



Government of Canada Gouvernement du Canada

**Screening Assessment
Petroleum Sector Stream Approach
Petrolatum and Waxes
[Stream 4]**

Chemical Abstracts Service Registry Numbers

8009-03-8

64742-61-6

64743-01-7

**Environment and Climate Change Canada
Health Canada**

June 2016

Cat. No.: En14-255/2016E-PDF
ISBN 978-0-660-05468-1

Information contained in this publication or product may be reproduced, in part or in whole, and by any means, for personal or public non-commercial purposes, without charge or further permission, unless otherwise specified.

You are asked to:

- Exercise due diligence in ensuring the accuracy of the materials reproduced;
- Indicate both the complete title of the materials reproduced, as well as the author organization; and
- Indicate that the reproduction is a copy of an official work that is published by the Government of Canada and that the reproduction has not been produced in affiliation with or with the endorsement of the Government of Canada.

Commercial reproduction and distribution is prohibited except with written permission from the author. For more information, please contact Environment and Climate Change Canada's Inquiry Centre at 1-800-668-6767 (in Canada only) or 819-997-2800 or email to ec.enviroinfo.ec@canada.ca.

© Her Majesty the Queen in Right of Canada, represented by the Minister of the Environment and Climate Change, 2016.

Aussi disponible en français

Synopsis

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA), the Ministers of the Environment and Climate Change and of Health have conducted a screening assessment of the following petrolatum and wax substances:

CAS RN ^a	DSL name ^b
8009-03-8	Petrolatum
64742-61-6	Slack wax (petroleum)
64743-01-7	Petrolatum (petroleum), oxidized

^a 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 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.

^b DSL: *Domestic Substances List*

Petrolatum and waxes have been identified as ingredients in many commercially available products and are considered to be of Unknown or Variable composition, Complex reaction products or Biological materials (UVCBs). These substances were included in the Petroleum Sector Stream Approach (PSSA) because they are related to the petroleum sector and are complex combinations of hydrocarbons.

During the categorization exercise, petrolatum and waxes under the three Chemical Abstracts Service Numbers (CAS RN) 8009-03-8 (Petrolatum), 64742-61-6 [Slack wax (petroleum)] and 64743-01-7 [Petrolatum (petroleum), oxidized] were identified as priorities for assessment, as they met the categorization criteria under subsection 73(1) of CEPA and/or were considered a priority based on other human health concerns.

Environmental concentrations of petrolatum and waxes are expected to be low. Most components of petrolatum and waxes have very low solubility in water, low bioavailability, and very low toxicity, such that if released, petrolatum and waxes are considered to pose a low risk of harm to organisms and the environment.

Considering all available lines of evidence presented in this screening assessment, there is a low risk of harm to organisms and the broader integrity of the environment from petrolatum and waxes. It is concluded that petrolatum and waxes 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.

Petrolatum is found as an ingredient in many products available to consumers, including personal care products, lubricants, household cleaning products, adhesives and sealants, and paints and coatings, and is permitted for use as a wax coating on fruits and vegetables, as a glazing agent on confectionery, and as a bakery release agent. Slack wax is found in a limited number of products available to consumers, including chimney cleaning logs. Oxidized petrolatum is restricted to industrial uses.

A critical health effect for the initial categorization of petrolatum and wax substances was carcinogenicity, based on classifications by international agencies. The European Commission classifies petrolatum, slack wax and oxidized petrolatum as Category 1B carcinogens (“may cause cancer”), but indicates they are not carcinogenic if the feedstocks are shown to be devoid of carcinogenic activity. The International Agency for Research on Cancer (IARC) concluded there is no evidence for the carcinogenicity in laboratory animals of class 5 (refined) petrolatum.

In Canada, the general population is exposed to petrolatum from certain foods and from petrolatum-containing products that are available for purchase in the marketplace. The highest estimated exposures by body weight are for toddlers (oral route) and for infants (dermal route). A lack of toxicity of petrolatum has consistently been demonstrated in laboratory animals after exposure to high doses, and clinically significant adverse health effects have not been observed in humans despite decades of product use. Therefore, risk to the general population from exposure to petrolatum is considered to be low.

Although petrolatum in the Canadian marketplace is subject to regulations (e.g., petrolatum used in approved food additive applications must conform to the standards of purity as defined by the *Food Chemicals Codex*), there has been general concern over potential risk from polycyclic aromatic hydrocarbons (PAHs) that might remain entrained within refined petrolatum. Compositional testing of products that contain petrolatum was therefore conducted and confirmed most did not contain PAHs, or had a residual level (sum total of 16 priority PAHs of less than 0.00001% by weight or 0.1 parts per million), indicating compliance with national and international purity standards.

To confirm the low potential for risk from the potential residual presence of PAHs in petrolatum-containing products, a theoretical cancer risk was characterized. A comparison of conservative exposure estimates with critical effect levels resulted in margins of exposure that are considered adequate to address uncertainties in health effects and exposure.

Exposure to slack wax is considered to be incidental and limited, and exposure to oxidized petrolatum is not expected.

Therefore, general population exposure to petrolatum and waxes from products and foods is not considered to constitute a risk to human health.

Based on the information presented in this screening assessment, it is concluded that petrolatum and waxes 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.

Overall Conclusion

It is concluded that petrolatum and waxes (CAS RNs 8009-03-8, 64742-61-6 and 64743-01-7) do not meet any of the criteria set out in section 64 of CEPA.

Table of Contents

Synopsis	i
1. Introduction	1
2. Substance Identity	4
3. Physical and Chemical Properties	7
4. Sources	10
4.1 Petrolatum	10
4.2 Slack Wax.....	10
4.3 Oxidized Petrolatum	11
4.4 Additional Source Information.....	11
5. Uses.....	12
5.1 Petrolatum	12
5.2 Slack Wax.....	15
5.3 Oxidized Petrolatum	15
6. Releases to the Environment	17
7. Environmental Fate	18
7.1 Environmental Persistence	20
7.2 Potential for Bioaccumulation	20
8. Potential to Cause Ecological Harm	22
8.1 Ecological Effects Assessment.....	22
8.1.1 Aquatic compartment.....	22
8.1.2 Terrestrial compartment.....	23
8.2 Ecological Exposure Assessment.....	23
8.2.1 Aquatic compartment.....	23
8.2.2 Atmospheric compartment.....	24
8.2.3 Terrestrial compartment.....	24
8.3 Characterization of Ecological Risk	24
8.4 Uncertainties in Evaluation of Ecological Risk	25
9. Potential to Cause Harm to Human Health.....	27
9.1 Exposure Assessment.....	27
9.1.1 Petrolatum (CAS RN 8009-03-8)	27
9.1.2 Slack wax (CAS RN 64742-61-6)	34
9.1.3 Petrolatum (oxidized) (CAS RN 64743-01-7).....	35
10. Health Effects Assessment	36
10.1 Characterization of Risk to Human Health.....	40
10.1.1 Petrolatum	40
10.1.2 Slack wax.....	43
10.1.3 Oxidized petrolatum	43
10.2 Uncertainties in Evaluation of Risk to Human Health.....	43
11. Conclusion.....	44
References	45
Appendices	58
Appendix A. Petroleum Substance Groupings	58
Appendix B. Types of Petroleum Wax.....	59
Appendix C. Potential for Ecological Harm	70

Appendix D. Petrolatum Exposure by Route and Age Group.....	71
Appendix E. Summary of Health Effects Information for Petrolatum and Waxes	73
Appendix F. Compositional Testing of Products Available to the Consumer.....	79
Appendix G. Potency Equivalence Factors for Certain PAH Species	80

Tables

Table 2-1. Substance identities of petrolatum and waxes	4
Table 3-1. Melting point of petrolatum and waxes	7
Table 3-2. Boiling point.....	7
Table 3-3. Density	7
Table 3-4. Vapour pressure	7
Table 3-5. Log K_{ow} , octanol-water partition coefficient.....	7
Table 3-6. Water solubility	8
Table 5-1. Estimated finished petrolatum market share by major use area in Canada	12

1. Introduction

Pursuant to sections 68 and 74 of the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999), the Minister of the Environment and Climate Change and the Minister of Health conduct screening assessments of substances to determine whether these substances present or may present a risk to the environment or to human health.

A key element of the Government of Canada's Chemicals Management Plan (CMP) is the Petroleum Sector Stream Approach (PSSA), which involves the assessment of approximately 160 petroleum substances that are considered high priorities for action ("high priority petroleum substances"). These substances are primarily related to the petroleum sector and are considered to be of Unknown or Variable composition, Complex reaction products or Biological materials (UVCBs).

High-priority petroleum substances fall into nine groups of substances based on similarities in production, toxicity and physical-chemical properties (Appendix A). In order to conduct the screening assessments, each high-priority petroleum substance was placed into one of five categories ("Streams") depending on its production and uses in Canada, as follows:

Stream 0: substances not produced by the petroleum sector and/or not in commerce;

Stream 1: site-restricted substances, which are substances that are not expected to be transported off refinery, upgrader or natural gas processing facility sites;¹

Stream 2: industry-restricted substances, which are substances that may leave a petroleum-sector facility and may be transported to other industrial facilities (for example, for use as a feedstock, fuel or blending component), but that do not reach the public market in the form originally acquired;

Stream 3: substances that are primarily used by industries and consumers as fuels; or

Stream 4: substances that may be present in products available to the consumer.

An analysis of the available data resulted in the determination that 67 high-priority petroleum substances may be present in commercially available products under Stream 4, as described above. These 67 substances were further sub-grouped as follows, based on their physical and chemical properties and potential uses: aromatic extracts, gas oils, heavy fuel oils (HFOs), low boiling point naphthas (LBPNS), natural gas condensates (NGCs), solvents, petroleum and refinery gases, base oils, petrolatum and waxes, and asphalt.

This screening assessment addresses three substances. These petrolatum and waxes were identified as priorities for assessment, as they met the categorization criteria under

¹ For the purposes of the screening assessment of PSSA substances, a "site" is defined as the boundaries of the property where a facility is located.

section 73 of CEPA and/or were considered a priority based on human health concerns. These substances were included in the PSSA because they are related to the petroleum sector and are complex mixtures.

According to information submitted under section 71 of CEPA (Environment Canada 2008, 2011), these substances can be found in a variety of industrial products and/or products available to the consumer.

Screening assessments focus on information critical to determining whether substances within a grouping meet the criteria as set out in section 64 of CEPA, by examining scientific information to develop conclusions by incorporating a weight of evidence approach and precaution.²

This screening assessment includes consideration of information on chemical properties, environmental fate, hazards, uses and exposure, including additional information submitted by stakeholders. Relevant data were identified up to June 2014. Empirical data from key studies as well as some results from models were used to reach conclusions. When available and relevant, information presented in assessments from other jurisdictions was considered.

The screening assessment does not represent an exhaustive or critical review of all available data. Rather, it presents the most critical studies and lines of evidence pertinent to the conclusion.

This screening assessment was prepared by staff in the Existing Substances Programs at Health Canada and Environment and Climate Change Canada and incorporates input from other programs within these departments. The ecological and human health portions of this assessment have undergone external written peer review and/or consultation. Comments on the technical portions relevant to human health were received from Dr. Glenn Talaska [University of Cincinnati, United States (US)], Dr. Susan Griffin [United States Environmental Protection Agency (US EPA)], Dr. Donna Vorhees (Boston University School of Public Health, US) and Mr. Robert Lee (Neptune and Company Inc., US). Additionally, the draft of this screening assessment 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.

² A determination of whether one or more of the criteria of section 64 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 the use of consumer products. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Controlled 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 undertaken under other sections of CEPA or other Acts.

The critical information and considerations upon which the screening assessment is based are given below.

2. Substance Identity

For the purposes of this document, the three substances in question will be referred to as petrolatum and waxes. They have been grouped together, as they are each produced from paraffinic refinery streams (lubricating oil basestocks) that are produced by lubricating oil refineries. The details of the production of petrolatum and wax substances are summarized in the US EPA High Production Volume (HPV) Program report on Waxes and Related Materials (OSHA 1999; US EPA 2011).

Table 2-1. Substance identities of petrolatum and waxes

CAS RN	8009-03-8	64742-61-6	64743-01-7
DSL name	Petrolatum	Slack wax (petroleum)	Petrolatum (petroleum), oxidized
Chemical group (DSL Stream)	UVCB–organic	UVCB–organic	UVCB–organic
Major chemical class	Refinery Streams	Refinery Streams	Refinery Streams
Major components	Aliphatic and aromatic hydrocarbons	Aliphatic and aromatic hydrocarbons	Aliphatic and aromatic hydrocarbons
Carbon range	More than C ₂₅ (C ₁₂ –C ₈₅) ^a	More than C ₂₀ (C ₁₂ –C ₈₅) ^a	C ₃₃ – C ₄₃ (C ₁₂ –C ₈₅) ^b
Molecular weight (g/mol)	375–630 ^a	350–600 ^c	2037 (average) ^b

^a US EPA 2003. Includes the range of potential hydrocarbon components.

^b US EPA 2006. Indicates carbon range of starting materials. Potential hydrocarbon range is based on the previously stated range for petrolatum and slack wax.

^c Imperial Oil 2002. Product data sheet for slack wax.

Petrolatum (CAS RN 8009-03-8) is a complex combination of hydrocarbons obtained as a semi-solid from de-waxing paraffinic residual oil. Petrolatum can also originate from a heavy distillate from lubricating oil basestock, from bright stock oil or from vacuum residuals, depending on the physical-chemical properties of the crude oil feedstock and intermediate streams. Blended petrolatums are produced by combining white [i.e., United States Pharmacopeia (USP)-grade] mineral oils and petroleum waxes for use in products and pharmaceutical applications (Parkash 2010c). Petrolatum consists predominantly of saturated crystalline and liquid hydrocarbons having carbon numbers primarily greater than C₂₅.

Petrolatum was originally patented under the brand name *Vaseline* by the inventor of petroleum jelly, Robert Chesebrough, in his US patent for the process of making petroleum jelly (US Patent 127,568) in 1872. Alternative names for the substance are petroleum jelly and soft paraffin (Bennett 2012; Unilever 2012). However, petrolatum (CAS RN 8009-03-8) is sometimes used non-specifically in the scientific literature and therefore may refer to various stages of petrolatum, including “semi-finished” petrolatum (also referred to as “petroleum wax”) that contains a higher proportion of microcrystalline wax, and “finished” (or “refined”) petrolatum, a highly-refined blend of

high-viscosity mineral oil and microcrystalline wax that can be of varying quality grades. Additional processing is required to produce finished petrolatum from semi-finished petrolatum (STN 2013).

Finished petrolatum can be generally grouped into two categories: USP and industrial grades. USP grade petrolatum meets pharmaceutical standards for purity, consistency, melting point and maximum colour (Faust 2003, 2012; USP 2014a,b). USP petrolatums are blended from high quality medicinal grade white oils and medicinal grade petroleum waxes (Parkash 2010b). These blending components meet pharmaceutical purity standards for residual polycyclic aromatic hydrocarbons (PAHs) (USP 2014c,d). Modern refining procedures including solvent extraction and deep hydrotreating also results in the virtual elimination of 3–7 ring PAHs from USP petrolatum (Kane 1984; Parkash 2010a-c). It has been indicated that manufacture of USP petrolatums meets United States Food and Drug Administration (US FDA) food-grade standards (21 *CFR* 172.880) of purity (Faust 2012; Parkash 2010c). Industrial grades of petrolatum meet less stringent physical-chemical property criteria and therefore may contain higher levels of PAHs.

A standard composition of residual PAHs that may be found in USP petrolatum is difficult to assign because of variance in the type, ratio and levels depending on the source of feedstock, and the identity and quality of blending components.

In this assessment, petrolatum (CAS RN 8009-03-8) refers to the USP (or equivalent) grade of petrolatum, as this grade is expected to be found in products available to the consumer. Slack wax (CAS RN 64742-61-6) was assessed and considered independently of petrolatum.

Slack wax (CAS RN 64742-61-6) is a complex combination of hydrocarbons obtained by solvent crystallization (solvent de-waxing) of a light paraffinic distillate from a lubricating oil basestock, or as a distillation fraction from a very waxy crude. It consists primarily of saturated straight and branched chain hydrocarbons having carbon numbers predominantly greater than C₂₀ (STN 2013).

Oxidized petrolatum (CAS RN 64743-01-7) is a complex combination of organic compounds, predominantly high molecular weight carboxylic acids, obtained by the air oxidation of petrolatum (STN 2013; ESIS 2014). The typical composition of petroleum oxidates, including CAS RN 64743-01-7, is 40–50% unreacted petroleum starting material and 30–35% monocarboxylic acid, with the remainder consisting of dicarboxylic acids, oxyacids, aldehydes and ketones (EPA 2006).

Further details on petrolatum, slack wax and oxidized petrolatum substance identities are provided in Table B.1 in Appendix B.

These UVCB substances are complex combinations of hydrocarbon molecules that originate in nature or are the result of chemical reactions and processes that take place during the upgrading and refining process. Given their complex and variable

compositions, they could not practicably be formed by simply combining individual constituents.

3. Physical and Chemical Properties

There may be variability in the composition and physical-chemical properties of petrolatum and waxes based on the crude oil or bitumen source as well as in the processing steps used to produce the substances. Experimental data for the physical and chemical properties of the three petrolatum and wax substances assessed in this report are presented in Tables 3-1 to 3-6.

Table 3-1. Melting point of petrolatum and waxes (°C)

CAS RN	Value	Reference
8009-03-8	36–60	US EPA 2003
64742-61-6	43–63	CONCAWE 1999
64742-61-6	57–63	IHCP 2013
64743-01-7	36–60	IHCP 2013
64743-01-7	39	US EPA 2006

Table 3-2. Boiling point of petrolatum and waxes (°C)

CAS RN	Value	Reference
8009-03-8	343	Anachemia 2008
64742-61-6	350–500	API 2003
64743-01-7	214 to >649 [417 to >1200°F]	US EPA 2006

Table 3-3. Density of petrolatum and waxes (kg/m³)

CAS RN	Value	Reference
8009-03-8	815–865 (at 60°C)	IHCP 2013
64742-61-6	764–805 (at 85°C)	Imperial Oil 2002 (MSDS)
64743-01-7	940–960 (at 15°C)	IHCP 2013

Table 3-4. Vapour pressure of petrolatum and waxes (Pa)

CAS RN	Value	Reference
8009-03-8	<133 [<1 mm Hg] (at 21°C)	Anachemia 2008 (MSDS)
64742-61-6	n/a	n/a
64743-01-7	<1 (at 25°C)	US EPA 2006

Table 3-5. Log K_{ow}, octanol-water partition coefficient of petrolatum and waxes ^a

CAS RN	Value	Reference
8009-03-8	More than 6 (calculated)	IHCP 2013
64742-61-6	More than 6.0	IHCP 2013
64743-01-7	4.7–6	API 2000
64743-01-7	More than 4.9	US EPA 2006

^a Calculated using isomers of the lowest molecular weight component (C₁₃ hydrocarbons) in waxes.

Table 3-6. Water solubility of petrolatum and waxes (mg/L)^a

CAS RN	Value	Reference
8009-03-8	Insoluble in cold water	Anachemia 2008 (MSDS)
64742-61-6	Insoluble	US EPA 2003
64743-01-7	0.027–5.96 (at 25°C)	API 2000
64743-01-7	3.47 [3.47 ppm] (at 25°C)	US EPA 2006

^a This represents the highest solubility for the smallest possible components of the mixture (C₁₃). Higher molecular weight compounds will have decreased solubility.

To predict the overall behaviour of complex petroleum substances, such as petrolatum and waxes, representative structures were selected from each chemical class within the mixture to represent the range of components present. Thirty-six representative structures were chosen (Table B.2 in Appendix B) based in part on the boiling point, which fell within the range of petrolatum and waxes. Physical-chemical data for each representative structure were assembled from the EPI Suite (2008) group of environmental models (Table B.3 in Appendix B).

While Table B.3 (Appendix B) provides physical-chemical property data for the individual structures, it should be noted that some of these properties will differ when the substances are present in a mixture, such as petrolatum and waxes. The vapour pressures of the components of a mixture will be lower than their individual vapour pressures due to Raoult's Law (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 solubility of components in a mixture are lower than when they are present individually (Banerjee 1984). Concurrently, however, components that are normally solid under environmental conditions when part of a mixture may have lower melting points (and therefore be in a liquid state) and increased vapour pressure and water solubility (Banerjee 1984). This is not reflected in Table B.3.

Typically, non-oxidized petrolatum and waxes contain >C₂₀ straight and branched alkanes, cycloalkanes and monoaromatic and diaromatic hydrocarbons (Range: C₁₂ to >C₅₀, Table B.3 in Appendix B). As a wax is further refined, the proportion of aromatics decreases while the proportion of isoalkanes and cycloalkanes increases (Table B.4 in Appendix B; Mohamed and Zaky 2004).

Historically, some food-grade petroleum waxes and petrolatum were shown to contain polycyclic aromatic hydrocarbons (PAHs). Food waxes and products containing petrolatum showed levels of PAH species (ranging from not detected to 640 parts per billion) in white petrolatum, medicinal oil, and food and food-packaging petroleum waxes (Howard et al. 1965; Lijinsky et al. 1963; Popl et al. 1975; Shubik et al. 1962).

