-55-8, 64742-56-9, 64742-57-0, 64742-62-7, 64742-65-0, 72623-86-0, and 72623-87-1

## 5.1 Release from petroleum refineries

Base oil streams originate from vacuum distillation columns at refineries, either as distillates or residue (bottoms product). Thus, the potential locations for the controlled release of base oils include relief valves and venting valves or drain valves on piping or equipment (e.g., vessels). Under typical operating conditions, releases of base oils would be captured in a closed system, according to defined procedures, and returned to the processing facility or to the wastewater treatment plant. Under both scenarios, exposure of the general population is not expected.

Unintentional releases of base oils may occur at production facilities. Existing management practices cover releases of base oils and include requirements at the federal, provincial, and territorial levels to prevent or manage the unintentional releases of petroleum substances and streams from facilities (SENES 2009). Non-regulatory measures (e.g., guidelines, best practices) are also in place at petroleum sector facilities to reduce unintentional releases.

Additionally, existing occupational health and safety legislation specifies measures to reduce occupational exposures of employees, and some of these measures also serve to reduce unintentional releases (CanLII 2001). Due to the low volatility of base oils, evaporative emissions do not significantly contribute to overall site emissions at production facilities. Thus, on-site releases are not expected to be a significant source of base oils in the environment.

## 5.2 Release from transportation and storage

In general, three operating procedures are involved in the process of transportation: loading, transit and unloading. Loading and unloading of base oils is normally conducted at sites with limited access to the general public.

The handling of base oils at petroleum facilities for the purpose of transportation is regulated at both the federal and provincial levels, with legislation covering loading and unloading. Collectively, this legislation establishes requirements for the safe handling of petroleum substances and is intended to minimize or prevent potential releases during loading, transportation and unloading operations (SENES 2009). Releases of base oil vapours from storage tanks into the air are expected to be negligible due to their low volatility.

Spills of base oils during transportation and storage are considered in section 5.5.

Releases from washing or cleaning transportation vessels are not considered in this screening assessment, as tanks or containers for transferring petroleum substances are

typically dedicated vessels and, therefore, washing or cleaning is not required on a routine basis (US EPA 2008).

### **5.3 Release from other industrial facilities**

Base oils are used in various sectors other than petroleum refineries which might lead to the release of base oils in wastewater. The industrial wastewater may be treated at an on-site wastewater treatment system prior to release to the receiving water, or it may be discharged to a sewer to be treated at an off-site wastewater treatment system<sup>10</sup>. Due to differences in the physical-chemical properties of the components of base oils, there is differential removal of petroleum hydrocarbon components during wastewater treatment such that the relative proportions of components of the base oil differs in the effluent discharged to the receiving water as compared to the base oil that entered the wastewater treatment system.

### **5.4 Release from products available to consumers**

Base oils can be found in many products available to consumers, which include transmission oil, hydraulic fluids, lubricating oils, and others as noted in section 4.2 and summarized in ECCC (2018a). Generally, the volume of base oil released from products containing a base oil and available to consumers is small for each consumer application, and the releases from these uses are expected to be dispersed across Canada. Thus, releases of base oils to the environment from consumer applications are considered to be much lower than those from other sources and are not considered to be a significant point source of base oils in the environment. According to the Meridian (2009) database, minimal releases of base oils occur from their uses including automotive care and maintenance products, lubricants, and paints and coatings.

### **5.5 Release from spills**

Base oils may be spilled to the environment during storage, transport or use. For those base oils which did not have any identified product use, spills would be the only significant route for release to the environment.

Releases of base oils through spills were assessed through the analysis of spills reported to Environment and Climate Change Canada between 2008 and 2012. Spills of petroleum substances under the following descriptions were considered: “hydraulic

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<sup>10</sup> In this assessment, the term “wastewater treatment system” refers to a system that collects domestic, commercial and/or institutional household sewage and possibly industrial wastewater (following discharge to the sewer), typically for treatment and eventual discharge to the environment. Unless otherwise stated, the term wastewater treatment system makes no distinction of ownership or operator type (municipal, provincial, federal, indigenous, private, partnerships). Systems located at industrial operations and specifically designed to treat industrial effluents will be identified by the terms “on-site wastewater treatment systems” and/or “industrial wastewater treatment systems”.



oil”; “mineral oil”; “transformer oil”; “lube oil”; “petroleum distillate”; “hydrotreated light”; “transmission fluids”; “vehicle fluids”; “mineral oil and grease (NOS)”; and “other/unknown”. Spills due to aircraft crashes, collisions, earthquakes/slides, ice/frost, road conditions, storms/floods, subsidence, or vandalism were not considered in the analysis. In addition, only spills considered to be unused oils or those not physically and/or chemically altered by the nature of their intended use (see section 2) were considered in the analysis.

Following this analysis, only one spill incident was found despite the general nature of some of the petroleum categories considered (i.e., petroleum distillate, mineral oil and grease, other/unknown), which would include some substances other than base oils and thus make the analysis conservative. This spill incident was due to a train derailment, which led to an estimated release of 180 000 L of base oils into the environment. As expected, releases of base oils during bulk transport have the potential of being large; however, since such spills are infrequent, they are not considered further in the context of this assessment.

## **6. Environmental fate and behaviour**

### **6.1 Environmental distribution**

When petroleum substances are released into the environment, the major fate processes include dissolution in water, volatilization, adsorption, biodegradation and photodegradation. These processes will cause changes in the composition of these substances.

As noted previously (Section 3), the solubility and vapour pressure of components within a mixture will be proportional to their concentrations in the mixture and thus lower than their individual water solubilities and vapour pressures, or for components that are normally solid, than their subcooled water solubilities and vapour pressures. for components that are normally solid.

Biodegradation almost always occurs when petroleum mixtures are released into the environment. Studies have found populations of bacteria and other organisms (e.g., fungi and yeasts) that are capable of degrading petroleum hydrocarbons in both fresh and marine waters and sediments, as well as soils (Atlas 1981). Degradation occurs both in the presence and absence of oxygen. In general, aromatic components tend to be degraded more slowly than aliphatic components, although the degradation of some higher molecular weight cycloalkanes may be very slow (Atlas 1981; Potter and Simmons 1998).

Three weathering processes—dissolution in water, volatilization, and biodegradation—typically result in the depletion of the more readily soluble, volatile, and degradable compounds and the accumulation of those most resistant to these processes in residues. Due to the complex interaction of components within a mixture that impacts

their physical-chemical properties and behaviour, it is difficult to predict the fate of a complex mixture. Therefore, as a general indication of the fate of base oils, the physical-chemical properties of representative structures of base oils (ECCC 2018a) were examined.

Air is not expected to be an important receiving medium for base oils. However, the moderate vapour pressure of some lower molecular weight components, such as the C<sub>15</sub>–C<sub>20</sub> alkanes and aromatics and C<sub>15</sub>–C<sub>30</sub> isoalkanes suggests that if released into air, they may have some potential to remain within this medium. The higher molecular weight aliphatic and aromatic representative structures have low vapour pressures and, if released to air, are expected to adsorb to suspended particulates, with possible subsequent removal from air through dry and wet deposition.

When released into water, a number of processes will act to determine the distribution and fate of base oil. All representative structures have very low water solubility ( $6 \times 10^{-21}$  to 0.9 mg/L); however, some representative structures such as the C<sub>15</sub> and some C<sub>20</sub> mono-, di- and poly-cycloalkanes (including cycloalkane aromatics) (i.e., naphthenics) and aromatics are relatively soluble ( $10^{-3}$  to 0.9 mg/L). Very high sorption potential ( $\log K_{oc} > 3.3$ ) for all representative structures, however, indicates that all base oil components will tend to partition to particulates suspended in the water column and/or sediment, though the tendency to sorb is greater for the aliphatic than for the aromatic structures.

Within soil, the movement of components will be determined by their partitioning between soil particulates, soil pore water, and soil pore air. Base oil components have high adsorptivity and will adsorb strongly to soil particulates, with all having  $\log K_{ow}$  values in the range of 5 to 25 (high) and  $\log K_{oc}$  values in the range of 4.2 to 22 (very high) (ECCC 2018a). This high adsorptivity suggests that base oil components will have low mobility in soil.

Although no direct releases to soil are anticipated, indirect releases may result from the application of biosolids to land from wastewater treatment systems receiving wastewater that contains base oils.

## 6.2 Environmental persistence and bioaccumulation

Due to the complex nature of base oils, their persistence and bioaccumulation potential were assessed on the basis of empirical and/or modelled data for representative petroleum hydrocarbons expected to be or similar to those released into the environment. These representative structures do not include all possible substances present within a base oil, nor do they necessarily provide a complete picture of the full range of persistence potential for any given chemical class (e.g., alkanes, one-ring aromatics) or carbon number (e.g., C<sub>15</sub>). Thus, the modelling results do not indicate the persistence and bioaccumulation potential of all substances in a specific class and carbon range but instead give a more general indication of these properties.

## 6.2.1 Environmental persistence

Empirical data on the persistence of base oils as a single substance was considered. However, as base oils consist of hundreds to thousands of individual components, each with different susceptibilities to biodegradation, the results of such degradation studies can only indicate that some components are susceptible to biodegradation, and cannot determine the biodegradation potential of all components.

Primary and ultimate (ready) biodegradation data for several base oils are available (API 2011a; CONCAWE 1997) and are summarized in ECCC (2018a). The ready biodegradation studies indicate that none of the base oils undergo 60% or greater of mineralization in 28 days. While most robust study summaries did not comment on the biodegradation rate at 28 days, one did note the virtual cessation of biodegradation by this time (API 2011b). The results of primary biodegradation tests indicate that base oils can undergo primary degradation, though the rate and/or degree of this varies (e.g., 13-79% degradation in 21-days).

Persistence of a suite of representative petroleum hydrocarbons for base oils was characterized on the basis of empirical and/or modelled data. Model results and the weighing of information are reported in the technical document on petroleum substance persistence and bioaccumulation (Environment Canada 2014) and results are summarized in ECCC (2018a).

Empirical and modelled atmospheric half-lives for most representative structures of base oils are less than 2 days, indicating that most base oil components are unlikely to persist in air (Environment Canada 2014). However, some four- to six-ring aromatic components have the potential to remain in the atmosphere for longer periods, allowing for their possible transport long distances and to remote regions as a result of sorption to particulate matter in the atmosphere (Environment Canada 2014).

On the basis of their chemical structure, components of base oils are not expected to hydrolyze under environmental conditions (Lyman et al. 1990; Environment Canada 2014).

On the basis of modelled biodegradation results for representative structures in water, soil and sediment, the following components of base oils are expected to have half-lives greater than 6 months in water and soils and greater than 1 year in sediments: C<sub>30</sub> isoalkanes, C<sub>50</sub> one-ring cycloalkanes, C<sub>15</sub>–C<sub>50</sub> two-ring cycloalkanes, C<sub>18</sub>–C<sub>22</sub> polycycloalkanes, C<sub>30</sub>–C<sub>50</sub> and some C<sub>20</sub> one-ring aromatics, C<sub>15</sub>–C<sub>20</sub> cycloalkane monoaromatics, C<sub>15</sub>–C<sub>50</sub> two-ring aromatics, C<sub>30</sub>–C<sub>50</sub> three-ring aromatics, C<sub>16</sub>–C<sub>20</sub> four-ring aromatics, C<sub>20</sub>–C<sub>30</sub> five-ring aromatics and C<sub>22</sub> six-ring aromatics (Environment Canada 2014). These substances therefore have high potential to persist in these media. The C<sub>30</sub> one-ring cycloalkanes and C<sub>15</sub> one-ring aromatics have half-lives greater than a year in sediments, and have high potential to persist in sediment.

## 6.2.2 Potential for bioaccumulation

Bioaccumulation potential for a suite of representative petroleum hydrocarbons for base oils was characterized on the basis of empirical and/or modelled data. Bioaccumulation factors (BAFs) are the preferred metric for assessing the bioaccumulation potential of substances, as the bioconcentration factor (BCF) may not adequately account for the bioaccumulation potential of substances via the diet, which predominates for substances with log Kow greater than approximately 4.5 (Arnot and Gobas 2003).

In addition to fish BCF and BAF data, bioaccumulation data for aquatic invertebrate species were also considered. Biota-sediment/soil accumulation factors (BSAFs), trophic magnification factors and biomagnification factors were also considered in characterizing bioaccumulation potential.

Empirical and modelled bioaccumulation data for petroleum hydrocarbons can be found in Environment Canada (2014).