Therefore, 20 marketplace petrolatum products currently available for purchase in Canada were tested for the concentration of 16 PAHs, [known as the 'priority pollutant' PAHs (Menzie et al. 1992; US EPA 2014)] that are routinely analyzed as residuals (Appendix F). Products such as skin lotions/creams, face/body soaps, hair gels, skin/eye ointments, lip balms, denture adhesives, petroleum jellies etc. were analysed.

There were ten different product types/uses represented, from 15 different suppliers/brands. The petrolatum ingredient reported on each product label was typically “petrolatum”, “white petrolatum”, “petrolatum USP” or “petrolatum BP”.

The petrolatum products were solvent-extracted to isolate PAHs, then subject to gas chromatography and high resolution mass spectroscopy detection. Limits of detection in μg PAH per kg product (parts per billion) of 0.5 or 1 (liquid) and 5 or 10 (gel or solid) were obtained for each PAH depending on the physical state of the product. Surrogate recoveries (85 to 111% and 80 to 117%, respectively) on samples spiked with 10 ppb of each PAH were within acceptable limits. The methodology used was based on standard US EPA guidance (US EPA 1986).

Most products contained no PAHs or less than 0.00001% by weight (w/w) sum total of the PAHs examined (Appendix F). The sum total of detected PAHs ranged from not detected to less than 10 ppb (in nine products), 10 to 100 ppb (in five products), less than 250 ppb (in five products) and approximately 400 ppb (0.4 parts per million) (in one product). Therefore, all of the marketplace petrolatum products contained less than 0.5 parts per million ($<0.00005\%$ w/w) total sum of 16 PAH species that are routinely analysed as residuals. The median concentration of a PAH species, when detected, was 12.6 parts per billion (0.000001% w/w). However, when non-detects are considered to be representative of the presence of a PAH species at half the limit of detection, the median PAH concentration (based on all data points, detects and non-detects) ranges from 0.5 to 5 parts per billion (0.00000005 to 0.0000005% w/w) (Appendix F). These results show that marketplace petrolatums contain only residual or undetectable levels of PAHs.

4. Sources

The petrolatum and wax substances considered in this screening assessment are not naturally occurring. Feedstocks for slack wax and petrolatum production are generated by the petroleum industry in Canada.

4.1 Petrolatum

No recent information on manufacturing and import quantities could be identified in the literature. Petrolatum was not required to be reported under either the *Notice with respect to certain high priority petroleum substances* or the *Notice with respect to certain high priority petroleum substances on the Domestic Substances List*, published under section 71 of CEPA (Environment Canada 2008, 2011). Statistics Canada does not publish production figures for petrolatum or petroleum jelly.

Estimates of the North American market for finished petrolatum were obtained from a US consultant specializing in waxes and lubricating oils, from a major finished petrolatum manufacturer and from an industry organization (the US National Petrochemical and Refiners Association). It was estimated that the Canadian finished petrolatum market is approximately seven kilotonnes per year (6500 tonnes USP grade and 500 tonnes technical/industrial grade, Cheminfo 2009).

Canadian refineries do not produce finished petrolatum but do produce feedstocks that are used in their manufacture. Finished petrolatum from petrolatum feedstocks, including USP grade [2 kt per annum (kta)] and industrial grade (2 kta) are produced in Canada. Only USP (pharmaceutical) grade petrolatum is expected to be in products available to the consumer that include drugs, natural health products and cosmetics (Cheminfo 2009; Faust 2012; IGI 2014; Parkash 2010; Sonneborn 2014). An unknown quantity of finished petrolatum is imported into Canada as a component in various products; these products are expected to contain USP grade petrolatum (Cheminfo 2009) and, especially from North American manufacturers, to meet the highest standards of purity (i.e., US FDA food-grade standards of purity, 21 CFR 172.880) (Faust 2012; Parkash 2010c).

4.2 Slack Wax

According to the information collected through the *Notice with respect to certain high priority petroleum substances on the Domestic Substances List* published under section 71 of CEPA (Environment Canada 2011), 1 000 000 to 10 000 000 kg of slack wax (CAS RN 64742-61-6) were imported, with 100 000 to 1 000 000 kg used in 2010. Results of the *Notice with respect to certain high priority petroleum substances* published under section 71 of CEPA (Environment Canada 2008) indicated that $\geq 1\,000\,000$ kg of slack wax was manufactured in 2006.

Base oil stocks are one product derived from the crude oil refining process and are produced and used in the manufacture of lubricating oils. Waxy hydrocarbons, including

those found in slack wax, are removed from these oil stocks by solvent extraction (dewaxing); some are suitable (after further refining) as blending components in finished petrolatum.

4.3 Oxidized Petrolatum

According to the information collected through the *Notice with respect to certain high priority petroleum substances on the Domestic Substances List*, published under section 71 of CEPA (Environment Canada 2011), 1000 to 10 000 kg of oxidized petrolatum (CAS RN 64743-01-7) were imported in 2010, with no uses reported above the 100 kg reporting threshold. No manufacture of oxidized petrolatum was reported.

4.4 Additional Source Information

Internationally, CAS RNs 8009-03-8, 64742-61-6 and 64743-01-7 have each been identified by the Organisation for Economic Co-operation and Development (OECD) as high production volume chemicals, with 1000 tonnes or more produced per year (OECD 2004). In addition, the European Union (EU) and US EPA have both identified these petrolatum and wax substances as HPV chemicals. In the US, HPV chemicals are produced or imported in quantities of 453 tonnes or more per year.

5. Uses

According to the information collected through the *Notice with respect to certain high priority petroleum substances on the Domestic Substances List* published under section 71 of CEPA (for CAS RNs 64742-61-6 and 64743-01-7) (Environment Canada 2011), an in-depth literature review and a search of material safety data sheets (MSDSs), petrolatum and slack wax have been identified as being used in products available to the consumer and in industrial products, while oxidized petrolatum is only found in industrial products.

5.1 Petrolatum

Petrolatum has a range of applications in commercial and industrial products as outlined in the major use areas in Table 5-1. USP-grade petrolatum may be used by companies that package petroleum jelly for retailers and by manufacturers that use it as an ingredient in products available to the consumer. Industry also uses technical grade petrolatum for various purposes.

Table 5-1. Estimated finished petrolatum market share by major use area in Canada

Use	Grade	Share (of seven kt)	Annual use
Personal care products	USP	70–80%	5500 tonnes
Food applications	USP	5–10%	500 tonnes
Pharmaceuticals	USP	5–10%	500 tonnes
Industrial (including plastics) and miscellaneous	Technical/ Industrial	5–10%	500 tonnes

Source: Consultations with major North American petrolatum manufacturers conducted by Cheminfo Services Inc. (Cheminfo 2009). These estimates are based on an estimated 7-kilotonne Canadian market for petrolatum.

Based on notifications submitted to Health Canada under the *Cosmetic Regulations*, petrolatum is present in approximately 11 000 cosmetic products available in Canada (2013, emails from the Consumer Product Safety Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced). Uses of petrolatum in Canada include skin care products (e.g., creams and lotions, petroleum jelly, heavy-duty hand cleaners, antiperspirant sticks, deodorants and after-sun care lotions); lip care products and make-up (e.g., lipsticks, liners, balms and glosses); hair care products (e.g., styling products and hair wax); baby care products (e.g., diaper creams, ointments, lotions and creams); and other make-up and cosmetics (e.g., foundations, pressed powders and eye products, theatrical and Halloween products) (Schramme 2002; Healy 2005; Schueller 1999).

Other uses include adhesives and sealants (e.g., solder paste), food additive uses, healing ointments, denture adhesive creams and bug repellents (Meridian 2009;

Environment Canada 2011). Petrolatum is also found as a formulant in commercial and domestic insecticides and materials, and wood preservative (PMRA 2006, personal communication from Health Canada's Existing Substances Risk Assessment Bureau to Health Canada's Pest Management Regulatory Agency, dated February 2010; unreferenced).

In Canada, the use of petrolatum in/on food must comply with the provisions of the *Food and Drugs Act* and its regulations. Permitted food additive uses can be found in the *List of Permitted Glazing or Polishing Agents* incorporated by reference in the *Marketing Authorization for Food Additives That May Be Used as Glazing or Polishing Agents* and the *List of Permitted Food Additives with Other Generally Accepted Uses*, incorporated by reference in the *Marketing Authorization for Food Additives with Other Generally Accepted Uses*. Both of these marketing authorizations were made under the authority of the *Food and Drugs Act* (Health Canada 2012; Health Canada 2013b). According to these lists, petrolatum may be used at a maximum level of 0.3% to coat fresh fruits and vegetables, 0.15% (singly or in combination with mineral oil) as a release agent in bakery products, and 0.15% as a glazing or polishing agent in unstandardized confectionery. Further, section B.01.045(b) of the *Food and Drug Regulations* requires that petrolatum added to food meet the specifications set out in the most recent edition of the *Food Chemicals Codex* (FCC) as published by USP via United Book Press (USP 2014a). In addition, section B.01.046 of the *Food and Drug Regulations* prohibits the presence of petrolatum in foods, with certain exemptions to this prohibition being listed in B.01.047 (essentially the food additive uses), provided that good manufacturing practices require the use of the petrolatum. The *Codex General Standard for Food Additives*, published by the *Codex Alimentarius*, an international standards setting body for food quality and safety, also has provisions for the use of liquid petrolatum (mineral oil) as a food additive. Petrolatum has been identified to be used in interior coatings of cups, metal can ends, polypropylene/ polyethylene resins for food packaging applications, and as lubricants with incidental food contact in food processing (personal communication from Health Canada's Food Directorate to Health Canada's Existing Substances Risk Assessment Bureau, dated October 2014; unreferenced).

Petrolatum is listed in the Drug Product Database and the Health Canada Therapeutic Products Directorate's internal non-medicinal ingredients database as an active ingredient and non-medicinal ingredient in marketed human and veterinary drugs (DPD 2013, personal communication from Health Canada's Health Products and Food Branch to Health Canada's Existing Substances Risk Assessment Bureau, dated February 2013).

Petrolatum is listed in the Natural Health Products Ingredients Database (NHPID) with a non-medicinal role for use in natural health products as anti-foaming agent, coating agent, controlled release vehicle, lubricant, ointment base, protectant or skin conditioning agent, provided that it does not contribute to the health claim of a product (NHPID 2015). It is listed in the Licensed Natural Health Products Database (LNHPD) to be present as a non-medicinal ingredient in currently licensed natural health products (LNHPD 2015).

Additional products containing petrolatum from other jurisdictions include bath oils/beads, body washes, facial moisturizers/cleaners, fragrances, hair dyes, horse care applications, pain relief creams, primers, shampoos/conditioners, shaving creams/gels, and welding/soldering products [US Department of Health and Human Services, Household Products Database (HPD), 2010]. Other applications described in the literature include aluminum mills, animal feed, automotive (rust-preventatives in undercoating, and lubricant during transmission re-assembly), fishing bait (fishing lures manufacture), candles, concrete, crayons, electrical equipment, leather processing, modelling clay, munitions, paints and coatings (water sealants, lacquers, primers, and marine-based paints), paper applications (specialty paper manufacture), plastics and rubber (plasticizer and a mould release agent in plastics and rubber processing), polishes, printing ink, textiles (thread lubricant and as a finish for some fibres), veterinary applications (protective salve and lubricant), and food processing (food-grade grease, food release agent, and rust-preventatives for food processing equipment) (Healy 2005; CONCAWE 1999).

Due to the presence of PAHs at higher levels in unrefined (i.e., raw) petrolatum, and the possibility of carcinogenic activity, the European Commission's Consolidated List of C/M/R (Carcinogens, Mutagens, and Toxic to Reproduction Substances) includes all grades of petrolatums. However, when the full refining history is known for refined (e.g., USP-grade) petrolatum, and where the feedstocks have been shown to be devoid of carcinogenic activity, the European Commission considers petrolatum to not be carcinogenic (EC 2013). Therefore, USP and food-grade petrolatums are not considered to be carcinogenic (EC 2013; Faust 2012).

Petrolatum manufacturers in the US comply with specifications set out in the United States Pharmacopeia XX 1980 for white petrolatum or the National Formulary (NF) XV 1980 for petrolatum to ensure standards are met for consistency, colour, melting point and other physical-chemical parameters. The presence of PAHs is limited to residual levels by ensuring petrolatum satisfies the analytical procedure described in the *Code of Federal Regulations* (CFR) *Title 21 CFR 172.886(b)* (Faust 2012; US FDA 2014a), restricting the maximum PAH content of petrolatum by weight (w/w) to less than one part per million (Faust and Casserly 2003).

The US FDA requires that petrolatum intended for human consumption conform to impurity and use restrictions as set out in *172.880 (21 CFR 172.880)* (US FDA 2012). These regulations, as required to be met in Canada through compliance with the FCC, require that food-grade petrolatum be of USP or NF grades and comply with maximum UV absorbance limits (as set out in *21 CFR 172.886*). These regulations also set use limits for petrolatum in the US at 0.15% w/w in bakery products, 0.2% w/w in confectionery, 0.02% w/w in dehydrated fruits and vegetables, 0.1% w/w in egg white solids, and in raw fruits and vegetables in an amount not to exceed good manufacturing practices. Historical tests of food-grade waxes determined that most were well below the impurity limit and that manufacturers then, as now, easily produce food-grade petrolatum that meets these regulatory specifications (Faust 2012; Howard et al. 1965). A review of the USP for petrolatum is currently underway (US FDA 2014b).

The Food and Agriculture Organizations of the United Nations also require physical-chemical standards for petrolatum, as well as complying with UV absorbance limits (FAO/WHO 2006a; Howard et al. 1965). The European Food Safety Authority (EFSA) requires that petrolatum in foods be used on a *quantum satis* (the amount which is needed) basis as appropriate for the food type (EFSA 2013). EFSA estimates the petrolatum content in chewing gum to be 0.2% w/w, and the amounts on fruits, vegetables and confectionary items to be 0.02% w/w.

5.2 Slack Wax

In Canada, slack wax is found in chimney maintenance products (i.e., chimney cleaning logs), paints and coatings, and industrial metal protection materials, and may be found in a limited number of candles (Meridian 2009, Environment Canada 2011). It is classified as a List 3 formulant and is present in domestic weed control products and commercial-use wood preservative control products (PMRA 2006; personal communication dated May 2013).

Slack wax may also be used in lubricants (e.g., rust prevention, electrical connection lubrication, lubricant wax for smooth low tension wire and cable pulling), and paints and coatings (e.g., liquid membrane curing compound for concrete), and as polishing grease for industrial purposes (Meridian 2009). Paints and coating products can be used by consumers and industry (many distributors have been confirmed in Canada). Lubricant products have been confirmed in Canada but are industrial in nature. Polishing grease may be available to consumers through on-line purchase directly from the company (personal communication from Health Canada's Risk Management Bureau to Health Canada's Existing Substances Risk Assessment Bureau dated July 2010). Semi-finished petroleum waxes may also be present in fireplace logs and oriented strand board (OSB) (Kirk-Othmer Waxes 2001). Slack wax is also present in formulations of paraffin wax for paper coatings for food packaging applications (personal communication from Health Canada's Food Directorate to Health Canada's Existing Substances Risk Assessment Bureau, dated May 2013).

5.3 Oxidized Petrolatum

Industrial grade oxidized petrolatum is used for metal protection in industrial applications in Canada (Environment Canada 2011). Oxidized petrolatums, including CAS RN 64743-01-7, are also used as intermediates in industrial processes (US EPA 2006). No marketplace product uses were identified in Canada.

In Nordic countries, industrial uses of oxidized petrolatum in 2008 included wholesale and retail trade and repair of motor vehicles and motorcycles, manufacture of fabricated metal products, manufacture of machinery and equipment, wholesale trade, and manufacture of computer, electronic and optical products [Substances in Preparations in Nordic Countries (SPIN) database 2010]. Other use categories listed in the SPIN database include corrosion inhibitor (including rust inhibitors), surface treatment, lubricants and additives, paints, lacquers and varnishes, underseal materials, including

cavity seals, metal surface treatment remedies, lubricating grease and oil, base oils, surface treatment of metals (not paints, etc.), polishing agents, and lubricants (SPIN 2010).

Oxidized petrolatum is also used in industrial adhesives and sealants (corrosion prevention) as well as in industrial lubricants (lubricant for plastic, glass, metal and wood, etc.) (Meridian 2009; OECD 2014; personal communication from Health Canada's Risk Management Bureau to Health Canada's Existing Substances Risk Assessment Bureau dated July 2010; unreferenced), which could be found in Canada. As a rust preventative, it may be used in underseal products such as cavity seals (KEMI 2010). Other industrial uses include metal extraction as well as the refining and processing of metals (OECD 2014). The Swedish Products Register (KEMI 2010) lists 45 chemical products containing oxidized petrolatum, none of which are available to consumers (KEMI 2010).

6. Releases to the Environment

Petrolatum and waxes may be released into the environment from activities associated with production, transportation and/or storage, and as a result of commercial/industrial and consumer use.

Petrolatum and slack waxes are manufactured in Canada. Under typical operating conditions, release of these substances would be captured in a closed system, according to defined procedures, and returned to the processing facility or directed to a wastewater treatment plant. In both cases, exposure to the general population or the environment is not expected.

Non-regulatory measures (e.g., guidelines, best practices) are in place at petroleum sector facilities to reduce unintentional releases. Evaporative emissions of petrolatum and waxes are expected to be negligible.

Releases from washing or cleaning transportation vessels are not considered in this screening assessment because 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). Cleaning facilities require processing of grey water to meet local and provincial release standards.

Releases of petrolatum and slack wax (CAS RNs 8009-03-8 and 6472-61-6) to the environment may occur as a result of their presence in products available to the consumer (Meridian 2009). For example, petrolatum as found in some moisturizing lotions can be removed from the surface of the body after hand washing or showering, where it then enters the sewer or septic tank (CONCAWE 2001). Waxes float and are removed by primary and secondary treatment at municipal water treatment plants. These substances may compose a small fraction of total biosolids.

No manufacture in Canada of oxidized petrolatum (CAS RN 64743-01-7) was reported (Environment Canada 2011). This substance is expected to have minimal releases during loading, unloading, transport and industrial use due to the low import and use volumes reported (Environment Canada 2011). Additionally, current uses are limited to industry and, as such, releases are not expected to occur outside of industrial facilities.

Due to the low volatility of petrolatum, oxidized petrolatum and slack wax, losses to air would be negligible (CONCAWE 2001).

Petrolatum and waxes are not reportable to the National Pollutant Release Inventory (NPRI 2014). In addition, they are not identified in the US Toxics Release Inventory (TRI), as they are not tracked (TRI 2013). No additional data were found on releases to the Canadian environment.

7. Environmental Fate

When petroleum substances are released into the environment, four major fate processes will take place: dissolution in water, volatilization, biodegradation and adsorption. These processes will cause changes in the composition of these UVCB substances. In the case of spills on land or water surfaces, photodegradation—another fate process—can also be significant.

As noted previously, the solubility and vapour pressure of components within a mixture will differ from those of the component alone. These interactions are complex for complex UVCBs, such as petroleum hydrocarbons.

Each of the fate processes affects hydrocarbon families differently. Aromatics tend to be more water soluble than aliphatics of the same carbon number, whereas aliphatics tend to be more volatile (Potter and Simmons 1998). Thus, when a petroleum mixture is released into the environment, the principal water contaminants are likely to be aromatics, while aliphatics will be the principal air contaminants (Potter and Simmons 1998). The trend in volatility by component class is: alkenes = alkanes > aromatics = cycloalkanes. The most soluble and volatile components have the lowest molecular weight, which means there is a general shift to higher molecular weight components in residual materials.

Biodegradation is almost always operative when petroleum mixtures are released into the environment. It has been widely demonstrated that nearly all soils and sediments have populations of bacteria and other organisms capable of degrading petroleum hydrocarbons (Pancirov and Brown 1975). Degradation occurs both in the presence and in the absence of oxygen. Two key factors that determine degradation rates are oxygen supply and molecular structure. In general, degradation is more rapid under aerobic conditions. Decreasing trends in degradation rates according to structure are as follows (Potter and Simmons 1998):

- (1) *n*-alkanes, especially in the C₁₀–C₂₅ range, are degraded readily;
- (2) isoalkanes;
- (3) alkenes;
- (4) benzene, toluene, ethylbenzene, xylenes (BTEX) (when present in concentrations that are not toxic to microorganisms);
- (5) monoaromatics;
- (6) polynuclear (polycyclic) aromatic hydrocarbons (PAHs); and
- (7) higher molecular weight cycloalkanes (which may degrade very slowly (Pancirov and Brown 1975)).

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.

Some forms of slack wax are inherently biodegradable, with biodegradation rates from 26–48% over 28 days (Battersby et al. 1992). Primary biodegradation rates for slack wax over 21 days show a 50–73% loss (Battersby et al. 1992). There are no data on the biodegradation of petrolatum, although it is expected to contain similar components to slack waxes and therefore have similar biodegradation potential. Additionally, the *n*-alkane components in petrolatum are likely readily biodegradable, while the cycloalkanes and branched-chain alkanes are expected to degrade more slowly (CONCAWE 2001). Other studies have found that other waxes, not specific to this report, show between 21–80% degradation after 28 days and up to 98.5% mineralization after 137 days (API 2003). It was also found that the more refining a wax had undergone, the less rapid the biodegradation (API 2003) became. This is likely caused by the removal of readily biodegradable components during the refining process. No data on the biodegradation of oxidized petrolatum are available; however, other oxidized petrolatums showed slow hydrolysis (US EPA 2006).

Due to the complex interaction of components within a mixture that impact 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 petrolatum and waxes, the physical-chemical properties of representative structures of petrolatum and waxes (Table B.3 in Appendix B) were examined.