Overall, there is consistent empirical and predicted evidence to suggest that the following components have the potential for high bioaccumulation with BAF/BCF values greater than 5000: C<sub>15</sub> isoalkanes, C<sub>15</sub> one-ring cycloalkanes, C<sub>15</sub> two-ring cycloalkanes, C<sub>22</sub> polycycloalkanes, C<sub>15</sub> one-ring aromatics, C<sub>15</sub>–C<sub>20</sub> cycloalkane monoaromatics, C<sub>20</sub> cycloalkane diaromatics, C<sub>20</sub> three-ring aromatics, C<sub>16</sub>–C<sub>20</sub> four-ring aromatics, C<sub>20</sub> five-ring aromatics, and C<sub>22</sub> six-ring aromatics. These components are highly lipophilic and are associated with a slow rate of metabolism in certain organisms such that the rate of uptake greatly exceeds the total elimination rate. However, most of these components are not expected to biomagnify (relative to their concentration in the diet) in aquatic or terrestrial food webs, largely because the combination of metabolism (albeit slow), growth dilution, and low dietary assimilation efficiency of these components allows the elimination rate to exceed the uptake rate when exposure occurs from the diet only (Environment Canada 2014). In addition, fish and other vertebrates have a higher capacity to metabolize aromatic components than do invertebrates, which decreases the potential for trophic transfer of these components. However, one study (Harris et al. 2011) suggests that some higher alkylated three- and four-ring PAHs may biomagnify. While BSAFs were only found for some PAHs (Environment Canada 2014), it is possible that BSAFs will be greater than one for invertebrates, given that they do not have the same metabolic competency as fish. BSAFs will likely decrease beyond C<sub>22</sub> due to reduced bioavailability of the higher boiling point fractions (Muijs and Jonker 2010); however, for a given PAH, slight increases in BSAFs for invertebrates were noted with increasing alkylation of the parent PAH, suggesting some degree of bioaccumulation in invertebrates (Harris et al. 2011).

## 7. Potential to cause ecological harm

### 7.1 Ecological effects assessment

#### 7.1.1 Water

Empirical aquatic toxicity data for the base oils are presented ECCC (2018a) and summarized in Table 7.1.

Empirical toxicity data are available for two species of fish, three invertebrate species and one algal species, with endpoints reported as median effect (lethality or other effect) or no-observed-effect levels. Due to the very low water solubility of base oils, testing was conducted using water accommodated fractions (WAFs) of the oil or oil in water dispersions (OWDs). WAFs are laboratory-prepared aqueous media derived from low-energy mixing of a poorly soluble test material such as a petroleum product. WAFs are essentially free of particles of bulk material, containing only the fraction that is dissolved or present as a stable dispersion or emulsion (Singer et al. 2001). Oil in OWDs is dispersed as small particles of bulk material uniformly distributed in the water and generally require either high energy or a chemical agent to disperse the oil in the water (CONCAWE 1993). WAFs are the preferred metric as they better represent the oil that is dissolved in the water.

Exposure concentrations were not measured in the test solutions and results are reported in terms of the base oil loading rate<sup>11</sup> rather than concentrations (e.g., a median lethal loading (LL<sub>50</sub>) rather than a median lethal concentration (LC<sub>50</sub>)). This approach is common in testing with poorly water soluble UVCBs such as petroleum products.

Table 7.1 provides endpoint ranges for acute and chronic testing with fish, aquatic invertebrates and algae. All median effect values (I/E/LL<sub>50</sub>) are unbounded, indicating that 50% effect levels were not observed in test solutions up to the maximum 100 to 10 000 mg/L loading rates tested. As well, most no-observed-effect loading rates (NOELR) are between 100 and 10 000 mg/L, suggesting very low aquatic toxicity for base oils.

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<sup>11</sup> A loading rate is the amount of petroleum substance added to the exposure solution to generate a WAF or OWD and is reported in mg/L. When used to describe an effect endpoint, the loading rate is the amount of petroleum substance added to generate a WAF/OWD that results in the effect reported; e.g., the lethal loading rate 50 (LL<sub>50</sub>) is the amount of petroleum substance needed to generate a WAF/OWD that is lethal to 50% of the test organisms. A loading rate is not a direct measure of the concentration of the petroleum components dissolved in the exposure solution.

**Table 7.1 Summary of aquatic toxicity data for OWD or WAF testing with base oils (CONCAWE 1997; API 2011a)**

Type of testing (endpoint)	Number of studies	Range of values (mg/L)
Acute fish – 96-h LL <sub>50</sub> (lethality)	12	>100 – >5000
Acute fish – 96-h NOELR (lethality)	6	100 – 1000
Acute water flea – 48-h EL <sub>50</sub> (immobilization)	2	>10 000
Acute water flea – 48-h NOELR (immobilization)	2	10 000
Acute amphipod – 96-h EL <sub>50</sub>	2	>10 000
Acute amphipod – 96-h NOELR	2	10 000
Chronic fish – 7-d NOELR (survival, growth)	3	1000 – 5000
Chronic water flea – 7-d NOELR (survival, reproduction, growth)	5	550 – 5000
Chronic water flea – 21-d EL <sub>50</sub> (survival, reproduction, growth)	6	>1000
Chronic water flea – 21-d NOELR (survival, reproduction, growth)	6	1000
Chronic green alga – 96-h IL <sub>50</sub> (inhibition)	3	>1000

Abbreviations: EL<sub>50</sub>, loading rate of test substance resulting in a specified effect (e.g., immobilization, growth) in 50% of the test species exposed to the OWD or WAF; IL<sub>50</sub>, median inhibition loading rate, loading rate at which 50% algal inhibition occurs as measured by growth rate or biomass (area under growth curve) of cells exposed to the OWD or WAF; LL<sub>50</sub>, median lethal loading rate, loading rate of the test substance that results in 50% mortality in a population of test organisms exposed to the OWD or WAF; NOELR, no observed effect loading rate; OWD, oil-in-water dispersion; WAF, water-accommodated fraction, aqueous medium containing only the fraction of the petroleum substance that is dissolved or present as a stable dispersion or emulsion.

The toxicity data are for individual CAS RNs, but no information was provided on the composition of the specific CAS RN samples tested. As noted previously, the CAS RN and its description are insufficient to determine the degree and severity of processing, and thus the final composition of any specific sample of the CAS RN, especially in terms of its aromatic content, is variable as demonstrated in Tables B.1 and B.2 in Appendix B. Aromatic components contribute the greatest to toxicity of petroleum fractions, especially for heavier fractions such as base oils, due to their greater solubility in water compared to aliphatic components of equivalent carbon number (Verbruggen et al. 2008, Cermak et al. 2013, Gustafson et al. 1997).

For many base oil CAS RNs, the aromatic content can range from very low to up to approximately 45 wt% aromatics (see Section 2). Petroleum substances with a carbon range comparable to base oils and a significant aromatic content (i.e., Fuel oil no. 6; C<sub>20</sub> – C<sub>50</sub>, 29-55% aromatics) are significantly more toxic (EC<sub>50</sub> of 4.1 mg/L (Environment Canada, Health Canada 2014)) than what has been observed with the tested base oils reported in Table 7.1. Similarly, modelled results indicate greater toxicity for base oils with higher aromatic content (e.g., acute LL<sub>50</sub> less than 1 mg/L for some species for

base oils with an aromatic content of 35% or greater; see Table 7.2 below and ECCC (2018a)). There is uncertainty in the aromatic content of the base oils tested in Table 7.1 as this information was not reported; however, the higher toxicity observed with petroleum substances such as Fuel oil no. 6 and higher modelled toxicity for higher aromatic base oils suggests that the tested base oils had lower aromatic contents.

The industry association, CONservation of Clean Air and Water in Europe (CONCAWE) has developed an aquatic toxicity model specifically for petroleum hydrocarbon mixtures, called PETROTOX (2012). The basis of this model is chemical action via non-polar narcosis for acute toxicity, the primary mode of action for all petroleum hydrocarbons (CONCAWE 1996), and accounts for additive effects within the petroleum mixture by using a toxic unit approach. PETROTOX estimates petroleum hydrocarbon toxicity for substances in the C<sub>4</sub>–C<sub>41</sub> range that are dissolved in the water fraction.<sup>12</sup> Substances smaller than C<sub>4</sub> are considered too volatile to impart significant aquatic toxicity, while those larger than C<sub>41</sub> are considered too hydrophobic and immobile to impart significant aquatic toxicity. The model can also estimate a chronic no-observable-effect loading rate (NOELR) by utilizing an average acute-to-chronic ratio (ACR). The model generates toxicity estimates in terms of loading rates rather than concentrations (e.g., a median lethal loading (LL<sub>50</sub>) rather than a median lethal concentration (LC<sub>50</sub>)), thereby accounting for the poor solubility of petroleum substances in water.

The major sources of release of base oils to the aquatic environment occur following secondary wastewater treatment (see section 7.2). As base oils are UVCBs consisting of hundreds to thousands of individual components, each with its own physical and chemical properties that impact its removal during wastewater treatment, such treatment will result in the differential removal of components of base oils. Thus, the relative proportion of individual components in the base oil released following wastewater treatment is different from that of the base oil that originally entered the treatment system. In order to determine the toxicity of the modified base oil released in effluent following wastewater treatment, the removal of hydrocarbons during wastewater treatment and, thus, the composition of the post-wastewater treatment base oil, were estimated. The estimation of the removal of hydrocarbons utilizes the library of hydrocarbon representative structures, their physical-chemical properties, and the mapping scheme of hydrocarbons to certain hydrocarbon blocks found within the PETROTOX v3.06 model (PETROTOX 2012). The percent removal of hydrocarbon blocks during wastewater treatment is estimated on the basis of the removal of individual hydrocarbon representative structures using a wastewater treatment model (SimpleTreat version 3.1 (SimpleTreat 2003)); the model estimates removal of substances via sorption, volatilization and degradation but does not provide information on degradation products. From this, the new relative proportion of components in the base oil following wastewater treatment was estimated on the basis of the hydrocarbon

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<sup>12</sup> PETROTOX uses its own library of petroleum hydrocarbons and their associated physical and chemical properties. These properties may differ from those given for the same representative structures ECCC (2018).

blocks, and PETROTOX was used to estimate the acute toxicity and chronic NOELR for eight aquatic species utilizing the post-wastewater treatment composition of the released base oil. PETROTOX v.3.06 uses an ACR of 3.83 for determining the NOELR; however, more recent analysis has adjusted the average ACR to 5.22 (McGrath et al. 2018). Therefore, the ACR in PETROTOX v.3.06 was manually adjusted to 5.22 to account for this new analysis when calculating chronic values.

The acute lethal loading rate and NOELR were determined for a number of base oils ranging from 10 to 45% aromatics. The percent aromatics refer to that of the base oil prior to wastewater treatment. These data are reported in ECCC (2018a) and are summarized here in Table 7.2, Table 7.3 and Table Table 7.4 for base oils with different initial compositions for the most sensitive species, *Rhepoxyinus abronius*. PETROTOX was run using the low-resolution mode and two blocks; one up to C<sub>30</sub> and one above C<sub>30</sub>, with the low and high-end of the carbon range used dependent on the base oil considered. Compositions, in terms of carbon range, were determined on the basis of use and volume data reported pursuant to a CEPA section 71 survey (Environment Canada 2012), and are described in the Ecological Exposure section (section 7.2). The lowest NOELR for a given composition was used as the critical toxicity value (CTV).

**Table 7.2. Acute and chronic toxicity to *Rhepoxyinus abronius* of a heavy (C<sub>20</sub>-C<sub>50</sub>) base oil before and following secondary wastewater treatment<sup>1</sup>**

Percentage aromatics before wastewater treatment (wt%)	Acute LL <sub>50</sub> (mg/L) before wastewater treatment	Acute LL <sub>50</sub> (mg/L) after wastewater treatment	Chronic no-effect loading rate (mg/L) after wastewater treatment
45	0.15	0.070	0.0061
35	0.26	0.099	0.012
20	ND <sup>2</sup>	0.71	0.025
10	ND	>1000	0.075

<sup>1</sup> using a pre-wastewater treatment composition of 33 wt% below C<sub>30</sub>

<sup>2</sup> ND—not determined

**Table 7.3. Acute and chronic toxicity to *Rhepoxyinus abronius* of base oils (mix of both light and heavy base oils (C<sub>15</sub>-C<sub>50</sub>)) following secondary wastewater treatment<sup>1</sup>**

Percentage aromatics before wastewater treatment (wt%)	Acute LL <sub>50</sub> (mg/L) after wastewater treatment	Chronic no-effect loading rate (mg/L) after wastewater treatment
45	0.097	0.0080
35	0.15	0.011
30	0.20	0.013
25	0.29	0.017



20	0.49	0.023
10	5.57	0.065

<sup>1</sup> using a pre-wastewater treatment composition of 43 wt% between C<sub>15</sub> and C<sub>30</sub> and 57 wt% greater than C<sub>30</sub>

**Table 7.4. Acute and chronic toxicity to *Rhepoxyinus abronius* of a light and a 50:50 light:heavy base oil, both with 45 wt% aromatic content before wastewater treatment**

Base oil	Acute LL <sub>50</sub> (mg/L) after wastewater treatment	Chronic no-effect loading rate (mg/L) after wastewater treatment
Light (C <sub>15</sub> -C <sub>30</sub> )	0.045	0.0056
50:50 light:heavy (C <sub>15</sub> -C <sub>50</sub> ) <sup>1</sup>	0.064	0.0067

<sup>1</sup> using a pre-wastewater treatment composition of 66 wt% between C<sub>15</sub> and C<sub>30</sub> and 34 wt% greater than C<sub>30</sub>

For comparison, the acute toxicity of a base oil at two different aromatic contents was determined both prior to and after wastewater treatment (Table 7.2). The change in the relative proportion of individual components following wastewater removal indicated that the less toxic aliphatic components of base oils were more effectively removed than the more toxic aromatic components. This results in a proportional increase in the toxicity of the base oil following wastewater removal (as noted in Table 7.2); however, the overall release of base oils to effluent is greatly reduced (over 90%) during wastewater treatment, resulting in much lower exposure concentrations and absolute toxicity in the treated effluent.

### 7.1.2 Sediment

Only one study on the toxicity of a base oil to sediment-dwelling organisms was found. In this study, the toxicity of a high viscosity hydraulic oil (predominantly C<sub>19</sub>-C<sub>40</sub>) to *Vibrio fischeri*, *Corophium volutator*, and *Echinocardium cordatum* was determined. Sediment toxicity ranged from 1064 mg/kg dry weight (dw) (*E. cordatum*) to 9138 mg/kg dw (*C. volutator*) (Brils et al. 2002). These results indicate that the base oil tested has low toxicity to benthic organisms. No information was provided on the aromatic content of the hydraulic oil.

Toxicity studies on synthetic oil-based drilling mud fluids towards various sediment organisms can be used as read across for low aromatic content base oils. The synthetic drilling mud fluids tested contain high concentrations of *n*-alkanes and/or isoalkanes, similar to low aromatic base oils, although generally of lower carbon number than those found in base oils. The lower carbon number aliphatics in the drilling mud fluids are expected to have greater bioavailability, and thus toxicity, such that these studies are a conservative estimate of the toxicity of low aromatic base oils. Studies by Hamoutene et al. (2004) and Payne et al. (1995, 2001) indicate low toxicity to sediment organisms. The studies, which are summarized in ECCO (2018a), indicate that low aromatic base oils will also have low toxicity.

No sediment toxicity data were found for base oils confirmed to be high aromatic. Studies following a large spill of fuel oil no. 6 in marine water indicate the potential of heavy petroleum substances to adversely impact clams (e.g., initial acute lethality (Thomas 1973)), decrease population growth (Gilfillan and Vandermeulen 1978), and decrease growth (Gilfillan and Vandermeulen 1978, MacDonald and Thomas 1982). However, the data was not amenable to determining a toxicity value in terms of sediment concentrations, and no other data amenable to determining a toxicity value was identified. Therefore, no CTV for high aromatic base oils in sediment could be derived.

### **7.1.3 Soil**

The Canada-Wide Standards for Petroleum Hydrocarbons in soils (CCME 2008) provide soil standards for petroleum products based on toxicity to a variety of terrestrial organisms (invertebrates, plants). These standards are based on four fractions of total petroleum hydrocarbons (TPHs): Fraction 1 (F1) ( $C_6-C_{10}$ ), F2 (greater than  $C_{10}-C_{16}$ ), F3 (greater than  $C_{16}-C_{34}$ ) and F4 (greater than  $C_{34}$ ), and assume a ratio of 20% aromatics to 80% aliphatics. F3 and F4 encompass the carbon range of base oils. The standards are also divided into four land-use classes (agricultural, residential, commercial and industrial) and two soil types (coarse-grained and fine-grained soils) for the determination of remedial standards. The most sensitive land-use and soil type is typically agricultural coarse-grained soils. The standards for soil contact by non-human organisms for F3 and F4 are 300 and 2800 mg/kg dry weight (dw) of soil, respectively (CCME 2008).

Base oils could fall into either F3 or F4 categories, therefore, the lower value (300 mg/kg dw soil for F3) is used as a conservative terrestrial CTV.

## **7.2 Ecological exposure assessment**

On the basis of data collected from a mandatory survey under section 71 of CEPA (Environment Canada 2012), seven industrial sectors were identified as the main sources of high potential release to the environment according to use quantities. These are: wastewater treatment; pulp and paper; printing ink (and ultimately deinking); paints, coatings, adhesives and sealants; plastics; rubber (including tires); and lubricants. Of these, treatment of wastewater, lubricant plants, pulp and paper, and deinking are considered to represent the sectors with the greatest potential for releases of base oils to the environment, and thus these will be considered in the exposure assessment.

### **7.2.1 Estimation of the removal of petroleum hydrocarbon components during wastewater treatment**

The release of base oils from industrial facilities generally results in a discharge to systems that treat wastewater prior to release to the environment. The composition of the base oil remaining following wastewater treatment will differ from the original composition of the base oil. As described in section 7.1.1, the removal of petroleum hydrocarbons during wastewater treatment was estimated such that the post-wastewater treatment composition and concentration in effluent could be determined. The estimated concentration in effluent was used to estimate the predicted exposure concentration (PEC) in the receiving water.

### **7.2.2 Release from use of base oils in the treatment of wastewater**

On the basis of data collected from a mandatory survey under section 71 of CEPA (Environment Canada 2012), four heavy base oil CAS RNs were used in 2010 by wastewater treatment systems and industrial facilities for the treatment of wastewater. All these base oils are expected to end up in wastewater treatment systems, predominantly at the level of secondary treatment.

A wastewater treatment scenario is used to calculate the exposure to base oils in the receiving environment. This scenario represents the release and exposure conditions of secondary wastewater treatment with industrial input. The calculation was based on mass-balance using an estimated use quantity at a treatment system (3160 kg/y or 8.7 kg/d assuming 365 days per year operation), an estimated fraction (1.0) ending up in wastewater, an estimated wastewater treatment removal efficiency (0.92), and daily dilution water volume<sup>13</sup>. The daily dilution volume ranged from 0.1 to 5 billion L/d. This range resulted in PECs ranging from 0.14 to 6.1 µg/L. Further information on the exposure scenario and calculations is provided in ECCC (2018b).

As heavy base oils can have variable aromatic content and no information is available on the aromatic content of base oils used for wastewater treatment, the exposure estimate considers base oils with aromatic contents ranging from 10 wt% to 45 wt%.

Biosolids produced during wastewater treatment may be applied to agricultural fields as a soil amendment. The amount of base oils accumulated within the top 20 cm layer of soil over 10 consecutive years of biosolids application was determined, assuming no loss via degradation, volatilization, leaching or run-off (ECCC 2018b). As different wastewater treatment systems produce different quantities of biosolids, a range of

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<sup>13</sup> Dilution water volume = effluent discharge flow x 10 where 10 represents a 10-fold dilution for the receiving water near the discharge point of Canadian mills

PECs were determined for biosolids-amended soil. PECs ranged from 5 to 236 mg/kg dw.

### 7.2.3 Release of base oils from lubricants

The largest use quantity for base oils is in lubricants (Environment Canada 2012). The highest potential for release is considered to occur from the formulation of lubricants, therefore a scenario for the release of base oils from lubricant formulation facilities was developed (ECCC 2018b). Releases from use are considered to be lower and more dispersed. Release from formulators was estimated using a typical limit for the release of oil and grease to municipal sewers (15 mg/L which is the limit in Toronto (Toronto 2016)). Both light and heavy base oils may be used as lubricants. While many automotive lubricants are less than 10 wt% aromatics, some may contain greater than 10 wt% (API 2016). As a highly conservative estimate, the exposure estimate considered release of light (C15 to C30), heavy (C20 to C50) and a 50:50 mix of light and heavy base oils all with an aromatic content of 45 wt%.

A conservative PEC is estimated for the largest lubricant formulation facility in Canada using a conservative estimate of 1 000 000 tonne/yr as the maximum lubricant formulation quantity. The maximum aquatic PEC of base oils from lubricant formulation is estimated as 2.6 µg/L.

### 7.2.4 Release from use of base oils in the pulp and paper industry

Heavy base oils were identified as being used as processing aids by the pulp and paper industry, with a reported use quantity typically in the range of 1 000 to 10 000 kg per mill in 2010 (Environment Canada 2012).

A generic pulp and paper scenario is used to calculate the exposure to base oils in the receiving environment. This scenario represents the release and exposure conditions of the Canadian pulp and paper sector comprised of about 90 mills. The majority of mills are connected to on-site or off-site secondary wastewater treatment or equivalent which release treated wastewater to the receiving water. The calculation was based on mass-balance using an estimated use quantity at a mill (3160 kg/y or 9.0 kg/d assuming 350 days per year operation), an estimated fraction (0.5) ending up in wastewater, an estimated wastewater treatment removal efficiency (0.92), and an estimated dilution water volume. The effluent discharge flow at a mill ranged from 1 million to 2238 million L/d. This range resulted in a probabilistic distribution of PECs (Table 7.5). Further information on the exposure scenario and calculations is provided in ECCC (2018b).

**Table 7.5. Probabilistic distribution of estimated PECs for pulp and paper mills in Canada**

Percent of pulp and paper mills with releases ≤ PEC (%)	Aquatic PEC (µg/L)
0 (minimum)	0.016

Percent of pulp and paper mills with releases $\leq$ PEC (%)	Aquatic PEC ( $\mu\text{g/L}$ )
10	0.11
20	0.33
30	0.47
40	0.55
50	0.90
60	1.4
70	2.1
80	4.6
90	7.3
100 (maximum)	33

Similar to section 7.2.2, no information is available on the aromatic content of the heavy base oils used in the pulp and paper sector; thus, the exposure estimate considers base oils with aromatic contents ranging from 10 wt% to 45 wt%.

### 7.2.5 Release of base oils during deinking

A number of heavy and light base oils were identified as being used in Canada in printing inks in 2010, with a combined reported use quantity of 1 million to 10 million kilograms (Environment Canada 2012). Printing inks are expected to end up in deinking mills when printed paper products are recycled. While the quantity of base oil used in printing inks that are ultimately recycled at deinking mills in Canada could not be determined, the quantity of base oils used in printing inks reported in Environment Canada (2012) is used as an approximation. A fraction (42.5%) of this quantity is considered lost during printing operations due to volatilization.

A generic deinking scenario is used to calculate the exposure to base oils in the receiving environment. This scenario represents the release and exposure conditions of Canadian deinking mills (comprised of 20 mills). The total quantity of base oils in recycled paper sent to deinking mills is assumed to be evenly distributed among all mills. The calculation was based on mass-balance using an estimated quantity of base oils deinked at a mill (0.27 kg per tonne of pulp produced), an estimated fraction (0.04) ending up in wastewater, an estimated wastewater treatment removal efficiency (0.92), and an estimated dilution water volume. The effluent discharge flow at a mill ranged from 0.006 to 7 million L per tonne of pulp produced. This range resulted in a probabilistic distribution of PECs (Table 7.6). Further information on the exposure scenario and calculations is provided in ECCC (2018b).

**Table 7.6. Probabilistic distribution of estimated PECs for deinking mills in Canada**

Percent of deinking mills with releases $\leq$ PEC (%)	Aquatic PEC ( $\mu\text{g/L}$ )
0 (minimum)	0.013
10	0.043
20	0.10
30	0.62
40	1.2
50	1.5
60	2.9
70	4.1
80	6.2
90	11
100 (maximum)	15

Light (C<sub>15</sub>-C<sub>30</sub>) base oils accounted for 15% of the quantity, with the remainder being heavy (C<sub>20</sub>-C<sub>50</sub>) base oils. On the basis of these proportions, it is expected that base oil components in inks will range from C<sub>15</sub>-C<sub>50</sub>, with approximately 43 wt% of components falling between C<sub>15</sub> and C<sub>30</sub> and 57 wt% above C<sub>30</sub>. The range of aromatic content in inks can vary widely from less than 1% (Personal communication, email from hubergroup Canada Ltd. to Environment and Climate Change Canada, 26 June 2017) to at least 35 wt% (Calumet 2018a,b). As base oils can have variable aromatic content and no information is available on the maximum aromatic content of base oils used in inks, base oils with aromatic contents ranging from 10 wt% to 45 wt % were used in the exposure estimation. Further information on the exposure scenario and calculations is provided in ECCC (2018b).