The C₁₂–C₅₀ alkanes have boiling points from 216 to 816°C. The individual components of petrolatum and waxes are characterized by very low to low water solubility (1.4×10^{-20} to 2.2 mg/L), very low vapour pressures (3.1×10^{-18} to 18 Pa), low Henry's Law constants (0.04 to 2.0×10^{11} Pa·m³/mol), high log K_{ow} values (4.7 to 24.4) and moderate to high log K_{oc} values (2.7 to 21.2) (Table B.2 in Appendix B). The low vapour pressure and Henry's Law constants indicate that petrolatum and waxes will not partition to air.

If released into water, components of petrolatum and slack wax are not expected to partition to water due to low water solubility (1.4×10^{-20} to 0.9 mg/L), with the exception of C₂₀ mono- and dicarboxylic acids (0.2 to 2.2 mg/L) present within oxidized petrolatum, which are slightly soluble. Due to the density of petrolatum and waxes (764–960 kg/m³), the substances are expected to float on the surface of water and thus exposure to sediment is not anticipated; although, if they do come into contact with sediment or particulate matter, they may sorb to it due to high log K_{oc} values.

Most components of petrolatum and waxes are expected to have very high sorption to soil (i.e., expected to be highly immobile) based on their moderate-to-high estimated log K_{oc} values. If released into moist soil surfaces, these components are not expected to volatilize based on their low Henry's Law constants and vapour pressures.

7.1 Persistence and Bioaccumulation

Due to the complex nature of petroleum substances such as petrolatum and waxes, the persistence and bioaccumulation potential of components of these substances is characterized based on empirical and/or modelled data for a suite of petroleum

hydrocarbon structures. These representative petroleum hydrocarbon structures do not represent all possible structures in petroleum substances, nor do they necessarily represent the full range of persistence or bioaccumulation potential present in any given chemical class of structures (e.g., alkanes, monoaromatics, etc.) or carbon number (e.g., C₁₀). 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.

7.1.1 Environmental Persistence

Persistence was characterized based on empirical and/or modelled data for a suite of petroleum hydrocarbons expected to occur in petroleum substances.

Model results and the weighing of information are reported in the supporting documentation on petroleum substance persistence and bioaccumulation (Environment Canada 2014). These data are summarized below and in Table B.5 in Appendix B.

Considering biodegradation in water, soil and sediment, the following components are expected to have half-lives greater than six months in water and soils, and greater than one year in sediment: C₃₀ and greater isoalkanes, C₅₀ and greater monocycloalkanes, C₁₅ and greater dicycloalkanes, C₁₈ and greater polycycloalkanes, C₁₂ monoaromatics, C₁₂ and greater diaromatics, C₅₀ monocycloalkane carboxylic acids, C₅₀ dicycloalkane monocarboxylic acids, and C₅₀ dicycloalkane dicarboxylic acids. C₃₀ to C₄₉ monocycloalkanes, C₁₂ to C₁₄ dicycloalkanes, C₁₄ to C₁₅ polycycloalkanes, and C₁₃ and greater monoaromatics also have half-lives greater than one year in sediments.

7.1.2 Potential for Bioaccumulation

Bioaccumulation potential was characterized based on empirical and/or modelled data for representative structures expected to occur in petroleum substances.

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 diet, which predominates for substances with log K_{ow} 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 (BSAF), trophic magnification factors and biomagnification factors were also considered in characterizing bioaccumulation potential.

Empirical and modelled bioaccumulation data for petroleum hydrocarbons, as well as the weighing of information, can be found in the supporting document (Environment Canada 2014). A summary of the results for bioaccumulation is presented below and in Table B.6 in Appendix B.

Overall, there is consistent empirical and predicted evidence to suggest that the following components have the potential for high bioaccumulation (relative to their concentration in water) with BAF/BCF values greater than 5000: C₁₃ to C₁₅ isoalkanes, C₁₂ to C₁₅ monocycloalkanes, C₁₂ and C₁₅ dicycloalkanes, C₁₅ monoaromatics, C₁₂ to C₁₃ diaromatics, C₁₄ and C₂₂ polycycloalkanes, C₁₅ monocarboxylic acids and C₂₀ dicarboxylic acids. 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 invertebrates, which decreases the potential for trophic transfer of these components.

Components greater than C₂₀ could not be modelled as their log K_{ow}s are greater than 8, which is outside of the domain of the model; however, components with such high K_{ow}s are generally not considered bioavailable (Arnot and Gobas 2006).

8. Potential to Cause Ecological Harm

8.1 Ecological Effects Assessment

8.1.1 Aquatic compartment

There are no known experimental aquatic toxicity data for the petrolatum and waxes considered in this assessment. One study was found on the toxicity of an oxidized petrolatum (CAS RN 68603-11-2) similar to CAS RN 64743-01-7, which was used as read-across data. The 96-hr LL₅₀ for rainbow trout (*Oncorhynchus mykiss*) was 3540 mg/L, and the 48-hr LL₅₀ for *Daphnia magna* was 7070 mg/L (US EPA 2006), indicating low acute aquatic toxicity of oxidized petrolatum.

For petrolatum and slack waxes, studies on the toxicity of the components of petrolatum and waxes were considered.

Aliphatics, in general, have low toxicity to both aquatic invertebrates and aquatic vertebrates. Drilling mud, produced by offshore drilling, is primarily composed of various aliphatics, and little to no acute or chronic toxicity has been observed in several studies on drilling mud (Hamoutene et al. 2004; Payne et al. 1995; Payne et al. 2001). A chronic 10-day exposure of the amphipod *Rhepoxynius abronius* to drilling mud (C₁₀–C₃₂) resulted in mean survival of less than 90% only at the highest concentrations of alkanes in sediment (6300 mg/kg dw) (Payne et al. 2001).

Based on the work of Adema and van den Bos Bakker (1986), *n*-alkanes, isoalkanes and cycloalkanes with carbon numbers greater than C₁₂ have low aqueous solubility and are unlikely to reach concentrations that could cause acute toxicity. Petrolatum and waxes are predominantly composed of alkanes, isoalkanes and cycloalkanes greater than C₁₂ (CONCAWE 2001).

CONCAWE developed an aquatic toxicity model specifically for petroleum hydrocarbon mixtures called PetroTox (2009). This model assumes chemical action via narcosis and therefore accounts for additive effects according to the toxic unit approach. It can model petroleum hydrocarbon toxicity for C₄ to C₄₁ compounds dissolved in the water fraction. Substances smaller than C₄ are considered too volatile to impart any significant toxicity, and compounds larger than C₄₁ are considered too hydrophobic and immobile to impart any significant aquatic toxicity. PetroTox (2009) generates estimates of toxicity with a median lethal loading (LL₅₀) rather than a median lethal concentration (LC₅₀) due to the insolubility of petroleum substances in water. The LL₅₀ value is the amount of a petroleum substance needed to generate a water-accommodated fraction (WAF) that is toxic to 50% of the test organisms. It is not a measure of the concentration of the petroleum constituents in the WAF.

The modelled ecotoxicological data in Table C.1 (Appendix C) indicate that LL₅₀s for algae, invertebrates and fish are all greater than 1000 mg/L. These results are based on a conservative estimate of the aromatic to aliphatic ratio which assumed that the

aromatic content of petrolatum and slack waxes was as high as 5% when, likely, the aromatic content is much lower.

8.1.2 Terrestrial compartment

Stubblefield et al. (1995) used white petrolatum as a control when testing for the toxic effects of weathered crude oil on mallard duck (*Anas platyrhynchos*) eggs. Petrolatum lowered hatching success when more than 33% of the shell was coated, likely due to the blocking of gas exchange through the shell. Additionally, the location of the petrolatum coating affected hatching success; coating the top and middle third of the egg resulted in 6.7 and 8.9% hatching success, respectively, while coating only one sixth of the top or middle of the egg resulted in 71.1 and 75.6% hatching success, respectively. Hatchling survival was not significantly different based on egg coating by petrolatum or crude oil (Stubblefield et al. 1995).

Petrolatum is frequently used as a control for skin patch tests due to its lack of demonstrated toxicological effects on mice and rats (Chiang and Maibach 2013). Therefore, it is considered to be of very low toxicity to mammals.

No toxicity information was available for petrolatum and waxes on soil organisms, birds or mammals.

8.2 Ecological Exposure Assessment

8.2.1 Aquatic compartment

Petrolatum and slack waxes may enter the water via wastewater following the use of products available to the consumer containing these substances. The very low solubility of petrolatum and slack waxes indicates that they will have negligible exposure to aquatic organisms within the water column. When released into water, they are expected to sorb to sediments and particulate matter if they come in contact with such materials. No data are available on the concentrations expected in wastewater or in sediment.

There are no known spills of oxidized petrolatum to water. Oxidized petrolatum may potentially enter the water via wastewater from industrial uses of these substances. The hydrocarbon components of this substance have very low solubility, meaning that only very low concentrations of these components are expected in water. The low solubility of the carboxylic acid components of oxidized petrolatum may cause limited exposure to aquatic organisms; however, most of the carboxylic acid components are not expected to persist in water or sediments for long periods, with the exception of those with a high carbon number (i.e., C₅₀). In addition, the low quantities of oxidized petrolatum imported (1000 to 10 000 kg) and in use (no uses reported above the 100 kg reporting threshold) in Canada (Environment Canada 2011) indicate that exposure to this substance will be low.

8.2.2 Atmospheric compartment

As these substances are not expected to volatilize into air, this compartment will not be considered further.

8.2.3 Terrestrial compartment

There are no known spills of these substances to soil. They may, however, be added to soil through the application of biosolids. In addition, while many hydrocarbon components are persistent, there is evidence that they are inherently biodegradable with appreciable degradation rates (see Environmental Fate section). Most carboxylic acids are also not expected to be persistent. Therefore, exposure via the addition of biosolids is not considered further.

8.3 Characterization of Ecological Risk

The approach taken in this ecological screening assessment was to examine available scientific information and develop conclusions based on a weight-of-evidence approach, as required under section 76.1 of CEPA.

No releases of slack wax or oxidized petrolatum (petrolatum was not queried) to environmental media were reported under the section 71 *Notice with respect to certain high priority petroleum substances on the Domestic Substances List* (Environment Canada 2011). Releases of oxidized petrolatum through industrial wastewater are considered minimal due to the limited use of oxidized petrolatum in Canada (no uses reported above the 100 kg reporting threshold (Environment Canada 2011)). If petrolatum and waxes are released into wastewater, considering that they are solid at environmentally relevant temperatures, they are expected to be captured in filtration systems at water treatment plants.

No direct toxicity information was available for these petrolatum and waxes in aquatic or terrestrial systems; however, read across information suggests low toxicity. In fact, all toxicity values are much greater than the expected solubility in water. In addition, most components of these substances are expected to have low bioavailability (i.e., those with greater than 20 carbons or log K_{ow} greater than 8) and only a few of the less than 20 carbon components are expected to have high bioaccumulation potential; only a very small proportion of the substances are expected to consist of these highly bioaccumulative substances.

There is no indication that petrolatum and waxes are released directly to water. If released into wastewater, concentrations are expected to be low due to their low (carboxylic acids) to very low (hydrocarbons) water solubility, and much lower than concentrations required to elicit toxicity. In addition, these substances are expected to be removed from water at wastewater treatment facilities. Therefore, concentrations in aquatic systems are expected to be very low. These low expected aquatic

concentrations, coupled with the low toxicity and bioavailability of the substances, indicate a low risk of harm to aquatic organisms.

Similarly, while sorption to sediment is expected if these substances are released into water, sediment concentrations are expected to be low due to the low water concentrations. If there is a continuous source of these substances to sediments, the concentration in sediments of some components (particularly the higher molecular weight structures) might increase due to their long half-lives; however, the more persistent higher molecular weight components are not considered bioavailable (Arnot and Gobas 2006). This and the low toxicity of these substances indicate low risk of harm to benthic organisms.

Removal of petrolatum and waxes during wastewater treatment might result in these substances being present in biosolids that might be applied to soils. No information regarding concentrations of petrolatum and waxes in biosolids is available. While no toxicity data for terrestrial species are available, terrestrial toxicity is expected to be low, consistent with that observed with aquatic species. Similar to sediments, higher molecular weight components of these substances might persist in soil due to their long half-lives; however, these components are not considered bioavailable. Therefore, the presence of these substances in biosolids is considered a low risk of harm to soil organisms due to their low toxicity and bioavailability. Additionally, no evidence was found suggesting that acute or reproductive toxicity occurs with exposure of petrolatum and waxes to terrestrial organisms.

Considering all available lines of evidence presented in this screening assessment, there is a low risk of harm to organisms and the broader integrity of the environment from petrolatum and waxes. It is concluded that petrolatum and waxes (CAS RNs 8009-03-8, 64742-61-6, and 64743-01-7) 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 a danger to the environment on which life depends.

8.4 Uncertainties in Evaluation of Ecological Risk

The proportions of each component in each petrolatum and wax substance are generally not known. As there are no ecological toxicity data on the CAS RNs studied in this assessment, read-across data on oxidized petrolatum and toxicity data available for some of the components of these substances were used. However, the low ecological toxicity of most of the components makes this information gap relatively unimportant for the assessment of ecological risk.

All modelling of the substance's physical-chemical properties and persistence, bioaccumulation and toxicity characteristics is based on chemical structures. As petrolatum and waxes are UVCBs, they cannot be represented by a single, discrete chemical structure; additionally, the specific chemical compositions of petrolatum and

waxes are not well defined. Petrolatum and waxes under the same CAS RNs can vary significantly in the number, identity and proportion of constituent components, depending on operating conditions, feedstocks and processing units. Therefore, for the purposes of modelling, a suite of representative structures that would provide average estimates for the entire range of components likely present was identified. Specifically, these structures were used to assess the fate and hazard properties of petrolatum and waxes. Given that more than one representative structure may be used for the same carbon range and type of component, it is recognized that structure-related uncertainties exist for this substance. The physical-chemical properties of 36 representative structures were used to estimate the overall behaviour of petrolatum and waxes in order to represent the expected range in physical-chemical characteristics. Considering the large number of potential permutations of the type and percentages of the structures in petrolatum and waxes, there is uncertainty in the results associated with modelling. However, the limited number of hydrocarbons theoretically present in petrolatum and waxes (based on the required boiling point ranges for petrolatum and waxes, which limits the carbon ranges of the components) also reduces the uncertainty in this approach.

Given the uncertainties associated with the model-estimated values, the reliance on such methods generates uncertainties in the prediction of persistence, bioaccumulation and toxicity (i.e., PetroTox).

Additionally, for petrolatum, limited information was submitted under section 71 of CEPA. However, due to the low ecological toxicity potential of petrolatum, this information gap is not critical for the assessment of ecological risk.

9. Potential to Cause Harm to Human Health

9.1 Exposure Assessment

The focus of the exposure assessment is to conservatively assess the level of exposure to petrolatum from the use of products available to the consumer and from food. Short-term exposures and incidental uses of products are considered, in addition to exposures from foods and from products that can be repeatedly used over time.

No releases of slack wax or oxidized petrolatum to environmental media were reported under the section 71 *Notice with respect to certain high priority petroleum substances on the Domestic Substances List* (Environment Canada 2011). Petrolatum was not queried due to the extent of information publicly available. Based on physical and chemical properties, petrolatum and waxes are non-volatile and do not dissolve in water. They exist in a solid/semi-solid phase in the environment, and are expected to be captured via filtration at water treatment plants. Given the insolubility of waxes, primary and secondary treatment would capture petrolatum entering sewage or septic tanks after washing or showering.

Characterizing direct exposure from the use of products available to the consumer covers any potential low exposure that may derive from environmental media.

9.1.1 Petrolatum (CAS RN 8009-03-8)

9.1.1.1 Regulatory framework

As detailed in Section 5 (Uses), in Canada, petrolatum found in drugs and cosmetics is subject to regulations that require their quality and safety. Products are made from highly-refined petrolatum of pharmaceutical grade (e.g., they meet USP standards) (Health Canada 2014). There have been no reports of unacceptable impurities of petrolatum used in cosmetic products regulated by Health Canada (Health Canada 2014).

Cosmetics

Petrolatum is currently not included on the List of Prohibited and Restricted Cosmetic Ingredients (more commonly referred to as the Cosmetic Ingredient Hotlist or simply the Hotlist), an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances, when present in a cosmetic, may contravene the general prohibition found in section 16 of the *Food and Drugs Act* or a provision of the *Cosmetic Regulations* (Health Canada 2009).

Pesticides

Petrolatum, classified as a List 4B formulant (Regulatory Directive) by Health Canada's Pest Management Regulatory Agency (PMRA 2010), is used in pest control products as insecticide and material and wood preservative (PMRA 2006, personal communication dated February 2010). Assessments of environmental and health effects of pesticides are conducted by Health Canada's Pest Management Regulatory Agency.

Pharmaceuticals and natural health products

Petrolatum may be used in certain pharmaceuticals and natural health products. It can also act as a release agent in tablet and pill production (Swarbrick 2006; Schueller 1999; Schramm 2002). Exposure to petrolatum from use as a medicinal or non-medicinal ingredient in pharmaceuticals and natural health products is considered incidental and limited relative to the exposure scenarios developed for food intake and use of other products available to the consumer.

9.1.1.2 Exposure analysis

Exposure to petrolatum may occur from food (predominantly oral route), or by the use of products available to the consumer (predominantly dermal route) such as personal care products (some being cosmetics, drugs, or natural health products) and pharmaceuticals. For the purpose of this document, a personal care product is defined as a substance or mixture of substances which is generally recognized by the public for use in daily cleansing or grooming. Depending on how the product is represented for sale and its composition, personal care products may fall into one of three regulatory categories in Canada: cosmetics, drugs or natural health products.

For a given exposure scenario, the primary route of exposure was considered to cover any incidental exposures that might occur through a secondary route, such as for lip balm, where dermal (primary) and oral (secondary) exposure may occur, or for apples, where oral (primary) and dermal (secondary) exposure may occur. The consideration of various exposure scenarios indicated that produce coatings containing petrolatum presents the potential for highest oral exposure, while the use of skin creams presents the potential for the highest dermal exposure (Appendix D). Exposure scenarios and estimates were developed using well-established exposure parameters and models, conservatism and professional judgement.

Dermal exposure from products available to the consumer

The products selected for the focus of general population exposure modelling were chosen because they generate the highest potential petrolatum exposures for that product category (i.e., based on frequency and amount of product applied, and containing the highest percent of petrolatum as ingredient). Exposures to petrolatum from products available to the consumer were estimated per item per age group (due to differences in body weights and use patterns), allowing the highest-exposed age groups to be identified.

Estimates of general population exposure to petrolatum from the use of products available to the consumer were calculated using ConsExpo 4.1 (ConsExpo 2006). Exposure factors for the Canadian population were taken from Health Canada guidance documents (Personal Care Product Modules I, II, III) (Health Canada 2013a) and ConsExpo fact sheets. Dermal exposure estimates for seven product categories and six age groups (from infant to adult) are summarized in Table D.2 of Appendix D.

The highest estimated dermal exposure to petrolatum was 321 mg/kg-bw per day for infants (0-6 months of age) for a single product (Table D.2 in Appendix D). There can be relatively high topical applications of petrolatum for various age groups. Infants, toddlers and children have the highest exposures based on body weight. However, these estimates do not provide insight into the degree of dermal uptake (i.e., absorption).

Dermal absorption

There are multiple lines of evidence that indicate that petrolatum is restricted to the stratum corneum (i.e., the outermost layer of the epidermis) and does not get absorbed systemically. Historically, this was recognized after conducting dermal absorption studies in laboratory animals (Sutton 1906; Bernard and Strauch 1927; Unna and Frey 1929).

In humans, Strakosch (1943) conducted a controlled and validated dermal absorption study where 14 dyed ointments including “petrolatum” and “Vaseline” were visualized by light microscopy for their degree of penetration through the skin. Samples were applied to thigh, forearm, back or abdomen, with skin biopsies taken up to 24 hours post-exposure. Tissue samples were appropriately processed and sections counter-stained to visualize and discount migration of free dye molecules; this allowed confirmation of the location and depth of penetration of each ointment. Petrolatum and Vaseline were found to be the “worst” penetrants, having “no penetration through the stratum corneum... [and] never found deeper than the upper looser layer of the stratum corneum”.

More recently, technological advances in microscopy have allowed confirmation of the restriction of petrolatum to the stratum corneum. Ghadially et al. (1992) used a lipid-soluble red dye and lead nitrate to trace the penetration of “Vaseline petroleum jelly” through the skin of hairless mice, after application to their flanks twice per day for 3 days. Electron microscopy showed that petrolatum was limited to the intercellular spaces of the stratum corneum, in both normal and acetone-perturbed skin. These results were repeated in mice using electron microscopy, with additional analysis by fluorescence microscopy (Brown et al. 1995; Mao-Qiang et al. 1995). Mao-Qiang et al. (1995) also used petrolatum as a negative control in a study of physiologic lipid metabolism in the skin, primarily because it is restricted to the stratum corneum and remains unmetabolized.