### 7.3 Characterization of ecological risk

The approach taken in this ecological screening assessment was to examine the available scientific information and develop conclusions using a weight-of-evidence approach and precaution. Information was gathered to determine the potential for base oils to cause harm in the Canadian environment. Lines of evidence considered include those evaluated in this assessment that supports the characterization of ecological risk in the Canadian environment.

#### 7.3.1 Risk quotient analysis

Risk quotient analyses were performed by comparing the estimates of exposure (PECs; see section 7.2) with ecotoxicity information (predicted no-effect concentrations (PNECs)) to inform whether there is potential for ecological harm in Canada. Risk quotients (RQs) were calculated by dividing the PEC by the PNEC for relevant

environmental compartments and associated exposure scenarios. Aquatic PNECs were derived for each base oil composition following wastewater treatment as the NOELR for the most sensitive species determined by PETROTOX (Table 7.7). As this is a chronic NOELR for the most sensitive species, no assessment factor was applied to convert the NOELR to the PNEC. For terrestrial scenarios, the lowest of the two applicable Canada-wide standard for eco-soil contact in coarse-grained soil (i.e., 300 mg/kg dw for Fraction 3) (CCME 2008) was used as the PNEC (Table 7.7). Table 7.7 presents RQs for base oils.

**Table 7.7. Summary of risk quotients obtained for different environmental compartments and exposure scenarios for base oils**

Exposure scenario (compartment)	PEC range	PNEC	RQ range	Percentage of locations with RQ of 1 or greater
Wastewater treatment (water)	0.14 to 6.1 µg/L	6.1 to 75 <sup>a</sup> µg/L	0.002 to 1.0	5 or less
Wastewater treatment (Biosolids application to soil) <sup>b</sup>	5 to 236 mg/kg dw	300 mg/kg <sup>c</sup> dw	0.02 to 0.79	0
Lubricant formulation (water)	2.6 µg/L	5.6 to 6.7 <sup>d</sup> µg/L	0.39 to 0.46	0
Pulp and paper (water)	0.016 to 33 µg/L	6.1 to 75 <sup>a</sup> µg/L	0.0002 to 5.4	Less than 20 for 45 wt% aromatics; less than 10 for 20 and 35 wt% aromatics
Paper deinking (water)	0.013 to 15 µg/L	8 to 65 <sup>a</sup> µg/L	0.0002 to 1.9	Less than 20 for 45 wt% aromatics; 10 for 35 wt% aromatics; none for 20 wt% aromatics or lower

<sup>a</sup> For base oils ranging from 10 to 45 wt% aromatics

<sup>b</sup> Soil amendment of biosolids from municipal wastewater treatment

<sup>c</sup> From the Canada-wide Standard for petroleum hydrocarbons for Fraction 3 (greater than C<sub>16</sub> to C<sub>34</sub>)

<sup>d</sup> Range for light, heavy, and 50:50 light:heavy 45 wt% aromatic base oils

For the scenario where base oils are released during their use in the treatment of wastewater, a maximum RQ of 1.0 was determined for water for the smallest

wastewater treatment system considered in the PEC determination, which accounted for 5% or less of locations, but only if 45 wt% aromatic base oils are used. In addition, the application of biosolids produced during wastewater treatment to soil was considered. PECs were compared to the Canada-wide Standards for Petroleum Hydrocarbons in Soils (CCME 2008) resulting in RQs below one (Table 7.7).

For the scenario where base oils are released during the formulation of lubricants, all calculated PECs are less than the lowest PNEC, resulting in RQs less than one.

A distribution of PECs and PNECs is presented in Table 7.7 for the pulp and paper scenario. RQs greater than one were determined for less than 20% of locations for base oils if 45 wt% aromatic content is assumed, and for less than 10% of locations for base oils with 20 to 35 wt% aromatics.

Similarly, RQs greater than one were determined for less than 20% of locations for base oils with 45 wt% aromatic content, and 10% of locations assuming 35 wt% aromatics for the paper deinking scenario (Table 7.7).

### 7.3.2 Consideration of the lines of evidence

The aromatic content for base oils varies depending upon the source of the crude oil, the type and number of processing steps, and the severity of each processing step the base oil has undergone in its preparation. In general, unrefined or mildly refined base oils have higher proportions of aromatic compounds (up to approximately 45 wt%) than more highly refined base oils, for which the aromatic content is commonly less than 10 wt%. CAS RN descriptions do not describe the degree and severity of processing that a specific sample of base oil has undergone, and thus the aromatic content within a specific CAS RN may vary greatly (as demonstrated in Table B.2, Appendix B). Aromatic components have been shown to contribute the greatest to the toxicity of petroleum substances, and especially for heavier substances such as base oils, due to their greater solubility in water compared to aliphatic components (Verbruggen et al. 2008, Cermak et al. 2013, Gustafson et al. 1997). Because of this, the ecological risk of base oils was determined for a range of aromatic contents (i.e., 10 to 45 wt%) and not for any specific CAS RN.

Modelled data for base oils with low aromatic contents (i.e., 10 wt% or less) have negligible toxicity ( $LL_{50}$ s greater than 1000 mg/L), in concordance with what has been observed in empirical tests for samples with unknown aromatic content. However, modelled loading rates with higher aromatic base oils indicate that higher aromatic base oils may be more hazardous to aquatic organisms, in concordance with empirical toxicity tests with a high-aromatic petroleum substance (heavy fuel oil) with a similar carbon range to base oils.

The toxicity of higher aromatic content base oils was estimated using PETROTOX, a model developed to estimate the toxicity of petroleum substances. This model has



been validated for acute estimates for a number of different petroleum substances by Redman et al. (2012). A comparison conducted by ECCC between the modelled NOELR and empirical chronic data for two gas oils (Swigert et al. 2014), which have a lower carbon range than base oils, determined that the modelled values were similar to or more conservative than the empirical data (i.e., modelled toxicity values were lower). Therefore, in the absence of acceptable empirical data on the toxicity of base oils with varying aromatic contents, values modelled with PETROTOX for base oils are considered within the assessment with moderate confidence.

The major sources of release of base oils to the environment considered within this assessment are to water following the treatment of wastewater containing base oils. The removal rate for base oils is estimated to be 92% for secondary treatment (ECCC 2018b), which is within the range of measured oil and grease removal (52-98%) reported in CWWA (2001). The approach used to determine the removal of base oils from wastewater also allows for the estimation of the change in proportion of defined carbon ranges of aliphatics and aromatics in base oils, and thus an estimation of its toxicity utilizing PETROTOX (2012). Wastewater treatment preferentially removes aliphatic components compared to aromatics, resulting in an increase in the relative proportion of aromatics in the post-treatment base oil and an increase in its relative hazard (i.e., toxicity would be observed at lower loading rates). However, the high rate of removal of base oils from wastewater during secondary treatment results in a greater than 10-fold decrease in the concentration of base oils in the effluent compared to untreated wastewater, thus reducing the risk compared to untreated effluent.

Empirical and modelled data indicate that many base oil components have the potential to persist for long periods in water, soil and/or sediment. Empirical and modelled data indicate that many base oil components in the C<sub>15</sub> to C<sub>22</sub> range are highly bioaccumulative to fish and/or invertebrates; however, there is little evidence for biomagnification or trophic transfer of most of the individual hydrocarbon components within foodwebs

Properties of base oils indicate that organisms may be exposed to base oils via sediments. High partition coefficients for all base oil components indicate that most components, when released to water, will partition to sediments. The industrial uses of base oils considered in the exposure scenarios are assumed to result in continuous release to the aquatic environment via wastewater effluent, resulting in a continuous exposure. In addition, components of base oils, such as many PAHs and other aromatic components that are highly persistent may accumulate over time in sediments, resulting in higher exposure concentrations. A sediment toxicity study for one base oil suggests low risk to sediment organisms; however there was no information on the aromatic content of the base oil tested. Sediment studies on aliphatic petroleum substances support a determination of low toxicity to sediment organisms for low aromatic base oils; however, it is uncertain how applicable the base oil toxicity test results are to high aromatic base oils.

Predicted environmental concentrations for four high-use scenarios were estimated for base oils released to wastewater and subsequently treated in secondary wastewater treatment systems before release to the aquatic environment.

As described in Table 7.7, in the scenario where base oils are used in the treatment of wastewater, an RQ of one was determined only when considering base oils with the highest aromatic content (45 wt%) and only for the smallest wastewater treatment system considered. The PECs determined for smaller wastewater systems are considered to be conservative as the annual use quantity used in the PEC calculation may be an overestimate as smaller systems with lower wastewater volumes are expected to use less treatment chemicals. Use of a more realistic use quantity would result in an RQ lower than one. In addition, it is unlikely (though uncertain) that base oils with such high aromatic content are used in the treatment of wastewater. Therefore, the risk of harm to aquatic organisms from base oils used in the treatment of wastewater is expected to be low.

Biosolids produced during wastewater treatment can be applied to soil; therefore, soil PECs were determined for this scenario. These PECs are conservative as they assumed no loss of base oil due to any fate process (e.g., biodegradation and run off) over 10 years. These conservative PECs, when compared to the Canada-wide Standards for Petroleum Hydrocarbons in Soils (CCME 2008) result in RQs below one (Table 7.7). Therefore, the risk of harm to soil organisms from the application of biosolids containing base oils is considered to be low.

In the scenario considering the use of base oils by the pulp and paper industry, RQs greater than one were determined for base oils with 25 wt% or greater aromatic content for a low number of sites representing smaller mills. The highest RQ (5.4) was determined for a base oil with 45 wt% aromatics at the smallest mill; the RQ for 45 wt% aromatic base oils reduces to 1.2 at the 90<sup>th</sup> percentile of PECs for mills and is less than one at the 80<sup>th</sup> percentile. Therefore, less than 20% of locations had an RQ greater than one when considering base oils with the highest aromatic content (45 wt%). The number of sites which had an RQ greater than one dropped to less than 10% of sites when base oils with and aromatic content of 20 (RQs of 1.3 or less) to 35 wt% (RQs of 2.8 or less) are considered (Table 7.7). The PECs were determined using an annual use quantity based on the mid-point value of the annual quantity range, which overestimates the actual use quantity for smaller mills. Therefore, aquatic PECs determined for smaller mills (i.e., those in the upper percentiles of the PEC distribution) are considered to be overestimations, resulting in higher RQs. Thus, while RQs exceeding one are indicated for some smaller mills, the risk of harm to aquatic organisms is considered to be low because of the conservative base oil quantity estimate. In addition, it is uncertain if base oils with aromatic contents as high as 45 wt% are used in pulp and paper applications.

Similarly, in the deinking scenario RQs greater than one (maximum 1.9) were determined for less than 20% of locations for base oils with 45 wt% aromatic content, and 10% or less of locations for base oils with 30 to 35 wt% aromatics; no impact is

expected when the aromatic content is 25 wt% or less (Table 7.7). The range of aromatic content in inks can vary widely from less than 1% (Personal communication, email from hubergroup Canada Ltd. to Environment and Climate Change Canada, 26 June 2017) to at least 35 wt% (Calumet c2018a,b. While there is uncertainty as to the maximum possible aromatic content of base oils used in inks, the mixed papers undergoing deinking would contain a range of high and low aromatic base oils and, thus, the total aromatic content of base oils in the wastewater will be lower than 45 wt%. A conservative estimate of aromatic content, based on the mid-point (28 wt%) of the aromatic content range of 10 to 45 wt% rather than for the range 1 to 35%, is considered as an approximation of the total aromatic content of base oils in wastewater. As this is a mid-point value, confidence in this value is moderate. Using this conservative estimate for the aromatic content of base oils in effluent, the RQ for deinking operations is less than one. There is uncertainty in this exposure scenario (described in section 7.3.3), especially in the quantity of inks containing base oils that undergo deinking in Canada. However, the scenario conservatively assumes that the total quantity of ink is used on paper (i.e., none used on non-paper items), which may result in an overestimation of the quantity of ink used on paper products that are subsequently deinked.

Considering all available lines of evidence presented in this screening assessment, base oils have a low potential to cause ecological harm in Canada.

### **7.3.3 Sensitivity of conclusion to key uncertainties**

The composition of base oils as defined by the proportions of aliphatic and aromatic chemical classes, varies greatly depending on the degree and severity of processing, such that the aromatic content can vary greatly even within a substance defined by one CAS RN. Aromatic content is an important determinant of toxicity for base oils. To address the uncertainty in toxicity data, the toxicity of base oils ranging from 10 to 45 wt% aromatics was modelled using PETROTOX (2012). However, the interpretation of the comparison of these toxicity data with PECs developed for various exposure scenarios is difficult, as it is not known whether low or high aromatic base oils are used in the application or the degree to which the aromatic content of the base oil may vary for a given application. As limited risk was identified even for higher aromatic base oils, this uncertainty is considered to have a low impact on the conclusion.

There is uncertainty in the proportion of base oil-containing products used at various points in the pulp and paper process. The emission factor of 50% used in the determination of the PECs for the pulp and paper scenario is considered to be a conservative value. Refinement of the emission factor through additional information would result in lower PECs. Therefore, refinement of this scenario would have a low impact on the conclusion.

Biosolids from pulp and paper mills may also be applied to land. However, there were insufficient data on the production of biosolids at on-site wastewater treatment facilities at pulp and paper mills to calculate a PEC for a soil scenario. Development of this

scenario could have an influence on the conclusion with the direction of the risk being unknown.

The Canada-wide Standards for Petroleum Hydrocarbons in Soil (CCME 2008) assumes an aromatic to aliphatic ratio of 20:80. The relevancy of these standards to petroleum substances that deviate from this ratio is uncertain. As aromatic hydrocarbons have been found to be the primary contributors to toxicity in earthworms (Cermak et al. 2013), the standards are expected to be protective for base oils with aromatic contents lower than 20%. For base oils with a higher aromatic content the standards may be less protective. However, given that RQs were 0.79 or less based solely on the standard for Fraction 3 (the more conservative value; greater than C<sub>16</sub> to C<sub>34</sub>) which represents only a portion of the base oil carbon range, this uncertainty is not expected to influence the conclusion.

There are a number of uncertainties in the exposure assessment for base oils released during deinking operations. One uncertainty is the amount of base oil-containing inks in paper that is deinked in Canada. The quantity used is based on data collected on only 22 of the 39 base oils considered within this assessment; this data identified that 6 of the 22 CAS RNs were used in inks. It is not known if any of the remaining 17 CAS RNs may also be used in inks and at what quantities. The quantity used in the PEC derivation represents the total amount of base oil-containing inks reported by printing ink suppliers as being sold to printers. Import and export of paper products, paper for recycling, and bulk printing inks might result in a higher or lower PEC, depending on whether the balance is greatest for import or export, respectively. In addition, a proportion of the base oil used in both heatset and non-heatset ink is unknown and is assumed to be 50% for each in the exposure assessment. A greater loss of base oil due to evaporation during heatsetting is expected; thus, greater use of base oils in this type of ink would result in lower release; conversely, greater use of base oils in non-heatset ink would result in higher release. Therefore, refinement of this scenario for any of the above uncertainties could have influence on the conclusion, with the direction of this risk being unknown.

Base oils released to water are expected to partition to sediments and may accumulate over time. The one sediment test conducted on a base oil did not provide information on the aromatic content of the base oil tested, thus there is uncertainty in the applicability of the results across the entire range of possible aromatic contents. While release of low aromatic base oils are considered to pose a low risk to sediment organisms, there is uncertainty in degree of risk from high aromatic base oils due to the uncertainty in the applicability of the available data to these base oils. Additional information on the fate and effects of higher aromatic base oils in sediments near effluent discharge points could provide clarity on the risk of high aromatic base oils.

## **8. Potential to cause harm to human health**

### **8.1 Exposure assessment**

The focus of the exposure assessment is to examine the potential for general population exposure to base oils and their components of concern, in particular PAHs. Exposure is characterized for the environmental media via wastewater, as well as base oil production, transportation, and industrial use. It is also characterized for its use in products available to consumers, as well as its potential use as an extender oil for the manufacture of rubber and soft plastics.

#### **8.1.1 Environmental media**

Base oils are used in a number of industrial applications, such as in the pulp and paper industry as well as for municipal wastewater treatment. Used base oils in the industrial water stream are subject to wastewater treatment at the industrial facility, and any residual base oils which may be released along post-treatment water into streams and rivers and lakes would be expected to go through municipal waste water treatment.

Previous screening assessments reports of petroleum substances with low volatility (gas oils and heavy fuel oils) did not identify exposures to the general population from unintentional releases (i.e. leaks and spills) of these substances during production, transportation between facilities, and industrial on-site use (Environment Canada, Health Canada 2011a, 2011b, 2013a, 2013b). Given their low volatility, the site- and industry-restricted uses of base oils are similarly not expected to contribute to general population exposures, aside from the aforementioned releases to wastewater.

#### **8.1.2 Base oil products available to consumers**

Base oils are ingredients in products available to consumers from various product categories as determined by standard Health Canada search strategies, a contractor report, internal Health Canada product lists, and from submissions in response to section 71 surveys (Environment Canada 2008, 2011).

Base oils are listed as ingredients in products available to consumers in the automotive care, lubricant, paints and coatings, and adhesives and sealants categories. Use of these products may lead to dermal exposures to the hands or fingers. They are used with a frequency of once per month to once per year (RIVM 2006a, 2006b; Versar 1986).

Base oils are listed as ingredients in household cleaning products, primarily wood polishes, and stainless steel cleaners. These products are expected to lead to dermal exposure to base oils on the hands and fingers and are used with frequencies between once per week to once per months. (RIVM 2006a, 2006b; Versar 1986)

Due to their low vapor pressures (Sec. 3), no inhalation exposures to base oils from products available to consumers are expected.

#### **8.1.2.1 PAH compositional analysis of base oils products available to consumers**

Polycyclic aromatic hydrocarbons are naturally-occurring components of crude oil that co-migrate with normal and branched alkanes in the initial stages of refining (i.e., during atmospheric and vacuum distillation). Base oil streams can therefore contain PAHs. The proportion of PAHs in base oils varies depending on the source of crude oil and severity of refining steps. The presence of PAHs in base oils can be essentially eliminated with the most severe refining processes (Parkash 2010). The PAHs are considered to be the components of greatest health concern for base oils.

To determine the PAH content of base oil products available to consumers in Canada, chemical analyses of PAH in products (listed in Table C.4 of Appendix C) that contain 25-100% base oil substances were conducted by Health Canada (Health Canada 2017). Products available to consumers which contain base oils may also contain other petroleum based ingredients in addition to base oils. As a conservative assumption for assessing the health effects of the base oil components of the products, all PAHs in the whole product are considered to be attributed solely to the base oil ingredient regardless of whether there are other petroleum substances in the product.

The products available to consumers were selected for testing on the basis of having the highest base oil content, greatest use by the general population, and ready availability for purchase at national stores. Products from different manufacturers and suppliers and with home and outdoors use were included in the samples. To account for interchangeability of CAS RNs of base oils in products, whenever a product available to the consumer (such as a motor oil or stainless steel polish) containing a base oil substance CAS RN was identified, a number of similar-use products were also sampled and tested for PAHs, regardless of whether or not the same specific base oil substance was identified in these second group of products or not. This procedure leads to a functional sampling of typical products which have base oils with required physical chemical properties in their composition, regardless of the exact CAS RN assigned to the base oil. This can account for potential interchangeability of base oil CAS RNs in products. The product categories found to have base oil substances at high concentration were wood polishes, stainless steel polishes, spray and all-purpose lubricants, all-purpose cleaners, and motor oils.

Compositional analyses on 18 products available to consumers containing base oils or related petroleum substance as an ingredient were performed at a Health Canada chemical laboratory using standard solvent extraction followed by GC-MS methodology. In terms of extraction of the polycyclic aromatic compounds (PAC) components of the base oil mixture, the methodology of the composition analysis is consistent with the IP 346 method (IP 1985, 1993). The 18 products were tested for the 16 EPA standard PAHs of highest concern with regards to their health effect. These PAHs are naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene,

fluoranthene, pyrene, benz[*a*]anthracene, chrysene, benzo[*b*+*j*]fluoranthene, benzo[*k*]fluoranthene, benzo[*a*]pyrene, indeno[*1,2,3-cd*]pyrene, dibenz[*a,h*]anthracene and benzo[*ghi*]perylene.

The results of the chemical analysis showed the concentration of PAHs in all products was below the limit of quantification of the analytical method of 300 mg/kg (300 ppm or 0.03 wt%) of the individual PAHs in these 18 products. To further determine if these types of products contained the PAH of concern, fourteen additional base oil containing products were analysed via solvent extraction of PAHs from the sample followed by gas chromatography and high resolution mass spectrometry (GC/HRMS). Limits of detection of the analytical methodology for each PAH were determined to be either 0.5 or 1 parts per billion (ppb) (0.0005 or 0.001 ppm).

This high resolution chemical analysis showed the presence of residual to very low levels of PAHs in these products in amounts from the low ppb range to less than 20 ppm (0.020 % w/w). Many PAHs in the products were not detected at the limits of detection of 0.5 or 1 ppb. Tables C.1 to C.4 of Appendix C show the ranges of PAH concentration in marketplace products from the categories of household cleaning products, automotive products, and multipurpose lubricants, respectively.

Explicit concentrations of individual PAHs seen in different products are given in Table C.1 of Appendix C. [Health Canada 2017].

### **8.1.3 Base oil-containing extender oils**

Base oils can be used as extender oils in the processing and manufacture of rubber and soft plastics products. Extender oils are added to these compounds during their production to achieve an acceptable processability. Examples of products that may contain base oil extender oils include toys, grips/handles, tires, and personal apparel such as watch straps and sandals. Contact with these products may result in dermal and oral contact with residual base oil.

#### **8.1.3.1 PAH in rubber and soft plastics**

Refined base oils are used as alternatives to distillate aromatic extracts (DAE) as extender oils in the production of soft rubber and plastic products available to consumers. The potential for PAHs to be present in soft rubber and plastic products available to consumers was investigated previously in the DAE assessment (ECCC, HC 2017c). For that assessment, Health Canada undertook a compositional study of readily available soft rubber and plastic products available to consumers to determine PAH levels in products that could contain extender oils from base oil and DAE substances.

The levels of PAH species, including the EU-PAHs<sup>14</sup>, were determined for 67 product samples obtained from the Canadian marketplace (ECCC, HC 2017c). During product selection, emphasis was given to soft rubber and plastic products that are designed for use by children. The majority of products (66 of 67) contained low or non-detectable PAH levels, with 65 products below the limits of detection (LoD) of 0.04 mg/kg to 0.36 mg/kg (LoD ranged because of the PAH species being analyzed and the sample matrix). A youth sandal contained chrysene at 0.79 mg/kg. A single steering wheel cover was found to contain several PAHs at a concentration of higher than 1 mg/kg, a limit set in the EU for PAHs in rubber products that do not come in contact with children (ECCC, HC 2017c), however, retesting of seven additional steering wheel covers found them all to be below this limit, indicating the first sample was not representative of the product line and due to its higher PAH content was likely not formulated using a base oil sourced extender oil.

## 8.2 Health effects assessment

All base oils have low acute toxicity in laboratory animals. Dermal and oral LD<sub>50</sub>'s were not established in assessments of the potential for acute lethality (API 2011a), thus demonstrating low acute toxicity. None of the base oil substances tested were found to be dermal sensitizing agents (API 2011a, 2011b).

A summary of adverse effects on the basis of CAS for dermal repeated-dose, carcinogenicity, and reproductive and developmental toxicity is provided in Appendix E. Irrespective of specific CAS RN, it is apparent that toxicity increases with increasing aromatic content, namely the level of 3 to 7 ring PAHs in the base oil.

Unrefined base oils have been shown to be dermal carcinogens, and this activity is due to the presence of high levels of PAHs (Blackburn et al. 1984; McKee et al. 1989; Chasey and McKee 1993; Kane et al. 1984; Peristianis 1989). One method of characterizing the PAC content in petroleum streams is by the Institute of Petroleum method IP 346. The method relies on the ability of dimethyl sulfoxide (DMSO) to extract PACs, including PAHs, from petroleum substances. After back-extraction into cyclohexane, the solvent is removed and the DMSO-extract is weighed and expressed as a weight percent of the starting material wt (% DMSO Extractables) (CONCAWE 2016).