Brown et al. (1995) also used radiolabelled hydrocarbons as markers to assess the dermal absorption potential of petrolatum. Complimentary *in vitro* (pig skin) and *in vivo*

(acetone-treated, hairless mouse skin) tape stripping experiments with radiolabelled hexadecane (C_{16}) and docosane (C_{22}) mixed into different ointments including “Vaseline” and “petrolatum WITCO” were conducted. Radiolabelled hydrocarbons were not detected systemically (i.e., radioactivity was not found in receptor fluid nor in the blood). Approximately 99.3% and 98.8% of these two hydrocarbons, respectively, remained confined to the surface and stratum corneum *in vitro*. *In vivo*, approximately 98.4% of C_{22} was confined to the surface and stratum corneum (C_{16} was not used in this experiment). The log K_{ow} of these hydrocarbons are greater than 7.0, which may in part account for the restriction to the stratum corneum. Petrolatum typically contains hydrocarbons C_{25} - C_{85} and, therefore, the authors note their findings likely mimic a “worst-case” scenario for absorption (because their results are based on smaller hydrocarbons, the larger hydrocarbons found in petrolatum would be expected to exhibit less absorption). They state it is “extremely unlikely” that relevant quantities of hydrocarbons would become bioavailable from dermal exposure to petrolatum.

In recent studies in humans, microscopic analysis has confirmed the restriction of petrolatum to the surface of the skin and the stratum corneum (Patzelt et al. 2012; Stamatas et al. 2008). These studies were conducted in adults, but it is also known that neonatal skin including the stratum corneum is fully developed at term, and the structure and function of skin is fully developed before the first post-natal month (Zhai 2008). It has also been shown that the skin of 6-10 month olds has similar barrier characteristics as adult skin regarding lack of absorption of mineral oil (Stamatas et al. 2008). Therefore, petrolatum restriction to the stratum corneum is considered to be consistent across age groups.

Oral exposure from foods

After consideration of the food types that may contain petrolatum (e.g., fresh produce, dried fruits and vegetables, bakery goods, confectionary, etc.), wax coatings (i.e., a thin layer of petrolatum on certain fruits and vegetables) were considered to provide the largest potential exposures to petrolatum. Existing exposure factors were used to generate oral exposure estimates from the consumption of wax coatings on produce.

According to the *Food and Drug Regulations*, the highest level of petrolatum permitted in produce is 0.3% w/w. This value has been adopted for the petrolatum oral exposure scenario (Table D.1 in Appendix D). However, the residual concentration of petrolatum in a standard food coating has been estimated in one study to be 44 mg/kg-product (0.004% w/w) (Inchem 2010), 75 times less than the regulatory limit. Similarly, it is 1–2 orders of magnitude greater than measurements and estimations from European jurisdictions [EFSA 2013]. Therefore, the use of 0.3% w/w in generating the oral exposure estimates is considered conservative.

A generic exposure scenario was therefore developed. An apple (200 g) was considered to contain a petrolatum coating of 0.3% w/w (600 mg), and the peel fully consumed, while noting that infants (0-6 months of age) likely have low or no exposures. Petrolatum exposure estimates across age groups under this scenario

ranged up to 38.7 mg/kg-bw (for toddlers) for exposure from one apple (Table D.1 of Appendix D). This scenario is considered conservatively representative of ingestion of any produce item that may contain a petrolatum-based wax coating. In addition, use of the maximum default value for petrolatum content (0.3% w/w) introduces conservatism to cover the potential for exposure to petrolatum that may occur from other foods, or from ingestion of proportionally more petrolatum-coated produce items on any given day. It is acknowledged that refining the various conservative exposure parameters would likely result in lower estimates of exposure.

Next, the recommended number of servings by age group, according to Canada's Food Guide, was used to estimate total daily exposure from food. Total exposure from foods was calculated by multiplying the estimate from a single food item (Table D.1 of Appendix D), by the recommended number of fruits/vegetables. One-third of this daily intake was considered to contain an edible and frequently consumed skin/peel containing petrolatum, consistent with the fact that 8 of 24 fruit and vegetable types that may contain petrolatum have edible skins/peels (CMPA 2014). The edible skins/peels were not considered to be scraped or removed.

Daily oral exposure (per age group) = upper-bound petrolatum exposure estimate from one apple × recommended number of produce servings × fraction of petrolatum-coated produce with edible skins/peels

The highest estimated oral exposure to petrolatum was 51.6 mg/kg-bw per day for toddlers (6 months to 4 years of age) (Table D.1 in Appendix D).

The EFSA estimated the aggregate petrolatum exposure for different age groups based on their maximum permitted levels (MPLs) of petrolatum in different food groupings (EFSA 2013). Their exposure values are approximately an order of magnitude smaller than values calculated for oral exposures in Table D.1 of Appendix D. This is in part a reflection of the use of different maximum permitted levels by each jurisdiction in the respective calculations.

In the US, a detailed analysis by Heimbach et al. (2002), based on maximum allowed regulatory values in different food categories and consumption patterns of different foods, determined the average exposure to mineral hydrocarbons including white mineral oils, paraffin waxes, microcrystalline waxes, and petrolatum. The average petrolatum exposure was estimated to be 0.4 mg/kg-bw per day. This exposure was for the 60 kg weight group and is approximately 65 fold less than exposures calculated herein for a similar weight group (teenagers; see Table D.1 in Appendix D). This suggests the estimates in Table D.1 are conservative.

9.1.1.3 Compositional analysis of products available to the consumer

Although there are regulatory requirements (i.e., pharmacopeia standards) for marketplace petrolatums, there has been general concern over potential risk from

residuals that might remain after refining. Given this concern, 20 randomly selected, readily available Canadian products, with petrolatum contents from 20 to 100%, were tested at high resolution for 16 PAH species. The product categories identified for testing were chosen based on highest proportion of petrolatum as an ingredient, and greatest use frequency and/or volume by the general population, and included some products that can be used on infants, toddlers and children (see Section 3 Physical and Chemical Properties for more testing details).

Compositional testing revealed that most products did not contain PAHs, or contained only a few residues detectable on the order of low parts per billion (when a residual PAH was detected, its median concentration was approximately 0.000001% w/w) (Appendix F). The PAHs detected at the highest concentrations were found to have low toxicological potency relative to benzo[a]pyrene (B[a]P) (Appendix F,G). The residual level of PAHs in these products indicates that the petrolatum used as formulant/ingredient meets food grade standards for ingestible petrolatum (required to contain approximately <1000 ppb PAH residuals) (Faust and Casserly 2003; US FDA 2012). The purity of these products is also consistent with recent reports of the status of North American petrolatum manufacturers following best practices (Faust 2012).

Oral bioavailability

Because petrolatum in Canadian products was shown to meet purity standards of food-grade petrolatum, the product testing results were considered to be representative of food-grade petrolatum for the purpose of characterizing risk from potential oral exposures to residual PAHs. Using maximum estimates of exposure to petrolatum (Appendix D), together with the results from compositional testing of petrolatum-based products, proportional upper-bounding oral exposure estimates to residual PAHs were generated (see Characterization of Risk to Human Health). For these potential oral exposures to residual PAHs, bioavailability was considered to be 100%.

Dermal bioavailability

There are multiple lines of evidence to indicate that residual PAHs in petrolatum would exhibit limited diffusion through the skin following dermal exposure.

For absorption to occur (and given that petrolatum remains restricted to the stratum corneum), the residual PAH residues entrained within petrolatum would likely require preferential diffusion from the hydrophobic and viscous petrolatum matrix. For soils contaminated with PAHs, the US EPA uses a conservative migration/dermal uptake factor of 13% to account for the inhibitory effect of the soil matrix on PAH uptake by the skin. Knafla et al. (2011) recently determined that B[a]P spiked into clay and sandy-weathered soil had relative dermal retention of 2.2 to 4.4% compared with B[a]P in acetone. Similarly, the extent of B[a]P binding *in vivo* to mouse skin DNA showed approximately 10 to 15 times more binding from acetone compared with a low viscosity oil (Ingram and Phillips 1993). Higher viscosity oils were shown to inhibit PAH absorption by approximately six-fold, relative to lower viscosity oils (CONCAWE 1990).

Studies of the influence of matrix on migration have indicated that lipophilic solutes (such as PAHs) are best suited to migrate from aqueous solutions, whereas hydrocarbon-based vehicles (such as petrolatum) may compete with that migration (CONCAWE 2010, 1990; Zhai 2008). Additionally, Brown et al. (1995) showed that smaller hydrocarbons (with high log K_{ow} values) exhibit dermal uptake from petrolatum at less than 1 to 2%. The PAHs given in Appendix F are also highly hydrophobic, with log K_{ow} values ranging from 3.37 (naphthalene) to over 6.0 (Sangster 1989, de Maagd et al. 1997). Therefore, by analogy, these values indicate they would likely remain sequestered within petrolatum, and thus sequestered within the stratum corneum, resulting in limited uptake. In general, PAHs associated with carcinogenicity have a high log K_{ow} and are poorly adsorbed from a hydrophobic matrix.

Studies in humans of high dermal exposure to PAHs have indicated a limited potential for PAH absorption from matrices and ointments containing petrolatum. Van Rooij et al. (1993) used a 10% coal tar ointment (10% coal tar in 40% Vaseline, 25% zinc oxide, 25% starch and 10% paraffin) with a 6 hour occluded exposure followed by urinalysis of pyrene metabolites. Coal tar is a complex mixture predominantly composed of PAHs, and in this study, 11 of 16 priority pollutant PAHs comprised 5.6% of the coal tar ointment (roughly 6 to 7 orders of magnitude higher concentration than the residual levels found in marketplace petrolatum). In this study, pyrene uptake was found to occur at a low level (0.3-1.4%). The results are limited to analysis of a single PAH species of lower molecular weight, but the authors indicate the extent of absorption may be similar between structurally-related PAHs. It is also unknown how representative a 10% coal tar ointment is to a refined petrolatum that contains only residual PAHs. The coal tar ointment, having different physical-chemical properties, may exhibit greater dermal absorption/diffusion relative to petrolatum, especially given the high PAH concentration. Occlusion also likely enhanced the fraction of pyrene absorbed in this study.

In a similar study, Storer et al. (1984) used petrolatum spiked with 2% coal tar that was dermally applied (self-administered) to 5 human volunteers at their residences over a two day period. Blood PAH levels were compared pre- and post-exposure, with a 9-day period spanning these samples (Storer et al. 1984). Post-exposure, many PAHs were not detected in blood. In two individuals, of 23 PAH species analyzed, only 2 and 3 PAHs were found to be elevated in the blood after exposure; the other three individuals showed elevations for 9, 10 and 11 PAH species. Notably, a three to four fold variation between persons is not unusual, and three to four fold differences in adsorption coefficients are common. Table 3 in Van Rooij et al. (1993) shows a 1.93 fold 'between person' variability over all sites; Table 4 shows an average 2.7 fold 'between person' variability over all application sites. However, the combined results from the 5 volunteers in Storer et al. (1984) are difficult to reconcile unless they can be accounted for by striking inter-individual and inter-PAH differences in dermal uptake and/or metabolism. It has been shown that inter-individual differences only account for 7% of the variance in absorption rate constants for dermally-applied PAHs, as determined by surface disappearance measurements using fluorescence microscopy (Van Rooij et al. 1993). If a 7% variance is accurate, Storer et al. (1984) could have expected to see measurable increases of the same PAH species/metabolites in the blood across the 5

individuals. The disparate absorption results in Storer et al. put into question the study design, that may be explained by artefactual results due to the lack of controlling for important confounding factors such as oral and/or inhalation exposure to PAHs from other sources (from food and/or environment) that could have occurred during the 9-day period that elapsed between the baseline blood sample and the cessation of the 2-day exposure protocol. The possibility of the occurrence of exposures to other sources of PAHs cannot be ruled out. Although the study design is questionable, because these individuals were in fact dermally exposed to a high level of PAHs, the results do corroborate that systemic availability of PAHs is likely limited following dermal exposures. That is, many of the PAHs found in the coal tar ointment were not found in blood, or were shown to be only slightly elevated. Calculations based on assumptions of blood volume suggest most of the 'absorbed' PAHs exhibited 1-2% or less absorption (if in fact the PAHs that were shown to be absorbed originated from the coal tar ointment).

Quantifying the absorption potential of residual PAHs in general from USP petrolatum is not possible from the studies of dermal exposure to coal tar ointments, but the results do add to the multiple lines of evidence that indicate absorption is low. Negative findings in urinary mutagenicity studies after dermal petrolatum (control group) exposures also support limited or negligible PAH uptake following exposure (Wheeler et al. 1981).

Together, the evidence indicates dermal absorption of residual PAHs from petrolatum is limited.

9.1.2 Slack wax (CAS RN 64742-61-6)

Slack wax is found in a limited number of products available to the Canadian general population, including adhesives (e.g., wood sealer), pesticides and a limited number of candles. Use of these products by the general population may result in incidental dermal or oral exposures.

Additional slack wax products, including chimney maintenance products (i.e., chimney cleaning logs), paints and coatings and other industrial uses were considered but not expected to result in significant general population exposure, as most were industrial in nature or did not have major or repeated general population uses. The focus of the exposure assessment for slack wax was on potential broader exposures to the general population.

Slack wax is a List 3 formulant used in domestic weed control products and has commercial use in wood preservative control products (PMRA 2006, personal communication from Health Canada's Pest Management Regulatory Agency to Health Canada's Existing Substances Risk Assessment Bureau dated May 2013).

Slack wax may be found in a limited number of candles; although incidental dermal and oral (i.e., mouthing) exposure might occur, these types of exposure are not expected to cause toxicological harm based on the inert nature of the substance. The amount of wax absorbed at body temperature after oral exposure is unknown, although a certain

fraction of mineral hydrocarbons (approximately C₁₇–C₃₂) has been shown to be readily retained by humans (Concin et al. 2008, 2011). Longer chain hydrocarbons are expected to be metabolized, or not absorbed and pass through the gastrointestinal tract.

9.1.3 Petrolatum (oxidized) (CAS RN 64743-01-7)

Oxidized petrolatum was reported to be used only in industrial applications (Environment Canada 2011). Therefore, because use is restricted to industry, general population exposures to oxidized petrolatum from industrial uses are not expected. Any potential indirect exposures from the presence of oxidized petroleum residues on products (i.e., from its use as a metal polishing agent) are expected to be negligible and to be covered by the risk characterization of direct exposure to products available to the consumer containing petrolatum (CAS RN 8009-03-8).

10. Health Effects Assessment

The health effects database on petrolatum and waxes (CAS RNs 64743-01-7, 8009-03-8 and 64742-61-6) is limited, and therefore surrogate substances were also considered where appropriate (i.e., a read-across approach). Health effects data on substances with similar physical-chemical properties (i.e., similar streams from the refining process) were considered. Microcrystalline wax and high viscosity oils (white/medicinal and high viscosity mineral oils) were considered the most representative surrogates of petrolatum, whereas paraffin wax and low viscosity oils were considered most representative of slack wax. Some sources indicate that blended petrolatum contains microcrystalline and/or paraffin wax hydrocarbons and either low or high viscosity white oil (Parkash 2010a-c); therefore, these substances were also considered. Appendix E contains a summary of the available health effects information in laboratory animals for petrolatum and waxes. Key studies selected to illustrate the potential health effects are summarized below.

Petrolatum and wax substances have low acute toxicity in laboratory animals. Single oral or dermal exposures of up to 5000 mg/kg-bw had no adverse health effects, and a lethal dose (LD₅₀) was only established in one study for microcrystalline wax at 10 000 mg/kg-bw (Elder 1984). A petrolatum-paraffin wax mixture produced mild erythema in an open patch test as well as slight eye irritation in rabbits (CONCAWE 1999). Petrolatum was not sensitizing to guinea pig skin (Kuhn 1995) and in humans a USP grade was virtually non-sensitizing in approximately 80 000 individuals (Schnuch et al. 2006). However, some evidence suggests that certain individuals may be susceptible to sensitization by petrolatum (i.e., to residual levels of PAHs), but this is a rare effect and some consider the evidence equivocal (Dooms-Goossens and Degreef 1983; Faust 2012; Marzulli and Maibach 2008; Ulrich 2004).

Female F344 rats exposed to low melting point wax or class II/III medium/low viscosity white oils at 2% in their daily diet for 90 days exhibited accumulation of mineral hydrocarbons in the liver, small intestine, heart and kidneys. Histopathological findings included calcification in the kidneys, inflammation of the mitral valve, minimal to marked liver granulomas, and mesenteric lymph node histiocytosis and cell necrosis (BIBRA 1992, 1993, 1999; Miller et al. 1996; Scotter et al. 2003; Griffis et al. 2010). A more recent study did not observe accumulation of light white oils in female F344 rats after 90 days exposure to 0.02, 0.2 and 2% in the diet (McKee et al. 2012). Evidence suggests that the adverse effects listed above are more severe or consequential in the F344 rat (relative to SD rats) because mineral oil hydrocarbon elimination is lower and bioavailability higher. There is some evidence that these effects are reversible and may be related to increased hydrocarbon absorption, hepatic accumulation and immunological sensitivity of the F344 rat (Carleton et al. 2001; Griffis et al. 2010; Trimmer et al. 2004; JECFA 2012). Rat liver microgranulomas, due to oral exposure to class II/III low/medium viscosity oils, are considered a critical health effect by the World Health Organisation (JECFA 2012). In humans, a certain mineral hydrocarbon range (C₁₇–C₃₂) was shown to be retained in adipose tissue (Concin et al. 2008, 2011), and is

similar to the range accumulated in the rat (Scotter et al. 2003). Mineral oil-induced histological changes can also occur in the human liver and in the hepatic node and spleen; these include intra- and extracellular lipoid accumulations. These effects have been considered clinically unimportant in humans because there is no evidence of a concurrent inflammatory response (Carlton et al. 2001; Miller et al. 1996). With these considerations, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) recommended acceptable daily intakes (ADI) for high viscosity oils and class I medium/low viscosity oils at 0–20 and 0–10 mg/kg-bw per day, respectively (JECFA 2006, JECFA 2013b); ADIs for class II/III medium/low viscosity oils are pending a safety assessment (Trimmer et al. 2004; JECFA 2012), and specifications for medium viscosity mineral oils have recently been revised (JECFA 2013a).

The potential for carcinogenicity of petrolatum of varying purity has been investigated in several studies. A two-year feeding study in rats (50 per sex per group) used blended marketplace samples of each of three grades of petrolatum, grade A (“snow white”), grade B (“white”) and grade C (“yellow”), at 5% (approximately 3100 mg/kg-bw/day) in the diet. Necropsy and examination for development of various tumours revealed no significant differences other than an increased incidence of mammary adenocarcinoma (3% in control females vs. 4% in females receiving grade A, and 8% in females receiving either grade B or C). However, this was considered by the authors to be sporadic and not related to test substance. Periodic analysis of the blood, serum and urine, food efficiency and survival rates, and gross and histological organ examination revealed only a limited number of potentially exposure-related changes: an increased incidence of enlarged livers (13% for grade A; 7% for grade B) and lung congestion (28% for grade A; 16% for grade B) compared to 0% for rats fed grade C or for controls (Oser et al. 1965). It is unclear why rats fed grade C petrolatum, the least refined substance, did not exhibit the same changes, but these effects could be related to the presumable higher sensitivity of rats to mineral oil hydrocarbons, or possibly to differences in blending components across grades. The same authors also used the three blends of petrolatum for a single subcutaneous administration in mice (50 per sex per group) and conducted similar analyses. No substance-related effects were seen other than chronic inflammation and localized fibrotic changes consistent with the subcutaneous presence of foreign material (Oser et al. 1965).

Long-term petrolatum dermal exposure studies have also failed to show a carcinogenic effect. Lijinsky et al. (1966) applied a NF grade of amber petrolatum (60 µL of a 15% solution in isooctane) to the skin of mice twice weekly for two years. Two of the mice in the exposed group (n=70) and two mice in the vehicle control group (n=100) each developed a skin tumour that did not regress. Therefore, this sample of amber petrolatum was concluded by the authors to not be a dermal carcinogen. This particular sample was identified in a previous study as having over 14 parts per million PAHs, and would not have passed current US FDA purity standards for use in foods (Lijinsky et al. 1963, 1966). PAHs extracted and concentrated from this historical sample were shown to have some carcinogenic activity (Lijinsky et al. 1966).

Kane et al. (1984) applied petrolatum (derived from solvent-refined residual oil: CAS RN 64742-01-4) and slack wax (derived from solvent-refined heavy paraffinic distillate: CAS RN 64741-88-4) at 25 mg (830 mg/kg-bw) to mice twice weekly for 80 weeks. These test substances did not produce any skin tumours in two independent trials for each substance. Kane et al. (1984) also showed that medicinal paraffin oil was not a dermal carcinogen, and that solvent-refining of carcinogenic oil base stocks (similar to upstream petrolatum blending components) results in a significant reduction and elimination of carcinogenic activity.

Five petroleum waxes, selected to represent the range of PAH content of hundreds of food and food-packaging petroleum waxes, were assessed for their potential carcinogenicity in lifetime skin painting studies in mice and rabbits (Shubik et al. 1962). Wax solutions (15% in benzene) were used, resulting in repeated dermal exposures to petroleum waxes of approximately 250 mg/kg-bw for mice and 3.3 mg/kg-bw for rabbits. Desquamation and epilation were noted in the skin of both species. There were no significant differences in tumour formation between exposed and control groups, and tumours were mostly benign papillomas. Two skin papillomas were noted in one of the rabbit groups, but the results are reported to be within levels seen in historical controls and therefore were considered, by the authors, not to be treatment-related (Shubik et al. 1962). This is consistent with results of lifetime petroleum wax feeding studies, which were also negative for carcinogenicity (Oser et al. 1965; Shubik et al. 1962).