The US EPA previously identified PAHs that may be carcinogenic in animals and humans (US EPA 1992), ultimately listing 16 substances that became known as the priority (standard) PAHs. Some PAHs have lower potential to be carcinogenic than others and this is reflected in their potency factors. Several authors have created potency equivalency factors (PEFs) for numerous PAH compounds relative to B[a]P (i.e., estimates of their carcinogenic potency relative to that of B[a]P). Potency

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<sup>14</sup> Health Canada analysed benzo[j]fluoranthene that is known to co-elute with benzo[b]fluoranthene.



equivalency factors as developed by Nisbet and LaGoy (1992) were considered in this assessment to provide an indication of potency of the 16 standard PAHs measured in products available to consumers. These PEFs are given in Table D.1 of Appendix D.

There has been extensive experimental work examining the relationship between IP 346 DMSO extractable PAC in petroleum streams and dermal carcinogenicity. There has been shown to be a strong correlation between skin cancer incidence and DMSO extractable PAC content at 3% w/w and above, from over 130 mouse dermal carcinogenicity studies since the criteria was developed in 1994 (Chasey and McKee 1993). Of those studies, 92 samples are included in the CONCAWE categories of “other lubricant base oils”, and “highly refined base oils”. In this cohort, samples that had less than 3% DMSO extractable PAC, also showed negative results in the mouse dermal carcinogenicity studies 95% of the time (67 of 70 samples) (CONCAWE 2016).

In the IPIECA (2010) Guidance on the application of Globally Harmonized System (GHS) (UN 2011) criteria to petroleum substances it is noted that the mutagenicity and skin carcinogenic potential of petroleum substances containing PAHs is related to the level of 3-7 fused-ring PAHs. Under the GHS, base oils containing less than 3% w/w DMSO extractable as measured by IP 346 are not classified as carcinogens (EC 2008).

Using a modification of the standard Ames *Salmonella typhimurium* assay, there was a high correlation between mutagenic activity *in vitro* and carcinogenic activity *in vivo*. The modified assays were different from the standard assay in three ways. The first was the tests were performed on the DMSO extractable fraction only. The second was to use S-9 from aroclor-induced hamster liver at eight times the recommended concentration, and lastly was the exclusive use of TA98, the tester strain most responsive to complex mixtures of PAC (Chasey and McKee, 1993).

As well as unrefined base oils being potentially carcinogenic and mutagenic, Dalbey et al. (2014) showed that less refined lubricating oil base stocks (LOBs) can also produce systemic and developmental effects with repeated dermal exposures, due to its higher polycyclic aromatic compound (PAC) content (Feuston et al., 1994). Conversely, testing of highly refined low PAC LOBs (defined as having <3% w/w DMSO extractable PAC as measured by IP346) in ten 13-week dermal studies in SD rats, eight 4-week dermal studies in New Zealand white rabbits, and seven dermal developmental toxicity studies in SD rats, did not demonstrate adverse effects for systemic and developmental toxicity at doses ranging from 1000 to 2000 mg/kg/day, typically the highest dose tested (API 1986a, b, 2011a). Examination of parameters measured in the repeat dose and developmental toxicity studies (weight of reproductive organs, microscopic examination of testes and ovaries) indicated that reproductive toxicity with low PAC LOBs is also expected to be minimal, see Table E1 of Appendix E.

A critical health effect for the initial categorization of base oils was carcinogenicity, based primarily on classifications by international agencies. On the basis of the likelihood of base oils to contain polycyclic aromatic hydrocarbons (PAHs), the European Commission classifies the base oils CAS RNs as either Category 1A (“known

to have carcinogenic potential for humans”; 9 substances) or 1B (“Substances presumed to have carcinogenic potential for humans”; 29 substances). One of the base oils (CAS RN 68782-97-8) was not identified under subsection 73(1) of CEPA but was included in the assessment as it was considered a priority on the basis of human health concerns. However, the European Commission considers the Category 1B substances not carcinogenic if they are refined to contain less than 3% w/w DMSO extractable PACs as measured by IP346. The International Agency for Research on Cancer concluded there is no evidence for the carcinogenicity in laboratory animals for highly-refined oils (IARC 1987).

There is no data available on the toxicity of base oils via the oral and inhalation routes. For the data related to dermal toxicity, see Table E1 of Appendix E.

## **8.3 Characterization of risk to human health**

### **8.3.1 Environmental media**

As described in Section 8.1.1, there is the potential for base oils to be released to water bodies via wastewater releases. There is a potential concern for human health if these base oils are released to water bodies which become a source of drinking water. Canadian Federal guidelines and provincial / municipal regulations are in place for many PAHs in effluents from industry that are released to water, with considerations to both aquatic life as well as downstream use for human consumption including for example the Canadian Federal Water Quality Guidelines for treated wastewater, and the Canadian Drinking Water Quality Guidelines (CCME 1999; CCME 2004; CCME 2008; Ontario 1994; Ottawa 2011; Ottawa 2018). This framework of federal, provincial, and municipal guidelines and regulations across Canada is expected to ensure that exposure to PAHs, including those which may have originated from base oils, through drinking water or recreational water use is not expected at levels of concern to human health.

### **8.3.2 Soft rubber products that may contain base oils**

As noted in Section 8.1.3 soft rubber and plastic products may contain base oil-derived extender oils. Although Canada has no regulations regarding the PAH content of these products, the European Union does. Directive 2005/69/EC of the European Parliament restricts the level of certain PAHs in extender oils (including base oils) for use in tire manufacture to less than 1 mg/kg B[a]P, and less than 10 mg/kg for the sum BaP and 7 other individual category 1B carcinogenic PAHs (EU 2005). Additionally, Commission Regulation (EU) No 1272/2013 restricts the concentration of these same PAHs to 1 mg/kg by weight for each of the individual PAH in rubber or plastic components that come into direct as well as prolonged or short term repetitive contact with the human skin or oral cavity, and 0.5 mg/kg for rubber and plastic toys and childcare articles (EU 2013).

The product testing results demonstrated that 65 of 67 products contained no PAH above the 0.5 mg/kg limit for children. There was one product (a child's sandal) having a single PAH (chrysene) above the 0.5 mg/kg limit for children, but below the general limit of 1 mg/kg. (ECCC, HC 2017c) and a single steering wheel cover tested above the guideline. Testing of additional steering wheel covers were all below the lowest limit of 0.5 mg/kg. Given this information, it appears that, although Canada does not have specific regulations for PAH content in rubber and soft plastic products, the majority of products available in Canada meet the European Regulations and that base oils, in this context are not considered to be of concern for human health.

### **8.3.3 Base oils in products available to consumers**

Base oil-containing products available to consumers can be divided into two use types on the basis of expected exposure related to type and frequency of use. These are household cleaners, and multipurpose lubricants and automotive products, with higher direct and incidental exposures expected from household cleaners. In all cases, the majority of exposures are expected to be by the dermal route, of short duration, and of intermittent frequency.

In order to evaluate the potential for health effects of various PAH mixtures, a common method applied is to use potency factors for each PAH relative to benzo[a]pyrene (B[a]P) and then summing all PAHs in the mixture thereby representing them as a total B[a]P equivalent. This approach has been used previously in CMP assessments including Asphalts and Oxidized Asphalts and Distillate Aromatic Extracts (ECCC HC 2017b, 2017c).

Using the potency equivalent factors and the concentrations of each of the 16 standard PAHs determined by high resolution testing and given in Table C.1 of Appendix C, the total equivalent B[a]P concentration of each of the products in the different use categories are given in Table 8-1. In cases in Table C.1 of Appendix C where a PAH was not detected with the limit of detection (LOD) as given in Tables D.2 to D.4 of Appendix I, a conservative concentration of 0.5×LOD was assigned to the PAH for the purposes of calculating the total B[a]P equivalents.

**Table 8.1. Total concentration of 16 standard PAHs and B[a]P equivalent concentration in products available to consumers determined from the high resolution measurement and the use of potency equivalent factors of Table D.1 of Appendix D.**

<b>Product</b>	<b>Product category</b>	<b>Total PAH concentration (mg/kg or ppm)</b>	<b>Total B[a]P equivalent potency (mg/kg or ppm)</b>
Wood polish	Household cleaning	0.1119	0.00332
Steel polish	Household cleaning	0.0243	0.00329
Steel polish	Household cleaning	0.1551	0.00340
Wood cleaner	Household cleaning	0.0509	0.00326
Wood cleaner	Household cleaning	0.0241	0.00323
Steel cleaner	Household cleaning	0.1899	0.00340
Wood cleaner	Household cleaning	0.0349	0.00324
Wood conditioner	Household cleaning	0.0217	0.00323
Wood conditioner	Household cleaning	0.634	0.00384
Automotive oil	Automotive	1.534	0.18339
Engine cleaner	Automotive	4.906	0.00811
Mirror Glaze	Automotive	0.043	0.00338
Engine cleaner	Automotive	13.075	0.01791
Oil lubricant	Multipurpose Lubricant	10.937	0.11198
Oil lubricant	Multipurpose Lubricant	33.183	0.30017
Oil lubricant	Multipurpose Lubricant	18.086	0.32837
Oil lubricant	Multipurpose Lubricant	1.967	0.14507
Penetrating oil	Multipurpose Lubricant	1.237	0.00562

The potency equivalence factors relative to B[a]P of the PAH species found at the highest concentrations in these products, namely, fluorene, anthracene, pyrene, and naphthalene, are low or very low (0.01 or 0.001). The total B[a]P equivalent concentration of the household cleaning products was determined to be less than 5 ppb (or 0.005 ppm), while that of the automotive products and multipurpose lubricants are determined to be between 100 to 350 ppb (between 0.100 and 0.350 ppm).

Converting all 16 PAH into B[a]P equivalents, resulted in a total B[a]P equivalent that was lower than the EU individual PAH limit of 0.5 mg/kg set out for rubber and soft plastic toys and children's articles. In the case of household cleaners, the total B[a]P equivalents was more than 150 times lower than this limit, and also lower than the allowed limit of < 1 ppm PAH residual in food grade petrolatum (Faust and Casserly 2003; US FDA 2017).

## 8.4 Uncertainties in evaluation of risk to human health

Although it is a common method used to evaluate risks from PAH mixtures, the use of the PEF approach, including the assumption of additivity, and the determination of the potency of individual PAHs relative to B[a]P are sources of uncertainty (CCME 2010).

While effort was made to make the selection of products available to consumers representative of the most widely used products, there is uncertainty in the extent to which the base oil products chosen for PAH compositional testing represent the entire cross section of products available in the Canadian marketplace. In particular, there can be uncertainty in the composition of base oil CAS RN ingredient in the product, how the product is used, including amount used, frequency of use, and frequency of exposure.

Despite having guidelines and regulations concerning components of base oils, in particular PAHs, in drinking water and drinking water sources, monitoring data regarding the presence of base oils at individual municipal water treatment facilities was not collected and analysed. There is the uncertainty that the assumptions made regarding drinking water are not met at every facility, potentially leading to the underestimation of exposures to these substances.

## 9. Conclusion

Considering all available lines of evidence presented in this screening assessment, there is low risk of harm to the environment from base oils. It is therefore concluded that the 39 base oils do not meet the criteria under paragraphs 64(a) or (b) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that have or may have immediate or long-term harmful effects on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends.

On the basis of the information presented in this screening assessment, it is concluded that the 39 base oils do not meet the criteria under paragraph 64(c) of CEPA as they

are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

It is concluded that the 39 base oils listed in Appendix A do not meet any of the criteria set out in section 64 of CEPA.

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## Appendix A. Base oils on the Domestic Substances List identified as priorities for assessment

**Table A.1. Chemical Abstracts Service Registry Number (CAS RN) and Domestic Substance List (DSL) name of priority base oils**

CAS RN	DSL name
64741-50-0	Distillates (petroleum), light paraffinic
64741-51-1	Distillates (petroleum), heavy paraffinic
64741-52-2	Distillates (petroleum), light naphthenic
64741-53-3	Distillates (petroleum), heavy naphthenic
64741-76-0	Distillates (petroleum), heavy hydrocracked
64741-88-4	Distillates (petroleum), solvent-refined heavy paraffinic
64741-89-5	Distillates (petroleum), solvent-refined light paraffinic
64741-95-3	Residual oils (petroleum), solvent deasphalted
64741-96-4	Distillates (petroleum), solvent-refined heavy naphthenic
64741-97-5	Distillates (petroleum), solvent-refined light naphthenic
64742-01-4	Residual oils (petroleum), solvent-refined
64742-18-3	Distillates (petroleum), acid-treated heavy naphthenic
64742-19-4	Distillates (petroleum), acid-treated light naphthenic
64742-21-8	Distillates (petroleum), acid-treated light paraffinic
64742-34-3	Distillates (petroleum), chemically neutralized heavy naphthenic
64742-35-4	Distillates (petroleum), chemically neutralized light naphthenic
64742-36-5	Distillates (petroleum), clay-treated heavy paraffinic
64742-41-2	Residual oils (petroleum), clay-treated
64742-44-5	Distillates (petroleum), clay-treated heavy naphthenic
64742-52-5	Distillates (petroleum), hydrotreated heavy naphthenic
64742-53-6	Distillates (petroleum), hydrotreated light naphthenic
64742-54-7	Distillates (petroleum), hydrotreated heavy paraffinic
64742-55-8	Distillates (petroleum), hydrotreated light paraffinic
64742-56-9	Distillates (petroleum), solvent-dewaxed light paraffinic
64742-57-0	Residual oils (petroleum), hydrotreated
64742-62-7	Residual oils (petroleum), solvent-dewaxed
64742-63-8	Distillates (petroleum), solvent-dewaxed heavy naphthenic
64742-64-9	Distillates (petroleum), solvent-dewaxed light naphthenic
64742-65-0	Distillates (petroleum), solvent-dewaxed heavy paraffinic
64742-67-2	Foots oil (petroleum)
64742-68-3	Naphthenic oils (petroleum), catalytic dewaxed heavy
64742-76-3	Naphthenic oils (petroleum), complex dewaxed light
68782-97-8 <sup>a</sup>	Distillates (petroleum), hydrofined lubricating-oil
72623-85-9	Lubricating oils (petroleum), C20-50, hydrotreated neutral oil-based, high-viscosity
72623-86-0	Lubricating oils (petroleum), C15-30, hydrotreated neutral oil-based

<b>CAS RN</b>	<b>DSL name</b>
72623-87-1	Lubricating oils (petroleum), C20-50, hydrotreated neutral oil-based
74869-22-0	Lubricating oils
93763-38-3	Hydrocarbons, hydrocracked paraffinic distn. residues, solvent-dewaxed
93924-32-4	Foots oil (petroleum), clay-treated

<sup>a</sup> This substance was not identified under subsection 73(1) of CEPA but was included in this assessment as it was considered a priority on the basis of other human health concerns.

## Appendix B: Aromatic content of base oils

Information on the aromatic content (wt%) of some base oils available from company websites, product data sheets, or safety data sheets is presented below. This is not an exhaustive summary, nor do the entries listed reflect the proportion of base oils in use with low or high aromatic content. The information is given solely to demonstrate the range of aromatic content available, as well as some of the variability in aromatic content within a CAS RN.

**Table B.1: The percent by weight of the aromatic hydrocarbon class of various paraffinic base oils as determined by ASTM D2007 or high performance liquid chromatography (HPLC)**

CAS RN	Product	Aromatic content (wt%) (D2007)	Aromatic content (wt%) (HPLC)	Reference
64741-50-0	--	--	20.9	API 2011b
64742-56-9	Calpar 80	7.6 <sup>1</sup>	--	Calumet ©2015, ECHA 2018a
unknown	Calpar 150	6.5 <sup>1</sup>	--	Calumet ©2015
64742-65-0	Calpar 600	15.6 <sup>1</sup>	--	Calumet ©2015, ECHA 2018b

<sup>1</sup> Estimated as 100% minus total saturates.

**Table B.2: The percent by weight of the aromatic hydrocarbon class of various paraffinic base oils as determined by ASTM D2007 or high performance liquid chromatography (HPLC)**

CAS RN	Product	Aromatic content (wt%) (D2007)	Aromatic content (wt%) (HPLC)	Reference
64742-52-5	S 100B	12.4 <sup>1</sup>	--	PDS 2017 SDS 2017a
64742-52-5	T 22	36 <sup>1</sup>	--	PDS 2016a, SDS 2017b
64742-52-5	T 400	38.9 <sup>1</sup>	--	PDS 2016b, SDS 2017c
64742-52-5	T 110	40.2 <sup>1</sup>	--	PDS 2016c, SDS 2017d
64742-52-5	Cross B-2000	33.1 <sup>1</sup>	--	PDS 2012a, SDS 2014a
64742-52-5	Cross B-2400	40.4 <sup>1</sup>	--	PDS 2012b, SDS 2014b
64742-52-5	Cross L-200	32.4 <sup>1</sup>	--	PDS 2012c, SDS 2015a
64742-52-5	Cross L-2800	40.7 <sup>1</sup>	--	PDS 2012d, SDS 2015b

CAS RN	Product	Aromatic content (wt%) (D2007)	Aromatic content (wt%) (HPLC)	Reference
64742-52-5	Corsol 750	42 <sup>1</sup>	--	PDS 2012e, SDS 2014c
64742-52-5	Calsol 850	48.1	--	Calumet ©2018c, SDS 2015c
64742-52-5	Calight RPO	47.1	--	Calumet ©2018c, SDS 2015d
64742-52-5	--	--	33.4	Concawe 2012
64742-52-5	--	36	--	Neau and Rangstedt 2009
64742-52-5	--	--	46.9	API 2011b
64742-53-6	T 9	26.9 <sup>1</sup>	--	PDS 2016d, SDS 2017e
64742-53-6	Cross L-40	27.6 <sup>1</sup>	--	PDS 2012f, SDS 2015e
64742-53-6	Corsol 35	20.7 <sup>1</sup>	--	PDS 2013, SDS 2015f
64742-53-6	--	--	31.9	API 2011b

<sup>1</sup>aromatic content as measured by IP346 ((IP 1985, 1993) is less than 3 wt%.

## Appendix C: PAH compositional testing of products available to consumers

**Table C.1. High resolution testing results<sup>a</sup> for 16 PAHs in Canadian marketplace household cleaning products containing base oils (µg PAH per kg sample)**

PAH species	Concentration range <sup>b</sup>	Median concentration <sup>c</sup>
Naphthalene	5.36 – 32.7	9.10
Acenaphthalene	ND – 5.15	0.5*
Acenaphthene	ND – 141	3.27
Fluorene	ND – 33.6	2.26
Phenanthrene	2.4 – 58.7	4.44
Anthracene	ND – 4.46	0.25*
Fluoranthene	ND – 6.39	1.32
Pyrene	0.92 – 8.59	3.12
Benz[ <i>a</i> ]anthracene	ND	0.5*
Chrysene	ND	0.5*
Benzo[ <i>b+</i> ]fluoranthene	ND – 1.07	0.5*
Benzo[ <i>k</i> ]fluoranthene	ND	0.5*
Benzo[ <i>a</i> ]pyrene	ND	0.5*
Indeno[ <i>1,2,3-cd</i> ]pyrene	ND	0.5*
Dibenz[ <i>a,h</i> ]anthracene	ND	0.5*
Benzo[ <i>ghi</i> ]perylene	ND – 1.27	0.5*

<sup>a</sup> Health Canada, unpublished (compositional analyses conducted in 2013-2014)

<sup>b</sup> Lower end based on limit of detection (LoD) of the methodology; “ND” indicates not detected at an LoD of 0.5 or 1.0 ppb

<sup>c</sup> For 10 of the PAH species (indicated by an asterisk), the median value is obtained by using ½ of the LoD, as in the majority of the products those PAHs were not detected

**Table C.2. High resolution testing results<sup>a</sup> for 16 PAHs in a sample Canadian marketplace automotive care product containing base oils (µg PAH per kg sample)**

PAH species	Concentration
Naphthalene	66.4
Acenaphthalene	2.4
Acenaphthene	3
Fluorene	13
Phenanthrene	19.8
Anthracene	4.71
Fluoranthene	29.4
Pyrene	77.2
Benz[ <i>a</i> ]anthracene	Less than 25
Chrysene	Less than 25
Benzo[ <i>b+</i> ]fluoranthene	446
Benzo[ <i>k</i> ]fluoranthene	50
Benzo[ <i>a</i> ]pyrene	89.6
Indeno[ <i>1,2,3-cd</i> ]pyrene	117
Dibenz[ <i>a,h</i> ]anthracene	Less than 10
Benzo[ <i>ghi</i> ]perylene	586

<sup>a</sup> Health Canada, unpublished (compositional analyses conducted in 2013-2014)

**Table C.3. High resolution testing results<sup>a</sup> for 16 PAHs in Canadian marketplace multipurpose lubricating oils containing base oils (µg PAH per kg sample)**

PAH species	Concentration range	Median concentration <sup>b</sup>
Naphthalene	66.7 – 1430	1150
Acenaphthalene	8.32 – 373	245
Acenaphthene	12.6 – 587	366
Fluorene	63.3 – 18 500	6040
Phenanthrene	29.3 – 4000	1830
Anthracene	45.5 – 3990	2975
Fluoranthene	323 – 847	670
Pyrene	218 – 2750	718
Benz[ <i>a</i> ]anthracene	less than 25 – less than 50	25*
Chrysene	less than 25 – 122	70.6
Benzo[ <i>b+</i> ]fluoranthene	187 – 445	347
Benzo[ <i>k</i> ]fluoranthene	26.2 – less than 50	25*
Benzo[ <i>a</i> ]pyrene	33.8 – 168	87.6*
Indeno[ <i>1,2,3-cd</i> ]pyrene	25.9 – 164	43.8*
Dibenz[ <i>a,h</i> ]anthracene	less than 10 – less than 25	8.7*
Benzo[ <i>ghi</i> ]perylene	49.1 – 238	103*

<sup>a</sup> Health Canada, unpublished (compositional analyses conducted in 2013-2014)

<sup>b</sup> For 5 of the PAH species (indicated by an asterisk), the median value is obtained by using ½ of the LoD, as in the majority of the products those PAHs were not detected

**Table C.4. Results of testing for 16 PAHs<sup>a</sup> in Canadian products available to consumers<sup>b</sup> (µg PAH per kg sample)**

Product (physical state)	NA	AY	AN	FE	PA	AA	FA	PY
Detection limit (µg/kg)	1	1	1	0.5	0.5	0.5	0.5	0.5
Wood polish (liquid)	8.63	3.51	33.8	33.6	26.5	ND	0.70	0.92
Steel polish (liquid)	9.56	ND	ND	2.58	3.24	ND	1.65	1.42
Steel polish (liquid)	32.7	1.02	6.85	32.4	58.7	4.46	6.39	8.59
Wood cleaner (liquid)	8.38	ND	ND	2.45	4.18	ND	0.98	0.98
Wood cleaner (liquid)	5.36	ND	4.69	2.85	4.18	ND	0.98	0.98
Steel cleaner (liquid)	25.4	5.15	141	ND	4.71	ND	1.92	7.2
Wood cleaner (liquid)	10.5	ND	ND	2.53	4.9	ND	3.55	8.19
Wood conditioner (liquid)	5.97	ND	2.12	1.36	2.4	ND	ND	4.81
Automotive oil	66.4	2.4	3	13	19.8	4.71	29.4	77.2
Multipurpose oil lubricant	954	178	229	5230	1100	1980	323	565
Multipurpose oil lubricant	1430	312	504	18500	4000	3970	847	2750
Multipurpose oil lubricant	1350	373	587	6840	2560	3990	700	871
Multipurpose oil lubricant	66.7	8.32	12.6	63.3	29.3	45.5	641	218

Product (physical state)	BA	CH	BF	BK	BP	IP	DA	BG
Detection limit (µg/kg)	1	1	1	1	1	1	1	1
Wood polish (liquid)	ND	ND	ND	ND	ND	ND	ND	ND
Steel polish (liquid)	ND	ND	1.07	ND	ND	ND	ND	ND
Steel polish (liquid)	ND	ND	ND	ND	ND	ND	ND	ND
Wood cleaner (liquid)	ND	ND	ND	ND	ND	ND	ND	1.27
Wood cleaner (liquid)	ND	ND	ND	ND	ND	ND	ND	ND
Steel cleaner (liquid)	ND	ND	ND	ND	ND	ND	ND	ND
Wood cleaner (liquid)	ND	ND	ND	ND	ND	ND	ND	ND
Wood conditioner (liquid)	ND	ND	ND	ND	ND	ND	ND	ND
Automotive oil	< 25	< 25	446	50	89.6	117	< 10	586
Multipurpose oil lubricant	< 25	52.4	187	< 25	33.8	25.9	< 10	49.1
Multipurpose oil lubricant	< 50	122	445	< 50	114	40.5	< 25	86.1
Multipurpose oil lubricant	< 50	88.7	329	< 50	168	47	< 25	120
Multipurpose oil lubricant	< 25	< 25	365	26.2	59.3	164	< 10	238

<sup>a</sup> PAHs tested were naphthalene (NA), acenaphthylene (AY), acenaphthene (AN), fluorene (FE), phenanthrene (PA), anthracene (AA), fluoranthene (FA), pyrene (PY), benz[a]anthracene (BA), chrysene (CH), benzo[b+j]fluoranthene (BF), benzo[k]fluoranthene (BK), benzo[a]pyrene (BP), indeno[1,2,3-cd]pyrene (IP), dibenz[a,h]anthracene (DA) and benzo[gh]perylene (BG).