Other lines of evidence support the lack of carcinogenic activity for finished petrolatums. IARC (1984) indicated that semi- and fully-refined petrolatums, when produced from oils subjected to severe hydrogen treatment, are not carcinogenic. It concluded there is no evidence in laboratory animals for the carcinogenicity of class 5 petrolatums and white oils (blending components of petrolatum) and that highly-refined oils are not classifiable as to their carcinogenicity to humans (Group 3; IARC 1984, 1987, 1998). These classifications and rationale are further supported by test results showing that refined feedstocks used as blending components of petrolatum (i.e., hydrogenated lubricating oil basestocks) easily pass the IP 346 test that determines PAH content (CONCAWE 1994; Faust and Casserly 2003; IP 1985, 1993). This test, adopted by the European Commission, is similar to US EPA Method 8100 (US EPA 1986) and measures the total weight of aromatics (that includes monoaromatics and PAHs) in a sample; if found to be less than 3%, the sample is not considered by the European Commission to be carcinogenic (CONCAWE 1995; OJ C 1994; US EPA 2006; Mackerer et al. 2003). Additionally, food-grade petrolatum must meet USP or National Formulary pharmacopeia standards, in addition to complying with UV absorption limits, thus limiting the level of PAHs and ensuring quality and a standard of purity. The available evidence demonstrates that fully-refined, marketplace petrolatum is not carcinogenic by either the dermal or oral exposure routes.

The European Commission has categorized petrolatum (CAS RN 8009-03-8), oxidized petrolatum (CAS RN 64743-01-7) and slack wax (CAS RN 64742-61-6) as Category 1B carcinogens ("may cause cancer") (European Commission 2008a). This derives from the possible carcinogenic potential of unrefined or mildly refined substances that may

contain carcinogenic PAHs. However, the EU considers these three CAS RNs not to be carcinogenic when their full refining history is known, and when their feedstocks are shown to be devoid of carcinogenic activity (European Commission 2008a). Thus, petrolatum and waxes that meet regulatory standards of purity are not classified as carcinogens.

Although only residual levels of PAHs were shown to be present in some petrolatum products, and therefore do not present a concern for carcinogenicity, PAH species can have a wide potency range. IARC (2010) recently reviewed the carcinogenicity data in experimental animals for 60 PAHs: 13 have sufficient evidence, 16 have limited evidence and 31 have inadequate evidence. Some PAHs, including benzo[a]pyrene (B[a]P) are classified as Category 1B carcinogens “*presumed to have carcinogenic potential for humans, largely based on animal evidence*” by the European Commission (2008a). PAH species that have sufficient toxicological information can be ranked according to toxicological potency relative to B[a]P (Appendix G).

The Government of Canada previously completed a human health risk assessment of certain PAHs, including benzo[a]pyrene (B[a]P), under the Priority Substances List Program. Based primarily on the results of carcinogenicity bioassays in animal models, five PAHs were considered “probably carcinogenic to humans,” substances for which there is believed to be some chance of adverse effects at any level of exposure (Canada 1994). PAHs were added to the List of Toxic Substances in Schedule 1 of CEPA.

The US EPA previously identified PAHs that may be carcinogenic in animals and humans (US EPA 1992, 2014), ultimately listing 16 substances that became known as the ‘priority pollutant’ PAHs (Menzie et al. 1992). They 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.

Several authors have created toxic or potency equivalency factors (PEFs) for numerous PAH species (i.e., estimates of their carcinogenic potency relative to that of B[a]P) (CCME 2008). PEFs as developed by Nisbet and LaGoy (1992) were used in this assessment (Table G.1 of Appendix G). The PEF approach to estimating carcinogenic potency is an accepted method for human health risk assessment of PAH-rich mixtures, and has been widely used by several international organizations (European Commission 2008b; WHO 1998, 2001). The PEF approach has been adopted herein as a method to characterize a theoretical risk of systemic carcinogenicity from oral exposure to petrolatum. It is noted that the empirical evidence to date supports and shows that marketplace petrolatum is not carcinogenic.

Using US EPA Benchmark Dose Software (BMDS 2.3.1) and a LogLogistic model, Health Canada used the B[a]P-specific tumour data in mice provided in Culp et al. (1998) to derive a lower limit of a one-sided 95% confidence interval of a carcinogenic

benchmark dose for B[a]P. This reference value, referred to as an oral BMDL₁₀, was calculated to be 0.545 mg/kg-bw/day, and is based on forestomach papillomas and/or carcinomas in female B6C3F1 mice (Health Canada 2015). This is of the same order of magnitude as oral BMDL₁₀ values for B[a]P derived by other groups, including the World Health Organization (WHO). Using tumour data based on exposure to coal tars in mice, JECFA calculated a BMDL₁₀ range for B[a]P of 0.1-0.23 mg/kg-bw per day (FAO/WHO 2006b). Wester et al. (2012) recently proposed 3 mg/kg-bw/day based on hepatocellular carcinomas in B[a]P-exposed Wistar rats. Health Canada's Guidelines for Canadian Drinking Water Quality proposed a maximum acceptable daily intake concentration of 0.04 µg/L for B[a]P (Health Canada 2015).

10.1 Characterization of Risk to Human Health

Petrolatum and waxes (CAS RNs 8009-03-8, 64742-61-6 and 64743-01-7) were identified as high priorities for action during categorization of the DSL, as they were determined to present the greatest potential or intermediate potential for exposure of individuals in Canada and were considered to present a high hazard to human health. A critical health effect for the initial categorization of these substances was carcinogenicity based on classifications by international agencies. Petrolatum, slack wax and oxidized petrolatum are classified as Category 1B carcinogens by the European Commission (European Commission 2008a), but with the disclaimer that they are not carcinogenic if their feedstocks are not carcinogenic.

10.1.1 Petrolatum

Dermal petrolatum exposure from products available to the consumer

The highest dermal exposure to petrolatum was estimated to be 321 mg/kg-bw per day for infants aged 0–6 months, from exposure to petroleum jelly (Appendix D). Adverse effects were not identified in short-term studies of laboratory animals orally or dermally exposed to high levels (2000 to 5000 mg/kg-bw) of petrolatum or related substances (CONCAWE 1997, 1999; Elder 1984; McKee et al. 1987b; US EPA 2006). Adverse effects were not identified in humans in a retrospective analysis of approximately 80 000 individuals dermally exposed to petrolatum (Schnuch et al. 2006). Additionally, the marketplace penetration of petrolatum is extensive, being available over many years in thousands of products. There is therefore no human or animal dermal toxicological endpoint on which to base a critical effect level for the generation of a margin of exposure; thus, the characterization of risk from dermal exposure is qualitative. The evidence demonstrates that petrolatum has low toxicity (i.e., it is inert), and dermal exposures are therefore not expected to constitute a risk to human health.

Oral petrolatum exposure from foods

The highest daily oral exposure to petrolatum from foods was estimated to be 51.6 mg/kg-bw/day for toddlers aged 6 months to 4 years, from a sentinel exposure scenario that considered consumption of wax coatings on produce (Appendix D). No

clinically-significant signs of toxicity were observed in laboratory animals exposed to 5000 mg/kg-bw petrolatum or related substances, and repeated dosing oral exposures have not resulted in relevant adverse health effects. While certain effects have been seen in Fisher rats after subchronic exposure to mineral oils, these are not considered to be relevant to humans. Therefore, the evidence demonstrates that petrolatum has low toxicity (i.e., it is inert), and oral exposures are not expected to constitute a risk to human health.

Dermal exposure to residuals

Due to the presence at residual levels of PAHs in some petrolatum products available to the consumer (Appendix F), and the known carcinogenic potential of some PAHs, it has been suggested that petrolatum may have carcinogenic activity. However, the empirical evidence indicates that petrolatum, as available to Canadian consumers, is not carcinogenic nor mutagenic in short-term genotoxicity studies. A diverse array of evidence demonstrates a lack of toxicity and lack of carcinogenicity for refined petrolatum. This includes corroboratory empirical evidence from toxicological studies in animals, from epidemiological studies in humans, and from a long history of product use. Product testing showed that residual PAH levels are lower than the approximately 1000 ppb level permitted in foods according to regulatory requirements. In addition, dermal exposure studies have consistently demonstrated that petrolatum remains restricted to the outermost layers of the skin (both in animals and in humans), indicating it (as well as any residual PAHs entrained within) likely has limited uptake. There is a high probability based on the octanol:water partition coefficients of PAHs that they would tend to remain in the lipophilic environment of petrolatum rather than traverse into the dermis.

Multiple historical studies have shown that petrolatum does not cause tumours from repeated exposures over the long term in animals (Kane et al. 1984; Lijinsky et al. 1963, 1966; Oser et al. 1965; Shubik et al. 1962). There is no evidence to date linking the use of petrolatum-containing products to a critical hazardous effect of petrolatum in humans.

Petrolatum is restricted to the outermost layers of the skin, as demonstrated by multiple studies. Strakosch (1943) showed in humans that petrolatum was the worst skin penetrant of 14 ointments. In mice, petrolatum remained restricted to the stratum corneum despite repeated dosing, or application to perturbed (i.e., acetone-treated) skin (Brown et al. 1995; Ghadially et al. 1992; Mao-Qiang et al. 1995). Spiked petrolatum containing radiolabelled short-chain hydrocarbons showed limited alkane diffusion from petrolatum into deeper layers of the skin, indicating that higher carbon number hydrocarbons (as found in petrolatum) would likely exhibit little or no absorption (Brown et al. 1995). Confirmation of restriction of petrolatum to the surface of the skin has recently been repeated in humans by laser scanning fluorescence and confocal microscopy (Patzelt et al. 2012; Stamatas et al. 2008). Summaries of these studies can be found in Section 10.1.1.2 'Exposure analysis'.

Regulations require that food-grade petrolatum meets pharmacopeia standards and passes UV absorbance criteria that sets impurity limits (US FDA 2012; US FDA 2014a); PAHs are therefore restricted to approximately less than 1 part per million (<1000 parts per billion) (Faust and Casserly 2003). High resolution testing of 20 (non-food) petrolatum-containing products available to the consumer has shown the median concentration of detectable PAHs (of 16 species analysed) of 12.6 parts per billion (0.000001% w/w) (Health Canada 2013, unpublished). Most PAHs were below the detection limit of 0.5 or 1 parts per billion or 5 or 10 ppb in most products. The results from this testing corroborate reports of petrolatum manufacturers consistently producing refined petrolatum that complies with regulatory specifications.

The weight of evidence demonstrates limited or negligible uptake of petrolatum after topical application. Negligible exposure to residual PAHs are expected, given their low levels (0.000001% w/w) (when present), and the viscosity and hydrophobicity of the petrolatum matrix that restricts diffusion and limits uptake of PAH molecules. Risk is therefore considered to be low.

Oral exposure to residuals

Although refined petrolatum in the Canadian market complies with regulations (i.e., food grade or pharmacopeia standards of purity, as applicable), there has been general concern over potential risk from residual PAHs that may remain after refining. A theoretical systemic risk of cancer, based on the carcinogenic potential of PAHs, was therefore characterized. Estimates of exposure to PAHs, as represented by exposure to potency equivalents of B[a]P, were developed using the results from the compositional analysis of 20 petrolatum-containing products in Canada. For each PAH, this derivation took into account its median concentration and an estimate of its potency relative to B[a]P (from Nisbet and Lagoy 1992) (Appendix F, G). Medians were used to be representative of exposures over a lifetime - a method commonly used for assessment of cancer risk. Summing these values across the 16 PAH species analyzed resulted in a total B[a]P equivalents of approximately 9 parts per billion (0.0000009% by weight relative to petrolatum). Because most products did not contain many of the 16 PAHs, the medians were predominantly based on a measure of the limit of detection of the testing apparatus, thus introducing conservatism in the estimate.

A margin of exposure approach was therefore used to characterize a theoretical long-term risk from oral exposure to petrolatum (considered to contain potency equivalents of B[a]P equal to 9 ppb). The highest upper-bounding estimate of petrolatum exposure was for toddlers (oral route = 51.6 mg/kg-bw/day). This exposure, when proportionally scaled by 9 parts per billion, results in a daily exposure estimate to potency equivalents of B[a]P of 4.6×10^{-7} mg/kg-bw. Compared with a conservative point of departure for B[a]P (BMDL₁₀ = 0.545 mg/kg-bw) (Health Canada 2015), a value lower or similar in magnitude as those derived by other organisations including the WHO, resulted in a margin of exposure of 1 185 000. This margin is considered adequate to address uncertainties in health effects and exposure.

10.1.2 Slack wax

Slack wax is found in a limited number of products available to the general population. No adverse effects were identified in short-term studies of animals orally exposed to high levels (5000 mg/kg-bw) of slack wax. Since petrolatum and waxes are inert and given the incidental nature of potential exposure to slack wax, short-term exposure to slack wax is not considered to constitute a risk to human health.

Long-term exposure to slack wax is not expected based on its limited presence in products available to the general population and the reported/documented normal use patterns of those products. Any incidental exposure is expected to be covered by the characterization of risk for the petrolatum exposure scenarios.

10.1.3 Oxidized petrolatum

Exposures to oxidized petrolatum are expected to be limited to indirect incidental dermal exposure from electronics and motor vehicles to residues from industrial uses as a polishing agent. Any incidental exposure of the general population is expected to be covered by the characterization of risk for the petrolatum exposure scenarios. Therefore, exposure to oxidized petrolatum is not considered to constitute a risk to human health.

Based on the information presented in this screening assessment, it is concluded that petrolatum and waxes 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.

10.2 Uncertainties in Evaluation of Risk to Human Health

There is uncertainty in the precise concentration of PAHs that may be present in food-grade petrolatum used in Canada, as only (non-food) petrolatum-containing products were tested, and those results were used to represent composition of food-grade petrolatum. However, regulatory standards are stringent for food-grade petrolatums, and the results showed that products available to the consumer meet the food-grade standard.

There are unknowns with respect to the influence on absorption of the physical-chemical properties of a diverse range of products available to the consumer, the potential influence of repeated dermal applications at the same skin site, as well as the influence of differences (i.e., variability in the structure, composition, and metabolism) in skin between sites.

11. Conclusion

Considering all available lines of evidence presented in this screening assessment, there is a low risk of harm to organisms and the broader integrity of the environment from petrolatum and waxes. It is concluded that petrolatum and waxes 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.

The general population may be exposed to petrolatum from products and from foods. Dermal and oral exposures to petrolatum are considered safe, as petrolatum lacks toxicity. Margins of oral exposure to residual PAHs are considered sufficient to address uncertainties related to health effects and exposure, and dermal exposures to residuals are considered to be negligible. There are limited or negligible exposures to slack wax and oxidized petrolatum. Considering all lines of evidence, general population exposure to petrolatum and waxes from products and foods is not considered to constitute a risk to human health.

Based on the information presented in this screening assessment, it is concluded that petrolatum and waxes 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 petrolatum and waxes (CAS RNs 8009-03-8, 64742-61-6 and 64743-01-7) do not meet any of the criteria set out in section 64 of CEPA.

References

- Adema DMM, van den Bos Bakker GH. 1986. Aquatic toxicity of compounds that may be carried by ships (Marpol 1973, Annex II). A progress report for 1986 from TNO to the Dutch Ministry of Housing, Physical Planning and the Environment. Report No. 86/326a.
- Anachemia. 2008. Material Safety Data Sheet: Petrolatum. [Internet]. Montreal (QC): Anachemia Canada. [cited Feb. 19, 2014; last updated Oct. 8, 2013]. Available from: www.anachemia.com/msds/english/7102.pdf
- [API] American Petroleum Institute. 2000. Robust Summary of Information on Waxes and Related Materials. Washington (DC): American Petroleum Institute.
- [API] American Petroleum Institute. 2003. Robust Summary of Information on Waxes and Related Materials. Washington (DC): American Petroleum Institute.
- Annot JA, Gobas FAPC. 2003. A Generic QSAR for Assessing the Bioaccumulation Potential of Organic Chemicals in Aquatic Food Webs. *QSAR Comb Sci*; 22(3):337–345. Available from: <http://www3.interscience.wiley.com/journal/104557877/home> [restricted access]
- Annot JA, Gobas FAPC. 2006. A review of bioconcentration factor (BCF) and bioaccumulation factor (BAF) assessments for organic chemicals in aquatic organisms. *Environ Rev* 14:257–297.
- Banerjee S. 1984. Solubility of organic mixtures in water. *Environmental Science & Technology* 18:587–591.
- Battersby NS et al. 1992. A correlation between the biodegradability of oil products in the CEC L-33-T-82 and modified Sturm tests. *Chemosphere*. 24:1989 2000. [cited in CONCAWE 2001]
- Bennett J. 2012. Cosmetics and Skin: Petrolatum/Petroleum Jelly. Available from: <http://cosmeticsandskin.com/bcb/petrolatum.php>
- Bernard H and Strauch CB. 1927. *Ztsch. kl. Med.* 106: 693. [as cited in Strakosch 1943]
- BIBRA. 1992. A 90-day feeding study in the rat with six different mineral oils (N15 (H), N70 (H), N70 (A), P15 (H), NIO (A) and P100 (H)), three different waxes (a low melting point wax, a high melting point wax and a high sulphur wax) and coconut oil. BIBRA Toxicology Advice and Consulting, Project no. 3.1010 (Surrey, UK).
- BIBRA. 1993. A 90-day feeding study in the rat with two mineral waxes identified as paraffin wax 64 (OFH-064) and micro/paraffin wax mixture. BIBRA Toxicology Advice and Consulting, Project no. 3.1205 (Surrey, UK).
- BIBRA. 1999. A subchronic 90-day dietary toxicity study of a low melting point paraffin wax in two rat strains. Study No. 95-2394, API Study No. HES1516-L-00880-Oral, BIBRA Toxicology Advice and Consulting (Surrey, UK).
- Brown BE, Diembeck W, Hoppe U, Elias PM. 1995. Fate of topical hydrocarbons in the skin. *J Soc Cosmetic Chem*, 46:1–9.
- Burdock GA. 1996. *Encyclopedia of Food and Color Additives*, Volume 3, CRC Press, Boca Raton, FL.

Cal EPA [California Environmental Protection Agency]. 2001. Summary of Toxicology Data. Mineral Oil & Petroleum Oil – Paraffin Hydrocarbons. Chemical Code # 000401 & 1641, Tolerance # 00149 SB 950 # 754 Original date: 7/19/01. File name: T010719. pp. 1–8.

Canada. 1978. *Food and Drug Regulations* (C.R.C., c. 870).
Available from: http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/

Canada. 1994. Polycyclic Aromatic Hydrocarbons. Ottawa (ON): Environment Canada; Health Canada. (Priority Substances List Assessment Report). Available from: http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl1-lsp1/hydrocarb_aromat_polycycl/index-eng.php

Canada. 1999. *Canadian Environmental Protection Act, 1999* (S.C., 1999, c. 33), *Canada Gazette* Part III, vol. 22, No. 3.

Carleton WW, Boitnott JK, Dungworth DL, Ernst H, Hayashi Y, Mohr U, Laurent-Parodi A, Pattengale PK, Rittinghausen S, Ward JM. 2001. Assessment of the morphology and significance of the lymph nodal and hepatic lesions produced in rats by the feeding of certain mineral oils and waxes. *Exp Toxic Pathol*. 53:247–255.

[CCME] Canadian Council of Ministers of the Environment. 2008. Canadian Soil Quality Guidelines for Carcinogenic and Other Polycyclic Aromatic Hydrocarbons (Environmental and Human Health Effects). Scientific Supporting Document.

Cheminfo Services Inc. 2009. Petrolatum, Final Report. Background Technical Study on the Use and Release Potential of Certain High Priority Petroleum Substances Under the Chemicals Management Plan (in Sectors Other than the Petroleum Sector). Unpublished confidential contract report. Gatineau (QC): Environment Canada.

Chesebrough RA. 1872. Improvement in products from petroleum. Specification forming part of Letters Patent No. 127,568. New York (NY). Dated June 4, 1872.

Chiang A, Maibach HI. 2013. Towards a perfect vehicle(s) for diagnostic patch testing: an overview. *Cutan Ocul Toxicol* 32:60-66.

[CMPA] Canadian Produce Marketing Association. Fresh Facts from Industry: Protective Coatings. Ottawa, Canada, 2014. Available from:
http://www.cpm.ca/pdf/HealthNutrition/CPMA_Fresh_Facts_Protective_Coatings_en.pdf

[CONCAWE] CONservation of Clean Air and Water in Europe. 1990. Factors affecting the skin penetration and carcinogenic potency of petroleum products containing polycyclic aromatic compounds. CONCAWE Report No. 90/55. Brussels (BE): CONservation of Clean Air and Water in Europe (CONCAWE). [as cited in Ingram and Phillips 1993]

[CONCAWE] CONservation of Clean Air and Water in Europe. 1993. White oil and waxes – summary of 90-day studies. Report No. 93/56. Brussels (BE): CONservation of Clean Air and Water in Europe (CONCAWE).

[CONCAWE] CONservation of Clean Air and Water in Europe. 1994. The use of the dimethyl sulfoxide (DMSO) extract by the IP 346 method as an indicator of the carcinogenicity of lubricant base oils and distillate aromatic extracts. Report No. 94/51. Brussels (BE): CONservation of Clean Air and Water in Europe (CONCAWE).

[CONCAWE] CONservation of Clean Air and Water in Europe. 1995. The classification and labelling of petroleum substances according to the EU dangerous substances directive. Report No. 95/59. Brussels (BE): CONservation of Clean Air and Water in Europe (CONCAWE).

[CONCAWE] CONservation of Clean Air and Water in Europe. 1997. Lubricating oil basestocks. Prepared by CONCAWE's Petroleum Products and Health Management Groups. Brussels (BE): CONservation of Clean Air and Water in Europe (CONCAWE). Product Dossier No. 97/108.

[CONCAWE] CONservation of Clean Air and Water in Europe. 1999. Petroleum waxes and related products. Prepared by CONCAWE's Petroleum Products and Health Management Groups. Brussels (BE): CONservation of Clean Air and Water in Europe (CONCAWE). Product Dossier No. 99/110.

[CONCAWE] CONservation of Clean Air and Water in Europe. 2001. Environmental classification of petroleum substances – Summary data and rationale. Brussels (BE): CONservation of Clean Air and Water in Europe (CONCAWE). Report No. 01/54.

[CONCAWE] CONservation of Clean Air and Water in Europe. 2010. Review of dermal effects and uptake of petroleum hydrocarbons. Brussels (BE): CONservation of Clean Air and Water in Europe (CONCAWE). Report No. 5/10.

[CONCAWE] CONservation of Clean Air and Water in Europe. 2012. REACH – Analytical characterisation of petroleum UVCB substances. CONCAWE PP/Analytical Information Task Force. Report No. 7/12. Brussels (BE): CONservation of Clean Air and Water in Europe (CONCAWE).

Concin N, Hofstetter G, Plattner B, Tomovski C, Fiselier K, Gerritzen K, Fessler S, Windbichler G, Zeimet A, Ulmer H, Siegl H, Rieger K, Concin H, Gorb K. 2008. Mineral oil paraffins in human body fat and milk. *Food Chem Toxicol* 46:544–552.

Concin N, Hofstetter G, Plattner B, Tomovski C, Fiselier K, Gerritzen K, Semsroth S, Zeimet AG, Marth C, Siegl H, Rieger K, Ulmer H, Concin H, Gorb K. 2011. Evidence for cosmetics as a source of mineral oil contamination in women. *J. Women's Health*. 20:1713–1719.

[ConsExpo] Consumer Exposure Model. 2006. Version 4.1. National Institute for Public Health and the Environment, (The Netherlands).

[ConsExpo] Consumer Exposure Model. 2012. Version 5. National Institute for Public Health and the Environment, (The Netherlands). [CTFA] Cosmetic, Toiletry and Fragrance Association. 1983. Summary for the Results of Surveys of the amount and Frequency of use of cosmetic products by Women. Report Prepared by Pitkin B, Rodericks JV, Turnbull D., Washington (DC): Environ Corporation.

Culp SJ, Gaylor DW, Sheldon WG, Goldstein LS, Beland FA. 1998. A comparison of the tumors induced by coal tar and benzo[a]pyrene in a 2-year bioassay. *Carcinogenesis* 19 (1): 117-124. Dietz WA et al. 1952. Properties of High Boiling Petroleum Products: Carcinogenicity Studies. *Ind Eng Chem* 44:1818–1827. [cited in CONCAWE 1999; US EPA 2006]

de Maagd PG-J, Ten Hulscher DThEM, van den Heuvel H; Opperhuizen A, Sijm DTHM. 1997. Physicochemical properties of polycyclic aromatic hydrocarbons: Aqueous solubilities, n-octanol/water partition coefficients, and Henry's law constants. *Environ Toxicol. Chem.* 17(2):251-257.

Dooms-Goossens A, Degreef H. 1983. Contact allergy to petrolatums. *Contact Dermatitis*. 9:175–185.

[DPD] Drug Products Database. [Database on the Internet]. 2013. Ottawa (ON): Health Canada. [cited 2014] Available at: www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php

[EC] European Commission. 2004. [Database on Internet] Cosmetics Directive. Health and Consumers, European Commission. Brussels, Belgium. [cited Feb 2014] Available from: <http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=29078&back=1>

[EC] European Commission. 2008a. Details on substances classified in Annex VI to Regulation (EC) No 1272/2008 [Database on the Internet]. Ispra (IT): European Commission, Joint Research Centre, Institute for Health and Consumer Protection. [cited 2014] Available from: <http://esis.jrc.ec.europa.eu/index.php?PGM=cla>

[EC] European Commission. 2008b. European Union risk assessment report. Coal-tar pitch, high temperature. CAS No.: 65996-93-2. EINECS No.:266-028-2. Risk assessment. Environment. May 2008. Luxembourg (NL): Office for Official Publications of the European Communities. [cited 2014] Available from: <http://echa.europa.eu/documents/10162/433ccfe1-f9a5-4420-9dae-bb316f898fe1>

[EC] European Commission. 2013. Chemicals - Market Restrictions. Limitations Directive for Dangerous Substances and Preparations. Directive 76/769/EEC. Accessed May 2014. Available from: http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/market-restrictions/index_en.htm

Elder R. 1984. Final report on the safety assessment of fossil and synthetic waxes. J Am College Toxicol 3:43–99.

[EFSA] European Union Food Safety Authority. 2013. Scientific Opinion on the re-evaluation of microcrystalline wax (E 905) as a food additive. ESFA J 11(4):3146. Available from: <http://www.efsa.europa.eu/en/efsajournal/doc/3146.pdf>

Encyclopedia for the Users of Petroleum Products, 2006. Fairfax (VA): ExxonMobil Lubricants and Specialties Division, ExxonMobil Oil Corporation. Available from: <http://www.petroliance.com/sites/default/files/PDF/Lubricants%20-%20General/Encyclopedia%20of%20Petroleum%20Terms.pdf>

Environment Canada. 2008. *Canadian Environmental Protection Act, 1999, Section 71: Notice with respect to certain high priority petroleum substances*. Canada Gazette, Part I, Vol. 142, no. 10. March 8, 2008. Available from: <http://canadagazette.gc.ca/rp-pr/p1/2008/2008-03-08/html/notice-avis-eng.html>

Environment Canada. 2011. *Canadian Environmental Protection Act, 1999, Section 71: Notice with respect to certain high priority petroleum substances on the Domestic Substances List*. Canada Gazette, Part I, Vol. 145, no. 51. Dec. 17, 2011. pp. 3740–3762. Available from: <http://gazette.gc.ca/rp-pr/p1/2011/2011-12-17/html/notice-avis-eng.html#d101>

Environment Canada. 2014. Technical document on the persistence and bioaccumulation potential of petroleum hydrocarbons. Environment Canada, Science and Technology Division. Unpublished.

[EPI Suite] Estimation Programs Interface Suite for Microsoft Windows [Estimation Model]. 2008. Version 3.4. Washington (DC): US Environmental Protection Agency, Office of Pollution Prevention and Toxics; Syracuse (NY): Syracuse Research Corporation. Available from: www.epa.gov/oppt/exposure/pubs/episuite.htm

[ESIS] European Chemical Substances Information System. 2014. [Database on the Internet] Database entry for oxidized petrolatum, CAS # 64743-0107. Available from: <http://esis.jrc.ec.europa.eu/>

[FAO/WHO] Food and Agriculture Organization of the United Nations / World Health Organization. 2006a. Food Safety and Quality. Petroleum Jelly. Available from: <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>

[FAO/WHO] Food and Agriculture Organization of the United Nations / World Health Organization. 2006b. Evaluation of Certain Food Contaminants: sixty-fourth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series: 930. Geneva: World Health Organization. [cited 2014] Available from: http://whqlibdoc.who.int/trs/WHO_TRS_930_eng.pdf

Faust HR, Casserly EW. 2003. Petrolatum and Regulatory Requirements. NPRA Publication LW-03-132, www.npra.org. Available from: http://www.babybutz.com/wp-content/uploads/2013/02/NPRA_Pet_Regulations.pdf

Faust H. 2012. Mineral Oil and Petrolatum Safety and Efficacy. Calumet Specialty Products, Inc. Indianapolis, Indiana, 2012. Available from: http://www.in-cosmetics.com/__novadocuments/9844

Ghadially R, Halkier-Sorensen L, Elias PM. 1992. Effects of petrolatum on stratum corneum structure and function. *J Am Acad Dermatol* 26:387–396.

Griffis LC, Twerdok LE, Francke-Carroll S, Biles RW, Schroeder RE, Bolte H, Faust H, Hall WC, Rojko J. 2010. Comparative 90-day dietary study of paraffin wax in Fischer-344 and Sprague-Dawley rats. *Food and Chemical Toxicology*. 48:363–373.

Hamoutene D, Payne JF, Rahimtula A, Lee K. 2004. Effect of water soluble fractions of diesel and an oil spill dispersant (Corexit 9527) on immune responses in mussels. *Bulletin of Environmental Contamination and Toxicology* 72:1260–1267.

Health Canada. 1998. Exposure Factors for Assessing Total Daily Intake of Priority Substances by the General Population of Canada. Health Canada, Environmental Health Directorate, Bureau of Chemical Hazards.

Health Canada. 2009. The cosmetic ingredient hotlist. September 2009. Ottawa (ON): Health Canada, Consumer Product Safety Directorate. Available from: <http://www.hc-sc.gc.ca/cps-spc/cosmet-person/indust/hot-list-critique/hotlist-liste-eng.php>

Health Canada. 2011. Be Active - Canada's Food Guide. Ottawa (ON): Health Canada, Health Products and Food Branch. Available from: <http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/maintain-adopt/weights-poids-eng.php>

Health Canada 2012. List of Permitted Glazing or Polishing Agents (Lists of Permitted Food Additives). Available from: <http://www.hc-sc.gc.ca/fn-an/securit/addit/list/7-glazing-glacage-eng.php>

Health Canada. 2013a. Personal Care Product Modules I, II and III. Ottawa (ON): Health Canada. Existing Substances Risk Assessment Bureau, Safe Environments Directorate, Healthy Environments and Consumer Safety Branch.

Health Canada. 2013b. List of Permitted Food Additives with Other Generally Accepted Uses (Lists of Permitted Food Additives). Available from: <http://www.hc-sc.gc.ca/fn-an/securit/addit/list/8-other-autre-eng.php>

Health Canada. 2014. Consumer Product Safety: Safety of Cosmetic Ingredients. Available from: <http://www.hc-sc.gc.ca/cps-spc/cosmet-person/labelling-etiquetage/ingredients-eng.php#a4.9>

Health Canada. 2015. Benzo[a]pyrene in drinking water [draft]. Ottawa (ON): Health Canada, Federal-Provincial-Territorial Committee on Drinking Water. Available from: http://www.hc-sc.gc.ca/ewh-semt/consult/_2015/bap/draft-ebauche-eng.php

Healy L, Butac G, Leur L. 2005. Slippery Competition: Vegetable Oil, Hydrocarbons and Esters Pose Slippery Competition for Petrolatum and Mineral Oil in Personal Care Products, Global Cosmetic Industry.

Heimbach JT, Bodor AR, Douglass JS, Barraj LM, Cohen SC, Biles RW, Faust HR. 2002. Dietary exposures to mineral hydrocarbons from food-use applications in the United States. *Food Chem Toxicol* 40(5): 555-571.

Howard JW, Haenni EO, Joe Jr. FL. 1965. An ultraviolet absorption criterion for total polynuclear aromatic hydrocarbon content of petroleum waxes in food additive use. *Journal of the AOAC* 48(2):304–315.

[HENRYWIN]. Henry's Law Constant for Windows. Version 3.20. 2008. Washington (DC): US Environmental Protection Agency, Office of Pollution Prevention and Toxics; Syracuse (NY): Syracuse Research Corporation. Available from: www.epa.gov/oppt/exposure/pubs/episuite.htm

[HPD] Household Products Database. 2010. [Database on the Internet] US Department of Health and Human Services, National Institutes of Health, US National Library of Medicine. Bethesda (MD). [cited 2014] Available from: <http://hpd.nlm.nih.gov/cgi-bin/household/list?tbl=TblChemicals&alpha=A>

[IARC] International Agency for Research on Cancer. 1984. IARC Working Group on the Evaluation of Carcinogenic Risks in Humans. Mineral oils. In: *Polynuclear Aromatic Hydrocarbons, Part 2, Carbon Blacks, Mineral Oils (Lubricant Base Oils and Derived Products) and Some Nitroarenes*. IARC Monogr Eval Carcinog Risks Hum 33:87–168.

[IARC] International Agency for Research on Cancer. 1987. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Overall Evaluations of Carcinogenicity: An Updating of *IARC Monographs* Volumes 1 to 42. Supplement 7: Mineral oils: untreated and mildly-treated oils (group 1) and highly-refined oils (group 3). Lyon (FR). pp. 276–278.

[IARC] International Agency for Research on Cancer. 1998. World Health Organization. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 3. Certain Polycyclic Aromatic Hydrocarbons and Heterocyclic Compounds. Lyon (FR).

[IARC] International Agency for Research on Cancer. 2010. World Health Organization. Monograph on Some Non-Heterocyclic Polycyclic Aromatic Hydrocarbons and Some Related Exposures. IARC Monographs vol. 92. Lyon (FR).

[IGI] International Group Inc. 2014. Petrolatum Products. International Group Inc., Toronto ON. Available from: <http://igiwax.com/igi-products/by-type/petrolatum.html>

[IHCP] Institute for Health and Consumer Protection. [Database on the Internet] Joint Research Centre. Ispra (IT): European Commission. [cited 2014] Available from: <http://esis.jrc.ec.europa.eu/>

Ingram AJ and Phillips JC. 1993. The dermal bioavailability of radiolabelled benzo[a]pyrene from acetone or from oils of differing viscosity, assessed by DNA and protein binding. *J Appl Toxicol* 13: 25-32.

Imperial Oil. 2002. Product data sheet for slack wax. [Internet] http://www.imperialoil.ca/Canada-English/Files/Products_Lubes/IOCAENWPOESSlack_wax.pdf

Inchem. International Program on Chemical Safety. 2010. [Internet] Available from: <http://www.inchem.org/documents/jecfa/jecmono/v50je04.htm>

[IP] Institute of Petroleum. 1985. Polycyclic Aromatics in Petroleum Fractions by Dimethyl Sulphoxide – Refractive Index Method. *Methods for Analysis and Testing*. IP 346/80. 2:346.1–346.6.

[IP] Institute of Petroleum. 1993. Determination of polycyclic aromatics in unused lubricating base oils and asphaltene free petroleum fractions – Dimethyl sulphoxide extraction refractive index method. IP 346/92. In: *Standard Methods for Analysis and Testing of Petroleum and Related Products*, Vol. 2, Wiley (Chichester, UK).

[JECFA] Joint FAO/WHO Expert Committee on Food Additives. 2006. Online Edition: Combined Compendium of Food Additive Specifications". Mineral Oil (High Viscosity). Available from: <http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-282.pdf>

[JECFA] Joint FAO/WHO Expert Committee on Food Additives. 2012. Evaluation of certain food additives. Seventy-sixth report. WHO Technical Report Series No. 974.

[JECFA] Joint FAO/WHO Expert Committee on Food Additives. 2013a. Summary and Conclusions. Seventy-seventh meeting. Document: JECFA/77/SC Rev. 1. Available from: http://www.fao.org/fileadmin/templates/agns/pdf/jecfa/JECFA_77_Summary_Report_Final_revised_Oct_2013.pdf

[JECFA] Joint FAO/WHO Expert Committee on Food Additives. 2013b. Online Edition: Combined Compendium of Food Additive Specifications". Mineral Oil (Medium Viscosity). Available from: <http://www.fao.org/ag/agn/jecfa-additives/specs/monograph14/additive-527-m14.pdf> Kane ML, Ladov EN, Holdsworth CE, Weaver NK. 1984. Toxicological characteristics of refinery streams used to manufacture lubricating oils. *Am J Ind Med* 5:183–200.

KEMI. Swedish Chemicals Agency. 2010. Available from: <http://www.kemi.se/>

Kirk-Othmer Encyclopedia of Chemical Technology. 2001. Wiley Online Library. Available from: <http://onlinelibrary.wiley.com/book/10.1002/0471238961>

[KOCWIN] Organic Carbon Partition Coefficient Program for Windows [Estimation Model]. 2009. Version 2.00. Washington (DC): US Environmental Protection Agency, Office of Pollution Prevention and Toxics; Syracuse (NY): Syracuse Research Corporation. Available from: www.epa.gov/oppt/exposure/pubs/episuite.htm

[KOWWIN] Organic Carbon Partition Coefficient Program for Windows [Estimation Model]. 2008. Version 1.67a. Washington (DC): US Environmental Protection Agency, Office of Pollution Prevention and Toxics; Syracuse (NY): Syracuse Research Corporation. Available from: www.epa.gov/oppt/exposure/pubs/episuite.htm

Kuhn JO. 1995. Dermal sensitization study in guinea pigs, 4531 pet blend white USP. Study conducted for Penzoil Products Company. Study No. 1588-94. Sugar Land (TX): STILLMEADOW Inc. [cited in EC 2008]

Licensed Natural Health Products Database. 2015. [Database on the Internet] Ottawa (ON): Health Canada, Drugs and Health Products. [cited 2015] Available from: <http://webprod3.hc-sc.gc.ca/lnhpd-bdpsnh/start-debuter.do>

- Lijinsky W, Domskey I, Mason G, Ramahi HY, Safavi T. 1963. The chromatographic determination of trace amounts of polynuclear hydrocarbons in petrolatum, mineral oil, and coal tar. *Anal Chem* 35:952–956.
- Lijinsky W, Saffiotti U, Shubik P. 1966. Skin tumorigenesis by an extract of amber petrolatum. *Toxicology and Applied Pharmacology*. 8:113–117.
- Loretz LG, Api AM, Barraj LM, Burdick J, Dressler WE, Gettings SD, Han Hsu H, Pan YHL, Re TA, Renskers KJ, Rothenstein A, Scrafford CG, Sewall C. 2005. Exposure data for cosmetic products: lipstick, body lotion, and face cream. *Food Chem Toxicol* 43:279–291.
- Loretz L, Api AM, Barraj L, Burdick J, Davis DA, Dressler W, Gilberti E, Jarrett G, Mann S, Pan YHL, Re T, Renskers K, Scrafford C, Vater S. 2006. Exposure data for personal care products: Hairspray, spray perfume, liquid foundation, shampoo, body wash, and solid antiperspirant. *Food Chem Toxicol* 44:2008–2018.
- Mackereer CR, Griffis LC, Grabowski JS Jr., Reitman FA. 2003. Petroleum mineral oil refining and evaluation of cancer hazard. *Applied Occupational and Environmental Hygiene*. 18:890–901.
- McKee RH, Plutnick RT, Traul KA. 1987a. Assessment of the potential reproductive and subchronic toxicity of EDS coal liquids in Sprague-Dawley rats. *Toxicology*. 46:267–280. [cited in CONCAWE 1997]
- McKee RH, Pasternak SJ, Traul KA. 1987b. Developmental toxicity of EDS recycle solvent and fuel oil. *Toxicology*. 46:205–215. [cited in CONCAWE 1997]
- McKee RH, Drummond JG, Freeman JJ, Letinski DJ, Miller MJ. 2012. Light white oils exhibit low tissue accumulation potential and minimal toxicity in F344 rats. *Inter J Toxicol* 31:175–183. Available from: <http://ijt.sagepub.com/content/31/2/175.full.pdf+html>
- Mao-Qiang M, Brown BE, Wu-Pong S, Feingold KR, Elias PM. 1995. Exogenous nonphysiologic vs physiologic lipids. Divergent mechanisms for correction of permeability barrier dysfunction. *Arch Dermatol* 131: 809–816.
- Menzie CA, Potocki BB, Santodonato J. 1992. Exposure to carcinogenic PAHs in the environment. *Environ Sci Technol* 26:1278-1284.
- Meridian. 2009. Meridian MSDS Database for Petroleum Products. [Database]. Meridian Environmental Inc. Calgary, AB. Health Canada Internal Document.
- Miller MJ, Lonardo EC, Greer RD, Bevan C, Edwards DA, Smith JH, Freeman JJ. 1996. Variable responses of species and strains to white mineral oils and paraffin waxes. *Reg Toxicol Pharm* 23:55–68.
- Mohamed NH, Zaky MT. 2004. Separation of microcrystalline waxes from local crude petrolatums using solvent-antisolvent mixtures. *Petroleum Science and Technology* 22:1553–1569.
- [MPBPWIN] Melting Point Boiling Point for Windows. Version 1.43. 2008. Washington (DC): US Environmental Protection Agency, Office of Pollution Prevention and Toxics; Syracuse (NY): Syracuse Research Corporation. Available from: www.epa.gov/oppt/exposure/pubs/episuite.htm
- Natural Health Products Ingredients Database. 2015. [Database on the Internet]. Ottawa (ON): Health Canada, Drugs and Health Products. [cited 2015] Available from: <http://webprod.hc-sc.gc.ca/nhpid-bdipsn/search-rechercheReq.do>

Nisbet ICT, LaGoy PK. 1992. Toxic equivalency factors (TEFs) for polycyclic aromatic hydrocarbons (PAHs). Regul. Toxicol. Pharmacol. 16:3, 290–300.