<sup>b</sup> Health Canada, 2014 (unpublished study)

ND – Not detected



## Appendix D. Potency equivalence factors for certain PAH species

**Table D.1. Potency equivalence factors for 16 PAH species measured in the compositional testing of products available to consumers**

PAH species <sup>a</sup>	Relative B[a]P potency <sup>b</sup>
naphthalene	0.001
acenaphthylene	0.001
acenaphthene	0.001
fluorene	0.001
phenanthrene	0.001
anthracene	0.01
fluoranthene	0.001
Pyrene	0.001
benz[a]anthracene	0.1
chrysene	0.01
benzo[b+j]fluoranthene	0.1
benzo[k]fluoranthene	0.1
benzo[a]pyrene	1
indeno[1,2,3-cd]pyrene	0.1
dibenz[a,h]anthracene	5
benzo[ghi]perylene	0.01

<sup>a</sup> High-resolution testing examined 16 PAHs (the US EPA “priority pollutants”). Lower resolution testing did not test for naphthalene, but additionally tested for benzo[e]pyrene, coronene and retene (relative B[a]P potency not available for these 3 PAHs).

<sup>b</sup> Adapted from Nisbet and LaGoy, 1992

## Appendix E. Summary of health effects information for base oils and related substances following dermal exposure

**Table E.1. Summary of health effects information for base oils and related substances following dermal exposure**

Endpoint	CAS RN	Results
Repeated-dose (short-term)	64741-50-0 Unrefined	<b>LOAEL = 2000 mg/kg/day</b> based on moderate proliferative changes of the skin in both sexes of New Zealand White rabbits. Undiluted test substance (sample API 84-01) was applied to the shorn dorsal skin of male and female rabbits (groups of 5 per sex per dose) at 200, 1000 and 2000 mg/kg-bw per day, 3 times per week for 4 weeks. Application site skin turned dry, scaly, rough, and/or reddened, and the dermis thickened. One of the five males in the high dose group developed testicular bilateral diffuse tubular hypoplasia accompanied by aspermatogenesis and hypoplasia of the epididymis. These changes were considered to represent immature testes (API 1986a, 2011a), and the study was not of the length typically used to assess effects on the reproductive system.
Repeated-dose (short-term)	64742-53-6	<b>LOAEL = 200 mg/kg/day</b> based on aspermatogenesis changes in the testes or epididymes in New Zealand White rabbits (5 per sex per dose) exposed (with occlusion for 6 hours) via the shorn dorsal skin to undiluted test substance (sample API 83-12) at 200, 1000 and 2000 mg/kg-bw per day, 3 times each week for 4 weeks. Minimal irritation was noted at 200 mg/kg-bw. Moderate irritation was seen at 1000 mg/kg-bw in females, and at 2000 mg/kg-bw in males. Body weight gain was reduced for the highest dose groups and for the mid-dose females. Application site skin was dry, scaly, rough, fissured, crusted and/or thickened in all groups exposed to test substance. Histopathological examination revealed slight to moderate proliferative changes in the skin of all high dose rabbits. These changes were accompanied by an increased granulopoiesis of the bone marrow. The testes of 3 males in the high dose group had bilateral diffuse tubular hypoplasia accompanied by aspermatogenesis and the absolute and relative testes weights were lower in high dose males. Aspermatogenesis changes were observed in either the testes or epididymes of the male rabbits in the mid or low dose groups, but incidence was not provided (API 1986b, 2011a). The study was not of the length typically used to assess effects on the reproductive system. Additionally, the test substance was not refined and is not representative of refined base oils that enter the marketplace.
Repeated-dose (subchronic)	64742-54-7	<b>LOEL = 800 mg/kg-bw</b> for increased absolute and relative liver and relative adrenal weights in females, and decreased body weights in males. Sprague-Dawley rats (15 per sex per dose) were exposed to 0, 800 and 2000 mg/kg-bw test substance via unoccluded clipped back skin, 5 days per week for 13 weeks. Collars were fitted to minimize ingestion. Histopathology revealed chronic inflammation of the dermis in approximately half of the males and in approximately 65% of the females.  The NOAEL for systemic effects was indicated by the authors to be 2000 mg/kg-bw.

Endpoint	CAS RN	Results
Carcinogenicity	64741-50-0  (Unrefined)	<b>Light paraffinic distillate (sample #3)</b>  In a skin painting test, groups of 50 male C3H-HeJ mice were exposed via the shaven interscapular region to 50 mg (1667 mg/kg-bw) <sup>a</sup> undiluted test substance, twice weekly for 80 weeks. Control groups received either 50 mg of toluene (solvent controls) or 50 mg of a 0.05% solution of benzo[a]pyrene (B[a]P) in toluene (positive control). In the test substance group, there were 27 mice with benign or malignant skin tumors, and 42 final effective number (f.e.n.) of mice either at the time of appearance of the median tumour, or at 60 weeks (whichever was earlier). The f.e.n. includes the number of mice that had died with tumours by that time (Blackburn et al. 1984).
Carcinogenicity	64742-34-3 (Mild)  64742-52-5  (Hydrotreated heavy)	<b>Chemically neutralized / hydrotreated heavy naphthenic distillate (sample #5)</b>  Skin painting test was conducted according to Blackburn et al. 1984 (50 mice per group). In the test substance group, there were 12 mice with benign or malignant tumors, and 20 final effective number (f.e.n.) of mice either at the time of appearance of median tumour, or at 60 weeks (whichever was earlier). The f.e.n. includes the number of mice that had died with tumours by that time (Blackburn et al. 1984).
Carcinogenicity	64742-52-5  64741-96-4  (Solvent refined heavy)	<b>Solvent refined / hydrotreated heavy naphthenic distillate (sample #7)</b>  Skin painting test was conducted according to Blackburn et al. 1984 (50 mice per group). No mice developed benign or malignant tumors in the test substance group (Blackburn et al. 1984).
Carcinogenicity	64742-01-4  64742-62-7	<b>Solvent refined / dewaxed residual oil (sample #8)</b>  Skin painting test was conducted according to Blackburn et al. 1984 (50 mice per group). No mice developed benign or malignant tumors in the test substance group (Blackburn et al. 1984).
Carcinogenicity	64742-54-7  64741-88-4	<b>Solvent refined / hydrotreated heavy naphthenic distillate (sample #10)</b>  Skin painting test was conducted according to Blackburn et al. 1984 (50 mice per group). No mice developed benign or malignant tumors in the test substance group (Blackburn et al. 1984).
Carcinogenicity	64742-57-0  64742-01-4	<b>Solvent refined / hydrotreated residual oil (sample #12)</b>  Skin painting test was conducted according to Blackburn et al. 1984 (50 mice per group). No mice developed benign or malignant tumors in the test substance group (Blackburn et al. 1984).
Carcinogenicity	64741-88-4  64742-65-0	<b>Solvent refined / dewaxed heavy paraffinic distillate (sample #13)</b>  Skin painting test was conducted according to Blackburn et al. 1984 (50 mice per group). No mice developed benign or malignant tumors in the test substance group (Blackburn et al. 1984).

Endpoint	CAS RN	Results
Carcinogenicity	64742-52-5  (Hydrotreated heavy)	<p>Two different samples of hydrotreated heavy naphthenic distillate were tested via skin painting as in Blackburn et al. 1984 (50 mice per group). In the test substance groups, there were 36 and 21 mice with benign or malignant tumors, and 41 and 23 final effective number (f.e.n.) of mice either at the time of median tumour appearance, or at 60 weeks (whichever was earlier). The f.e.n. includes the number of mice that had died with tumours by that time (Blackburn et al. 1984).</p> <p>Four different samples of hydrotreated test substance were shown to be skin carcinogens in mice (46%, 10%, 48% and 14% of mice with cutaneous tumours, with mean latencies of 45, 46, 46 and 64 weeks, respectively). The primary goal of this study was to assess the usefulness of a short-term subcutaneous suppression assay to detect dermal carcinogens (Peristianis 1989). The processing histories and substance purities were not provided. The samples tested in the above study were not refined and, therefore, the results are not considered representative of refined base oils that are found in the marketplace. This conclusion is supported by Chasey and McKee (1993) that concluded oils refined under experimental conditions are not representative of those refined for commercial purposes, and that highly-refined oils, with low polycyclic aromatic hydrocarbon contents are not carcinogenic. Kane et al. (1984) also provided evidence that non-solvent-refined, hydrofinished streams (CAS RNs 64742-53-6 and 64742-52-5) have tumourigenic activity but that this activity is lost after solvent-refining.</p>
Carcinogenicity	64742-53-6	<p>Four different samples of hydrotreated test substance were tested for skin carcinogenicity in mice (8%, 10% and 6% of mice had cutaneous tumours, with mean latencies of tumour development of 56, 51, and 92 weeks, respectively). One sample did not cause the formation of dermal tumours. However, the aim of this study was to assess the usefulness of a short-term subcutaneous suppression assay to detect dermal carcinogens (Peristianis 1989). The processing histories and substance purities were not provided.</p>
Carcinogenicity	64742-55-8	<p>Kane et al. (1984) demonstrated that an acid-treated, solvent-dewaxed and hydrofinished light paraffinic distillate (derived from feedstocks CAS RNs 64742-21-8 and subsequently CAS RN 64742-56-9) had moderate carcinogenic activity in a skin painting study. Of 50 mice exposed twice weekly to 50 mg of test substance, 7 developed advanced tumours and 4 developed benign tumours with 47 weeks for time to first tumour, and average latency of 68 weeks. In the negative and vehicle control groups (50 mice not exposed, and 50 exposed twice weekly to 50 mg toluene), none developed skin tumours.</p>
Carcinogenicity	64741-53-3  (Mild)	<p>Mice intermittently exposed to 216 mg/kg-bw test substance over 36 weeks resulted in application site tumours and tumours of the appendages (tumorigenic and neoplastic by RTECS criteria) (US EPA 1992). No other study details were given.</p>
Carcinogenicity	Multiple CASRN	<p>In a test examining the dermal carcinogenicity in mice of over 116 base oil substances (from various stages of refining), 57 base oils produced no tumours, 37 produced one or more, and 22 reached</p>

Endpoint	CAS RN	Results
		<p>statistical significance producing 5 or more tumours. All raw vacuum distillates, raw extracts, and hydrotreated extracts produced tumours. Ames testing was conducted on 30 of the 116 samples, from the range of carcinogenicity potency seen in the skin painting study, and a results concordance of 80% (positive or negative in both the skin painting and Ames test) was observed (Chasey and McKee 1993).</p> <p>Observations of sebaceous gland suppression and results of long-term bioassays correlate well; those oils that produce skin tumours in mice also suppressed sebaceous glands in this study (Peristianis 1989).</p>
Developmental and Reproductive	64741-53-3	<p><b>LOAEL = 1000 mg/kg-bw per day.</b> Fischer 344 rats (5 per sex per dose) were dermally exposed to 500, 1000 and 2000 mg/kg-bw heavy naphthenic distillates via shaved skin. Dose-dependent reductions in food consumption, body weight, and body weight gain were observed. Pregnancy rates, mean number of live and dead fetuses, total implantations, and corpora lutea were normal. An increase in resorptions with an associated decrease in live fetuses was observed at 2000 mg/kg-bw per day. Fetal sex ratio was comparable for all groups. Fetal litter weight was decreased at 1000 and 2000 mg/kg-bw per day and exhibited a dose-response trend (US EPA 1992).</p> <p><b>Developmental LOAEL = 1000 mg/kg/day</b> based on dose-related decrease in fetal litter weight.</p> <p><b>Reproductive LOAEL = 2000 mg/kg-bw per day</b> based on a decrease in live fetuses.</p>

<sup>a</sup> LO(A)EL, lowest-observed-(adverse-) effect level; LO(A)EC, lowest-observed-(adverse-) effect concentration; NOAEL, no-observed-adverse-effect level; NOAEC, no-observed-adverse-effect concentration.

<sup>b</sup> Assuming average mouse body weight of 30 grams.