[NPRI] National Pollutant Release Inventory. 2014. Substance Information [Database on the Internet]. Undated. Gatineau (QC): Environment Canada. Available from: http://www.ec.gc.ca/pdb/npri/npri_pah_e.cfm

[OECD] Organisation for Economic Co-operation and Development. 2004. HPV. Available from: <http://www.oecd.org/dataoecd/55/38/33883530.pdf>

[OECD] Organisation for Economic Co-operation and Development. 2014. IUCLID Dataset. [Database on the Internet]. OECD Chemical Safety and Biosafety, Assessment of Chemicals. [cited 2014] Available from: <http://www.oecd.org/chemicalsafety/risk-assessment/electronictoolsfordatasubmissionevaluationandexchangeintheoecdcooperativechemicalsassessmentprogramme.htm>

[OJ C] Official Journal of the European Communities. 1994. Commission Directive 94/69/EC of 19 December 1994 adapting to technical progress for the twenty-first time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. No. L381, 31.12.1994

Oser BL, Oser M, Carson S. 1965. Toxicologic studies of petrolatum in mice and rats. Toxicol App Pharmacol 7:382–401.

[OSHA] United States Occupational Safety and Health Administration. 1999. Technical Manual. Section IV, Chapter 2. Washington (DC). Available from: https://www.osha.gov/dts/osta/otm/otm_iv/otm_iv_2.html

Pancirov R, Brown R. 1975. Analytical methods for polynuclear aromatic hydrocarbons in crude oils, heating oils, and marine tissues. Proceedings of a Conference on Prevention and Control of Oil Pollution, San Francisco, California. Washington (DC): American Petroleum Institute, pp. 103–113.

Parkash S. 2010a. *Lube Base Stocks*; pp. 189–210. In: Petroleum Fuels Manufacturing Handbook: Including Specialty Products and Sustainable Manufacturing Techniques. McGraw-Hill (USA). pp. 1–444.

Parkash S. 2010b. *Waxes*; pp. 277–294. In: Petroleum Fuels Manufacturing Handbook: Including Specialty Products and Sustainable Manufacturing Techniques. McGraw-Hill (USA). pp. 1–444.

Parkash S. 2010c. *White Mineral Oils*; pp. 377–428. In: Petroleum Fuels Manufacturing Handbook: Including Specialty Products and Sustainable Manufacturing Techniques. McGraw-Hill (USA). pp. 1–444.

Patzelt A, Lademann J, Richter H, Darvin ME, Schanzer, S, Thiede G, Sterry W, Vergou, T, Hauser M. 2012. *In vivo* investigations on the penetration of various oils and their influence on the skin barrier. Skin Res Techn 18:364–369.

Payne JF, Fancey LL, Hellou J, King MJ, Fletcher GL. 1995. Aliphatic hydrocarbons in sediments: a chronic toxicity study with winter flounder (*Pleuronectes americanus*) exposed to oil well drill cuttings. Canadian Journal of Fisheries and Aquatic Sciences 52:2724–2735.

Payne J, Andrews C, Whiteway S, Lee K. 2001. Definition of sediment toxicity zones around oil development sites: dose response relationships for the monitoring surrogates Microtox® and amphipods, exposed to Hibernia source cuttings containing a synthetic base oil. St. John's (NF). Canadian Manuscript Report of Fisheries and Aquatic Sciences No. 2577: vi + 10p.

[PetroTox] Spreadsheet model to calculate toxicity of petroleum hydrocarbons to aquatic organisms. 2009. Version 3.04. Brussels (BE): CONservation of Clean Air and Water in Europe (CONCAWE). Available from: www.concawe.be/content/default.asp?PageID=778

[PMRA] Pest Management Regulatory Agency. 2006. Available from: http://www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/dir/dir2006-02-eng.pdf

[PMRA] Pest Management Regulatory Agency. 2010. List of Formulants. Available from: http://publications.gc.ca/collections/collection_2010/arla-pmra/H114-22-2010-eng.pdf

Popl M, Stejskal M, Mostecký J. 1975. Determination of polycyclic aromatic hydrocarbons in white petroleum products. *Anal Chem* 47:13, 1947–1950.

Potter T, Simmons K. 1998. Composition of petroleum mixtures. Vol 2. Total Petroleum Hydrocarbon Criteria Working Group Series. Amherst (MA): Amherst Scientific Publishers.

Sangster J. 1989. Octanol-water partition coefficients of simple organic compounds. *J. Chem. Eng. Ref. Data*, 18(3):1111-1227.

SCCS [Scientific Committee on Consumer Safety] 2010. The SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation, 7th Revision, European Commission. Available from: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_006.pdf

Schnuch A, Lessmann H, Geier J, Uter W. 2006. White petrolatum (Ph. Eur.) is virtually non-sensitizing. Analysis of IVDK data on 80 000 patients tested between 1992 and 2004 and short discussion of identification and designation of allergens. *Contact Dermatitis* 54:338–343.

Schramm D. 2002. The North American USP Petrolatum Industry (Industry Overview), Soap & Cosmetics, National Petroleum Refiners Association (Houston).

Schueller R, Romanowski P. 1999. Conditioning Agents for Hair and Skin (Cosmetic Science and Technology), Vol. 21. New York (NY): Marcel Dekker.

Scotter MJ, Castle L, Massey RC, Brantom PG, Cunnings ME. 2003. A study of the toxicity of five mineral hydrocarbon waxes and oils in the F344 rat, with histological examination and tissue-specific chemical characterisation of accumulated hydrocarbon material. *Food and Chemical Toxicology*. 41:489–521.

Shubik P, Saffiotti U, Lijinsky W, Pietra G, Rappaport H, Toth B, Raha CR, Tomatis L, Feldman R, Ramahi H. 1962. Studies on the Toxicity of Petroleum Waxes. *Toxicol Appl Pharmacol* 4: 1–62.

Simpson BJ. 2005. Analysis of petroleum hydrocarbon streams on the Health Canada CEPA/DSL Draft Maximal List. Report to the Canadian Petroleum Products Institute (Ottawa) .

Smith WE, Sunderland DA, Sugiura K. 1951. Experimental analysis of the carcinogenic activity of certain petroleum products. *Arch Ind Hyg Occup Med* 4:299–314. [cited in IARC 1984 and CONCAWE 1999]

Sonneborn Refined Products. 2014. Food Grade Lubricants. Sonneborn, LLC. Petrolia, PA. Available from: <http://www.sonneborn.com/markets/food-grade-lubricants>

SPIN 2010. Substances in Production in Nordic Countries Database. Available from: <http://90.184.2.100/DotNetNuke/>

Stamatas GN, de Sterke J, Hauser M, von Stetten O, van der Pol A. 2008. Lipid uptake and skin occlusion following topical application of oils on adult and infant skin. *J Dermatol Sci* 50: 135-142.

[STN] Chemical Abstract Services, STN Easy Database. [cited in 2013] Available from: <https://www.cas.org/products/stn/dbss>

Strakosch EA. 1943. Studies on ointments: Penetration of various ointment bases. *J Pharmacol Exp Ther* 78:65–71.

Storer JS, DeLeon I, Millikan LE, Laseter JL, Griffing C. 1984. Human absorption of crude coal tar products. *Arch Dermatol* 120:874-877.

Stubblefield WA, Hancock GA, Prince HH, Ringer RK. 1995. Effects of naturally weathered *Exxon Valdez* crude oil on mallard reproduction. *Environmental Toxicology and Chemistry* 14(11):1951–1960.

Sutton RL. 1906. *Monatshefte Prak. Derm.* 43: 371 [as cited in Strakosch 1943]

Swarbrick J. 2006. *Encyclopedia of Pharmaceutical Technology*, Volume 5, 3rd Edition, CRC Press (Boca Raton, FL).

[TRI] United States Toxics Release Inventory. 2013. United States Environmental Protection Agency. Available at: <http://www2.epa.gov/toxics-release-inventory-tri-program>

Trimmer GW, Freeman JJ, Priston RAJ, Urbanus J. 2004. Results of Chronic Dietary Toxicity Studies of High Viscosity (P70H and P100H) White Mineral Oils in Fischer 344 Rats. *Toxicologic Pathology* 32:439–447.

Ulrich GS, Schmutz JL, Trechot Ph, Commun N, Barbaud A. 2004. Sensitization to petrolatum: an unusual cause of false-positive drug patch-tests. *Allergy* 59:1006–1009.

Unilever. Vaseline. 2012. [Internet] Vaseline Product Overview. Toronto, Canada. [cited 2014] Available from: <http://www.unileverme.com/brands/personalcarebrands/vaseline.aspx>

Unna E and Frey W. 1929. *Derm. Wsch.* 88: 327. [as cited in Strakosch 1943]

[US EPA] US Environmental Protection Agency. 1986. Method 8100. Polynuclear Aromatic Hydrocarbons. Washington (DC): US EPA. EPA-454/R-92-019. Available from: <http://www.epa.gov/osw/hazard/testmethods/sw846/pdfs/8100.pdf>

[US EPA] US Environmental Protection Agency. 1992. Peer Consultation Workshop on Approaches to Polycyclic Aromatic Hydrocarbon (PAH) Health Assessment. Washington (DC): US EPA. Available from: http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=54787

[US EPA] US Environmental Protection Agency. 2003. HPV test plan: waxes and related materials category submitted to the US EPA. Washington (DC): US EPA.

[US EPA] US Environmental Protection Agency. 2005a. Supplementary guidance for assessing susceptibility from early life exposure to carcinogens. Risk Assessment Forum. Washington (DC): US EPA EPA/630/R-03/003F.

[US EPA] US Environmental Protection Agency. 2005b. Guidelines for carcinogen risk assessment. Risk Assessment Forum. Washington (DC): US EPA EPA/630/P-03/001F.

[US EPA] US Environmental Protection Agency. 2006. HPV challenge program test plan for petroleum oxidates and derivatives thereof category 2002. Washington (DC): US EPA.

[US EPA] US Environmental Protection Agency. 2011. HPVIS. Screening-level hazard characterization. Waxes and related materials category. Washington (DC): US EPA. Available from: http://www.epa.gov/chemrtk/hpvis/hazchar/Category_Waxes%20and%20Related%20Materials_September_2011.pdf

[US EPA] US Environmental Protection Agency. 2014. Priority Pollutants. Webpage. Accessed July 7, 2015. Available from: <http://water.epa.gov/scitech/methods/cwa/pollutants.cfm>

[US FDA] United States Food and Drug Administration. 2012. 21 CFR 172.880. CFR - Code of Federal Regulations. Washington (DC): US FDA. Available from: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=172.880>

[US FDA] United States Food and Drug Administration. 2014a. 21 CFR 176.886 – Petrolatum Wax. CFR - Code of Federal Regulations. Washington (DC): US FDA. (Current as of June 24, 2015) Available from: <http://www.ecfr.gov/cgi-bin/text-idx?SID=2cf043b2689a6555298b3b1cc8aa0f49&node=21:3.0.1.1.3.9.1.56&rgn=div8>

[US FDA] United States Food and Drug Administration. 2014b. Available from: <http://www.usp.org/usp-nf/harmonization/monographs>

[USP] United States Pharmacopeia. 2014a. Food Chemicals Codex, 9th Edition. United States Pharmacopeia Convention, Rockville, MD. Available from: <http://www.usp.org/store/products-services/food-chemicals-codex-fcc>

[USP] United States Pharmacopeia and National Formulary (USP 37-NF 32). 2014b. Rockville, MD: United States Pharmacopeia Convention; pp 4254.

[USP] United States Pharmacopeia and National Formulary (USP 37-NF 32). 2014c. Rockville, MD: United States Pharmacopeia Convention; pp 6074-6075.

[USP] United States Pharmacopeia and National Formulary (USP 37-NF 32). 2014d. Rockville, MD: United States Pharmacopeia Convention; pp 6096.

Van Rooij JGM, De Roos JHC, Bodelier-Bade MM, Jongeneelen FJ. 1993. Absorption of polycyclic aromatic hydrocarbons through human skin: differences between anatomical sites and individuals. *J Toxicol Environ Health*. 38:355-368.

Venier CG, Skisak CM, Bell DA. 1987. Ames Tests of Lubricating Oil Products: The Effect of Processing Variables. *In Vitro Toxicology*. 1:253–261.

Wester PW, Muller JJA, Slob W, Mohn GR, Dortant PM, Kroese ED. 2012. Carcinogenic activity of benzo[a]pyrene in a 2 year oral study in Wistar rats. *Food Chem Toxicol* 50:3–4, 927–935.

Wheeler LA, Saperstein MD, Lowe NJ. 1981. Mutagenicity of urine from psoriatic patients undergoing treatment with coal tar and ultraviolet light. *J. Invest. Dermatol*. 77: 185-185.

[WHO] World Health Organization. 1998. Selected non-heterocyclic polycyclic aromatic hydrocarbons. Environmental Health Criteria 202. Geneva (CH): International Programme on Chemical Safety. [cited 2014] Available from: <http://www.inchem.org/documents/ehc/ehc/ehc202.htm>

[WHO] World Health Organization. 2001. Polycyclic aromatic hydrocarbons. In: Background material to WHO Regional Publications, European series, no. 91 (Air Quality Guidelines for Europe, Second Ed. 2000). Chapter 5.9: pp. 1-24. WHO Regional Office for Europe, Copenhagen, Denmark.

Wormuth M, Scheringer M, Vollenweider M, Hungerbühler K. 2006. What are the sources of exposure to eight frequently used phthalic acid esters in Europeans? *Risk Anal* 26(3):803–824.

[WSKOWWIN] Water Solubility from KOW for Windows. Version 1.41a. 2008. Washington (DC): US Environmental Protection Agency, Office of Pollution Prevention and Toxics; Syracuse (NY): Syracuse Research Corporation. Available from: www.epa.gov/oppt/exposure/pubs/episuite.htm

Wu X, Bennett DH, Ritz B, Cassady DL, Lee K, Hertz-Picciotto I. 2010. Usage pattern of personal care products in California households. *Food Chem Toxicol* 48:3109–3119.

Zhai H, Wilhelm KP, Maibach HI (eds). 2008. Marzulli and Maibach's *Dermatotoxicology*. 7th ed. Boca Raton (FL): CRC Press. pp. 1–1015.

Appendices

Appendix A. Petroleum Substance Groupings

Table A1. Description of the nine groups of petroleum substances

Group ^a	Description	Example
Crude oils	Complex combinations of aliphatic and aromatic hydrocarbons and small amounts of inorganic compounds, naturally occurring under the Earth's surface or under the seafloor	Crude oil
Petroleum and refinery gases	Complex combinations of light hydrocarbons primarily from C ₁ to C ₅	Propane
Low boiling point naphthas	Complex combinations of hydrocarbons primarily from C ₄ to C ₁₂	Gasoline
Gas oils	Complex combinations of hydrocarbons primarily from C ₉ to C ₂₅	Diesel fuel
Heavy fuel oils	Complex combinations of heavy hydrocarbons primarily from C ₁₁ to C ₅₀	Fuel Oil No. 6
Base oils	Complex combinations of hydrocarbons primarily from C ₁₅ to C ₅₀	Lubricating oils
Aromatic extracts	Complex combinations of primarily aromatic hydrocarbons from C ₁₅ to C ₅₀	Feedstock for benzene production
Waxes, slack waxes and petrolatum	Complex combinations of primarily aliphatic hydrocarbons from C ₁₂ to C ₈₅	Petrolatum
Asphalt	Complex combinations of heavy hydrocarbons having carbon numbers greater than C ₂₅	Asphalt

^a These groupings were based on classifications developed by Conservation of Clean Air and Water in Europe (CONCAWE) and a contractor's report presented to the Canadian Petroleum Products Institute (Simpson 2005).

Appendix B. Types of Petroleum Wax

Table B.1. Descriptions of general petroleum waxes

Petroleum wax	Description
1) Paraffin wax (macrocrystalline wax)	Paraffinic waxes have average molecular weights usually less than 450. They have a well-defined macrocrystalline structure of large needles or plates, with a melting point in the range of 43 to 68°C, typically around 55°C. They consist mainly of normal alkanes, varying amounts of isoalkanes, cycloalkanes and a very low concentration of alkylated aromatic hydrocarbons. Paraffin waxes have a translucent white to yellow colour (CONCAWE 1999).
2) Microcrystalline wax	Microcrystalline waxes have higher molecular weights than paraffinic waxes and consist of substantial amounts of iso- and cycloalkanes, usually with a lesser amount of normal alkanes and trace amounts of alkylated aromatic hydrocarbons. Although microcrystalline waxes contain small crystals, much of the material is amorphous. Microcrystalline waxes usually melt between 60 and 95°C (CONCAWE 1999b). Microcrystalline wax is a petroleum wax solid at room temperature. The microcrystalline structure can be explained by the presence of strongly branched isoparaffins and naphthenes, which inhibit crystallization. This class differs from paraffin wax in that it has poorly defined crystalline structure, darker colour and generally higher viscosity and melting point (Kirk-Othmer 2001).
3) Slack wax	Slack waxes consist mostly of paraffinic hydrocarbons of carbon number C₁₂ to C₈₅. They contain a residual amount of mineral oil ranging between 5 and 30%. Slack waxes derived from low viscosity oils contain predominantly normal paraffins. Upon dewaxing, heavier oil fractions yield slack waxes with increasing proportions of isoparaffins, cycloparaffins and alkylated aromatics, in addition to the normal paraffins. Commonly, slack waxes derive from solvent-refined vacuum distillates, in which case they contain a very low content of alkylated aromatic hydrocarbons. Due to their molecular weight distribution, slack waxes have a solid consistency at ambient temperatures. Melting takes place at around 50°C (Cheminfo 2009). Scale waxes are a related product. Scale waxes are soft, semi-refined wax, distinguished from slack wax by having a generally lower oil content; usually derived from slack wax by extracting most of the oil from the wax (Encyclopedia for Users of Petroleum Products 2006).

Table B.2. Representative hydrocarbon structures for petrolatum and waxes**Alkanes**

Chemical names (CAS RN)	Boiling point (°C)	8009-03-8 (more than 300°C)	64742-61-6 (350 to 500°C)	64743-01-7 (214 to more than 649°C)
C ₁₂ dodecane (112-40-3)	216	-	-	Yes
C ₁₅ pentadecane (629-62-9)	271	-	-	Yes
C ₂₀ eicosane (112-95-8)	343	Yes	-	Yes
C ₃₀ triacontane (638-68-6)	450	Yes	Yes	Yes
C ₅₀	-	Yes	Yes	Yes

Isoalkanes

Chemical names (CAS RN)	Boiling point (°C)	8009-03-8 (more than 300°C)	64742-61-6 (350 to 500°C)	64743-01-7 (214 to more than 649°C)
C ₁₅ 2-methyltetra- decane (1560-95-8)	250	-	-	Yes
C ₂₀ 3-methylnonadecane (6418-45-7)	326	Yes	-	Yes
C ₃₀ hexamethyl- tetracosane (111-01-3)	408	Yes	Yes	Yes

Mono-cycloalkanes

Chemical names (CAS RN)	Boiling point (°C)	8009-03-8 (more than 300°C)	64742-61-6 (350 to 500°C)	64743-01-7 (214 to more than 649°C)
C ₁₅ nonylcyclohexane (2883-02-5)	282	-	-	Yes
C ₂₀ tetradecyl- cyclohexane (1795-18-2)	360	Yes	Yes	Yes

Chemical names (CAS RN)	Boiling point (°C)	8009-03-8 (more than 300°C)	64742-61-6 (350 to 500°C)	64743-01-7 (214 to more than 649°C)
C ₃₀ 1,5-dimethyl-1-(3,7,11,15-tetramethyl-octadecyl)-cyclohexane	421	Yes	Yes	Yes
C ₅₀	674.24	Yes	-	Yes

Di-cycloalkanes

Chemical names (CAS RN)	Boiling point (°C)	8009-03-8 (more than 300°C)	64742-61-6 (350 to 500°C)	64743-01-7 (214 to more than 649°C)
C ₂₀ 2,4-dimethyl-octyl-2-decalin	323.91	Yes	-	Yes
C ₃₀ 2,4,6,10,14-pentamethyl-dodecyl-2-decalin	420.32	Yes	Yes	Yes
C ₅₀	663.83	Yes	-	Yes

Polycycloalkanes

Chemical names (CAS RN)	Boiling point (°C)	8009-03-8 (more than 300°C)	64742-61-6 (350 to 500°C)	64743-01-7 (214 to more than 649°C)
C ₁₄ hydrophenanthrene	255	-	-	Yes
C ₁₈ hydrochrysene	353	Yes	Yes	Yes
C ₂₂ hydropicene	365	Yes	Yes	Yes

Monoaromatics

Chemical names (CAS RN)	Boiling point (°C)	8009-03-8 (more than 300°C)	64742-61-6 (350 to 500°C)	64743-01-7 (214 to more than 649°C)
C ₁₅ 2-nonyl-benzene (1081-77-2)	281	-	-	Yes
C ₂₀ 1-benzyl-4,8-dimethyl-dodecane	335	Yes	-	Yes
C ₃₀ 1-benzyl-4,8,12,16-tetramethyl-eicosane	437	Yes	Yes	Yes
C ₅₀	697	Yes	-	Yes

Diaromatics

Chemical names (CAS RN)	Boiling point (°C)	8009-03-8 (more than 300°C)	64742-61-6 (350 to 500°C)	64743-01-7 (214 to more than 649°C)
C ₁₅ 4-isopropyl-biphenyl (7116-95-2)	309	Yes	-	Yes
C ₂₀ 2-isodecyl-naphthalene	366	Yes	Yes	Yes
C ₃₀ 2-(4,8,14,18-tetramethyl-hexadecyl)-naphthalene	468	Yes	Yes	Yes
C ₅₀	722	Yes	-	Yes

Monocarboxylic acids

Chemical names (CAS RN)	Boiling point (°C)	8009-03-8 (more than 300°C)	64742-61-6 (350 to 500°C)	64743-01-7 (214 to more than 649°C)
C ₁₅ pentadecanoic acid (1002-84-2)	339	-	-	Yes
C ₅₀ carboxylic acid	753	-	-	Yes
C ₁₅ monocycloalkane carboxylic acid	352	-	-	Yes
C ₅₀ monocycloalkane carboxylic acid	745	-	-	Yes
C ₂₀ dicycloalkane carboxylic acid	396	-	-	Yes
C ₅₀ dicycloalkane carboxylic acid	735	-	-	Yes

Dicarboxylic acids

Chemical names (CAS RN)	Boiling point (°C)	8009-03-8 (more than 300°C)	64742-61-6 (350 to 500°C)	64743-01-7 (214 to more than 649°C)
C ₁₅ pentadecane dicarboxylic acid	418	-	-	Yes
C ₅₀ monocycloalkane dicarboxylic acid	816	-	-	Yes
C ₂₀ dicycloalkane dicarboxylic acid	467	-	-	Yes
C ₅₀ dicycloalkane dicarboxylic acid	806	-	-	Yes

Table B.3a. Physical and chemical properties for representative structures of petrolatum and waxes (EPI Suite 2008)^a**Alkanes**

Chemical class, name (CAS RN)	Boiling point (°C)	Melting point (°C)	Vapour pressure (Pa) ^b	Henry's Law constant (Pa·m ³ /m ol) ^c	Log K _{ow}
C ₁₂ dodecane (112-40-3)	216.3 (expt.)	9.6 (expt.)	18.0 (expt.)	8.3×10 ⁵ (expt.)	6.1 (expt.)
C ₁₅ pentadecane (629-62-9)	270.6 (expt.)	9.9 (expt.)	0.46 (expt.)	1.3×10 ⁶ (expt.)	7.7
C ₂₀ eicosane (112-95-8)	343 (expt.)	36.8 (expt.)	6.2×10 ⁻⁴ (expt.)	2.2×10 ⁷	10.2
C ₃₀ triacontane (638-68-6)	449.7 (expt.)	65.8 (expt.)	3.6 ×10 ⁻⁹ (expt.)	6.8×10 ⁸	15.1
C ₅₀	-	-	-	-	-

Isoalkanes

Chemical class, name (CAS RN)	Boiling point (°C)	Melting point (°C)	Vapour pressure (Pa) ^b	Henry's Law constant (Pa·m ³ /m ol) ^c	Log K _{ow}
C ₁₅ 2-methyltetra-decane (1560-95-8)	250.2	1.5	5.8	4.6×10 ⁶	7.6
C ₂₀ 3-methyl-nonadecane (6418-45-7)	326.3	39.5	0.092	2.6×10 ⁷	10.1
C ₃₀ hexamethyltetracosane (111-01-3)	408.5	74.7	0.037	2.1×10 ⁹	14.6

Monocycloalkanes

Chemical class, name (CAS RN)	Boiling point (°C)	Melting point (°C)	Vapour pressure (Pa) ^b	Henry's Law constant (Pa·m ³ /m ol) ^c	Log K _{ow}
C ₁₅ nonylcyclohexane (2883-02-5)	282 (expt.)	10 (expt.)	0.33 (expt.)	5.3×10 ⁵	7.5
C ₂₀ tetradecylcyclohexane (1795-18-2)	360 (expt.)	24 (expt.)	0.022	3.0×10 ⁶	10.0
C ₃₀ 1,5-dimethyl-1- (3,7,11,15-tetramethyl- octadecyl)-cyclohexane	420.9	103.2	1.5×10 ⁻⁴	2.9×10 ⁸	14.5

C ₅₀	674.2	294.0	5.6×10 ⁻¹³	2.0×10 ¹¹	24.4
-----------------	-------	-------	-----------------------	----------------------	------

Dicycloalkanes

Chemical class, name (CAS RN)	Boiling point (°C)	Melting point (°C)	Vapour pressure (Pa) ^b	Henry's Law constant (Pa·m ³ /m ol) ^c	Log K _{ow}
C ₂₀ 2,4-dimethyl-octyl-2-decalin	323.9	41.0	0.10	7.2×10 ⁵	8.9
C ₃₀ 2,4,6,10,14-pentamethyl-dodecyl-2-decalin	420.3	105.9	1.4×10 ⁻⁴	3.9×10 ⁷	13.6
C ₅₀	663.8	289.1	1.2×10 ⁻¹²	5.7×10 ¹⁰	23.3

Polycycloalkanes

Chemical class, name (CAS RN)	Boiling point (°C)	Melting point (°C)	Vapour pressure (Pa) ^b	Henry's Law constant (Pa·m ³ /m ol) ^c	Log K _{ow}
C ₁₄ hydrophenanthrene	255.1	20.8	4.5	8590	5.2
C ₁₈ hydrochrysene	353 (expt.)	115 (expt.)	4.1×10 ⁻³	5680	6.2
C ₂₂ hydropicene	364.9	108.1	2.6×10 ⁻³	3750	7.3

Monoaromatics

Chemical class, name (CAS RN)	Boiling point (°C)	Melting point (°C)	Vapour pressure (Pa) ^b	Henry's Law constant (Pa·m ³ /m ol) ^c	Log K _{ow}
C ₁₅ 2-nonyl-benzene (1081-77-2)	280.5 (expt.)	24 (expt.)	0.761 (expt.)	1.0×10 ⁴	7.1 (exp.)
C ₂₀ 1-benzyl-4,8-dimethyl-dodecane	334.6	49.2	0.024	8.2×10 ⁵	8.8
C ₃₀ 1-benzyl-4,8,12,16-tetramethyl-eicosane	437.0	131.3	1.2×10 ⁻⁵	3.6×10 ⁶	13.5
C ₅₀	697.1	304.6	2.0×10 ⁻¹⁴	1.0×10 ⁹	23.8

Diaromatics

Chemical class, name (CAS RN)	Boiling point (°C)	Melting point (°C)	Vapour pressure (Pa) ^b	Henry's Law constant (Pa·m ³ /m ol) ^c	Log K _{ow}
----------------------------------	-----------------------	--------------------------	---	---	------------------------

C ₁₅ 4-isopropyl-biphenyl (7116-95-2)	309.0	43.7	0.11	98.7	5.5 (expt.)
C ₂₀ 2-isodecyl-naphthalene	366.4	99.5	1.4×10^{-3}	1190	8.1
C ₃₀ 2-(4,8,14,18-tetramethyl-hexadecyl)-naphthalene	468.5	170.6	7.1×10^{-7}	5.4×10^4	12.8
C ₅₀	721.5	316.1	3.1×10^{-15}	8.6×10^6	23.3

Monocarboxylic acids

Chemical class, name (CAS RN)	Boiling point (°C)	Melting point (°C)	Vapour pressure (Pa) ^b	Henry's Law constant (Pa·m ³ /mol) ^c	Log K _{ow}
C ₁₅ pentadecanoic acid (1002-84-2)	339.1 (expt.)	52.3 (expt.)	5.8×10^{-7} (expt.)	0.044	6.5
C ₅₀ carboxylic acid	753.4	331.0	5.6×10^{-8}	3.0×10^8	23.7
C ₁₅ monocycloalkane carboxylic acid	352.4	112.6	0.0021	1.8	6.3
C ₅₀ monocycloalkane carboxylic acid	745.1	327.1	5.2×10^{-16}	1.1×10^8	23.2
C ₂₀ dicycloalkane carboxylic acid	396.1	141.8	9.1×10^{-5}	3.5	7.7
C ₅₀ dicycloalkane carboxylic acid	735.7	322.2	1.2×10^{-15}	1.1×10^7	22.0

Dicarboxylic acids

Chemical class, name (CAS RN)	Boiling point (°C)	Melting point (°C)	Vapour pressure (Pa) ^b	Henry's Law constant (Pa·m ³ /mol) ^c	Log K _{ow}
C ₁₅ pentadecane dicarboxylic acid	418.1	165.7	1.4×10^{-5}	8.2×10^{-4}	4.7
C ₅₀ monocycloalkane dicarboxylic acid	816.9	349.8	3.1×10^{-18}	5.2×10^6	21.4
C ₂₀ dicycloalkane dicarboxylic acid	466.9	197.2	3.8×10^{-7}	6.8×10^4	5.8
C ₅₀ dicycloalkane dicarboxylic acid	805.5	349.8	6.0×10^{-18}	5.1×10^5	20.2

Table B.3b. Physical and chemical properties for representative structures of petrolatum and waxes (EPI Suite 2008)^a**Alkanes**

Chemical names (CAS RN)	Log K _{oc}	Aqueous solubility (mg/L) ^d
C ₁₂ dodecane (112-40-3)	5.3	3.7 ×10 ⁻³ (expt.)
C ₁₅ pentadecane (629-62-9)	6.7	7.6×10 ⁻⁵ (expt.)
C ₂₀ eicosane (112-95-8)	8.8	0.019 (expt.)
C ₃₀ triacontane (638-68-6)	13.1	8.6×10 ⁻¹¹
C ₅₀	5.3	3.7 ×10 ⁻³ (expt.)

Isoalkanes

Chemical names (CAS RN)	Log K _{oc}	Aqueous solubility (mg/L) ^d
C ₁₅ 2-methyltetradecane (1560-95-8)	6.6	3.3×10 ⁻³
C ₂₀ 3-methylnonadecane (6418-45-7)	8.8	1.1×10 ⁻⁵
C ₃₀ Hexamethyltetracosane (111-01-3)	12.7	2.0×10 ⁻¹⁰

Monocycloalkanes

Chemical names (CAS RN)	Log K _{oc}	Aqueous solubility (mg/L) ^d
C ₁₅ nonylcyclohexane (2883-02-5)	6.5	4.9×10 ⁻³
C ₂₀ tetradecylcyclohexane (1795-18-2)	8.7	1.7×10 ⁻⁶
C ₃₀ 1,5-dimethyl-1-(3,7,11,15- tetramethyl-octadecyl)- cyclohexane	12.5	4.2×10 ⁻⁷
C ₅₀	21.2	1.4×10 ⁻²⁰

Dicycloalkanes

Chemical names (CAS RN)	Log K _{oc}	Aqueous solubility (mg/L) ^d
C ₂₀ 2,4-dimethyl-octyl-2-decalin	7.7	1.2×10 ⁻⁴

C ₃₀ 2,4,6,10,14- pentamethyl-dodecyl-2-decalin	11.8	1.7×10 ⁻⁹
C ₅₀	20.2	1.4×10 ⁻¹⁹

Polycycloalkanes

Chemical names (CAS RN)	Log K _{oc}	Aqueous solubility (mg/L) ^d
C ₁₄ hydrophenanthrene	4.5	0.49
C ₁₈ hydrochrysene	5.4	0.011
C ₂₂ hydropicene	6.3	2.2×10 ⁻³

Monoaromatics

Chemical names (CAS RN)	Log K _{oc}	Aqueous solubility (mg/L) ^d
C ₁₅ 2-nonyl-benzene (1081-77-2)	6.2	0.034
C ₂₀ 1-benzyl-4,8-dimethyl-dodecane	7.6	5.5×10 ⁻⁴
C ₃₀ 1-benzyl-4,8,12,16-tetramethyl-eicosane	11.8	6.8×10 ⁻⁹
C ₅₀	20.7	1.7×10 ⁻¹⁹

Diaromatics

Chemical names (CAS RN)	Log K _{oc}	Aqueous solubility (mg/L) ^d
C ₁₅ 4-isopropyl-biphenyl (7116-95-2)	4.8	0.90
C ₂₀ 2-isodecyl-naphthalene	7.0	2.4×10 ⁻³
C ₃₀ 2-(4,8,14,18-tetramethyl-hexadecyl)-naphthalene	11.1	3.0×10 ⁻⁸
C ₅₀	20.2	5.6×10 ⁻¹⁹

Mono-carboxylic acids

Chemical names (CAS RN)	Log K _{oc}	Aqueous solubility (mg/L) ^d
C ₁₅ pentadecanoic acid (1002-84-2)	3.7	0.32
C ₅₀ carboxylic acid	13.2	7.3×10 ⁻⁷

C ₁₅ monocycloalkane carboxylic acid	3.6	2.2
C ₅₀ monocycloalkane carboxylic acid	13.0	7.3×10^{-7}
C ₂₀ dicycloalkane carboxylic acid	4.4	4.3×10^{-2}
C ₅₀ dicycloalkane carboxylic acid	12.3	7.3×10^{-7}

Dicarboxylic acids

Chemical names (CAS RN)	Log K _{oc}	Aqueous solubility (mg/L) ^d
C ₁₅ pentadecane dicarboxylic acid	2.7	1.2
C ₅₀ monocycloalkane dicarboxylic acid	12.0	7.3×10^{-7}
C ₂₀ dicycloalkane dicarboxylic acid	3.4	0.15
C ₅₀ dicycloalkane dicarboxylic acid	11.3	7.6×10^{-7}

^a All values are modelled unless denoted with an (expt.) for experimental data. Models used were: MPBPWIN (Version 1.43) for melting point, boiling point and vapour pressure, HENRYWIN (Version 3.20) for Henry's Law constants, KOWWIN (Version 1.67a) for log K_{ow}, KOCWIN (Version 2.0) for log K_{oc}, WSKOW (Version 1.41) for water solubility.

^b This is the maximum vapour pressure of the representative substance; the actual vapour pressure as a component of a mixture will be lower due to Raoult's Law (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).

^c Henry's Law constants for C₂₀ representative substances were calculated with Henrywin Version 3.10 from EPI Suite (2008), using both sub-cooled liquid solubility and sub-cooled liquid vapour pressure. Solubility data gave anomalously high values for substances that have negligible solubility and volatility.

^d Maximum water solubility was estimated for each representative substance based on its individual physical-chemical properties. The actual water solubility of a component in a mixture will decrease, as the total water solubility of an ideal mixture is proportional to the sum of the water solubilities of the mole fractions of each individual component (Banerjee 1984).

Table B.4. Composition of crude petrolatums, and unrefined and refined microcrystalline waxes (Mohamed and Zaky 2004)

Aliphatics

	<i>n</i> -alkanes	Iso- and cycloalkanes
Crude petrolatums	9.32–22.06%	43.09–56.98%
Microcrystalline waxes (unfinished)	8.09–13.36%	72.01–76.89%
Microcrystalline waxes (finished)	8.47–14.08%	75.86–80.53%

Aromatics

	Monoaromatics	Diaromatics
Crude petrolatums	17.33–21.90%	12.95–16.37%
Microcrystalline waxes (unfinished)	10.84–14.63%	0.0–4.18%
Microcrystalline waxes (finished)	8.85–10.06%	0.0–2.15%

Table B.5. An analysis of persistence data for petroleum hydrocarbons representative of petrolatum and waxes according to Environment Canada (2014)

# of carbons	C ₁₂	C ₁₄	C ₁₅	C ₁₈	C ₂₀	C ₂₂	C ₂₅	C ₃₀	C ₅₀
<i>n</i>-alkane	-	n/a	-	-	-	n/a	n/a	-	-
<i>i</i>-alkane	-	n/a	-	n/a	-	n/a	n/a	S, W, Sd	-
monocycloalkane	-	n/a	-	n/a	-	n/a	n/a	Sd	S, W, Sd
dicycloalkane	Sd	n/a	S, W, Sd	n/a	S, W, Sd	n/a	S, W, Sd	S, W, Sd	S, W, Sd
polycycloalkane	n/a	Sd	n/a	S, W, Sd	n/a	S, W, Sd	n/a	n/a	n/a
monoaromatic	S, W, Sd	n/a	Sd	n/a	-	n/a	n/a	Sd	Sd
diaromatic	S, W, Sd	n/a	S, W, Sd	n/a	S, W, Sd	n/a	n/a	S, W, Sd	S, W, Sd

A – Predicted half-life in air of 2 days or greater

S – Predicted half-life in soil of 6 months or greater

W – Predicted half-life in water of 6 months or greater

Sd – Predicted half-life in sediment of 1 year or greater

n/a – Not applicable. Indicates that no such carbon number exists within the group or it was not modelled.

- Indicates that these structures are not considered to persist for long periods of time in air, soil, water or sediment.

Table B.6. An analysis of experimental and modelled bioaccumulation data for petroleum hydrocarbons representative of petrolatum and waxes according to Environment Canada (2014)

# of carbons	C ₁₂	C ₁₃	C ₁₄	C ₁₅	C ₁₆	C ₁₈	C ₂₀	C ₂₂	C ₂₅
<i>n</i>-alkane	-	-	-	-	-	-	-	n/a	n/a
<i>i</i>-alkane	-	B	n/a	B	n/a	n/a	n/a	n/a	n/a
Monocyclo-alkane	B	n/a	n/a	B	n/a	n/a	n/a	n/a	n/a
Dicyclo-alkane	B	-	n/a	B	n/a	-n/a	n/a	n/a	n/a
Polycyclo-alkane	n/a	n/a	B	n/a	n/a	-	n/a	B	n/a
monoaromatic	-	n/a	n/a	B	n/a	n/a	n/a	n/a	n/a
diaromatic	B	B	-	-	n/a	n/a	n/a	n/a	n/a

B – Predicted highly bioaccumulative with a BCF/BAF greater than 5000.

n/a – Not applicable. Indicates that no such carbon numbers exist within the group or it was not modelled.

- Indicates that these structures are not considered highly bioaccumulative.

Appendix C. Potential for Ecological Harm

Table C.1. Modelled acute aquatic toxicity data for petrolatum and slack waxes (PetroTox 2009)^a

Test organism	Common name	LL ₅₀ ^b (mg/L) 8009-03-8	LL ₅₀ ^b (mg/L) 64742-61-6
<i>Palaemonetes pugio</i>	Grass shrimp	More than 1000	More than 1000
<i>Rhepoxynius abronius</i>	Marine amphipod	More than 1000	More than 1000
<i>Daphnia magna</i>	Water flea	More than 1000	More than 1000
<i>Onchorynchus mykiss</i>	Rainbow trout	More than 1000	More than 1000
<i>Selenastrum capricornutum</i>	Freshwater green alga	More than 1000	More than 1000
<i>Menidia beryllina</i>	Inland silverside	More than 1000	More than 1000

^a PetroTox was run in the low resolution mode that requires only an aromatic to aliphatic ratio and a boiling point range for each hydrocarbon block.

^b LL₅₀ refers to lethal loading, the amount of product necessary to be added in order to kill 50% of test organisms (Ar:Al, aromatic: aliphatic ratio which was 5:95).

Appendix D. Petrolatum Exposure by Route and Age Group

Table D.1. Upper-bound estimates of daily oral exposure to petrolatum

Age group	Exposure to petrolatum ^a from single food item (mg/kg-bw)	Recommended servings of food item	Total daily exposure ^b (mg/kg-bw per day)
Infant	n/a	n/a	n/a
Toddler	38.7	4	51.6
Child	19.4	5–6	38.7
Teen	10.1	7–8	26.9
Young adult	8.5	7–10	28.2
Adult	8.3	7	19.4

^a Age groups and body weights considered are adult 60+ years (72 kg), young adult 20–59 years (70.9 kg), teenager 12–19 years (59.4 kg), child 5–11 years (31 kg), toddler 6 months–4 years (15.5 kg) and infant 0–6 months (7.5 kg) (Health Canada 1998). Apple weight was considered to be 200 grams, and the maximum petrolatum content to be 0.3% w/w. One-third of the recommended serving was considered to contain petrolatum wax coating. Oral uptake is considered to be 100%.

^b Total daily exposure is based on the upper end of the recommended servings of food item..

Dermal exposures to petrolatum were estimated using ConsExpo (2006, 2012) and standard body weights as above. Frequencies of product use ranged from 10 times per year for hair bleach to 858 times per year for lip balm (not shown; available as supplemental material) (ConsExpo 2006; CTFA 1983; Loretz 2005, 2006; Wormuth 2005; Wu 2010). Petrolatum content of various products ranged from 3% in shampoo to 100% in creams and lotions. Amounts of product applied were according to ConsExpo (2006), CTFA (1983), Loretz (2005, 2006) and Health Canada (1995). Uptake fractions were 100% or according to SCCS (2010). Where ranges of exposure were obtained for a single age group, the upper value is shown in Table D.2. Health Canada's Consumer Product Safety Directorate was consulted on various product parameters (personal communication from Health Canada's Consumer Product Safety's Risk Assessment Division to Health Canada's Existing Substances Risk Assessment Bureau September 2013). For the baby cream exposure scenario for infants and toddlers, 1.4 grams of product, entirely composed of petrolatum, was considered to be applied 1.72 times per day, every day, for a daily dermal exposure to petrolatum of 2.4 grams (2400 mg). Only the products having the highest estimate of petrolatum exposure for each age group are shown in Table D.2.

Table D.2. Upper-bound estimates of dermal exposure to petrolatum (in mg/kg-bw per day) from the use of products available to consumers

Age group	Baby cream	Hand cream / body lotion
Infant	321	n/a
Toddler	154.8	n/a
Child	n/a	103
Teen	n/a	70.3
Young adult	n/a	68.2
Adult	n/a	67.2

Appendix E. Summary of Health Effects Information for Petrolatum and Waxes

Table E.1. Endpoints and effect levels for petrolatum and waxes and related substances

Endpoint	Substance	Effect levels ^a / Results
Acute	64743-01-7	Oral LD₅₀ >5000 mg/kg-bw. A corn oil solution of oxidized petrolatum was used for oral dosing of 10 male rats. No deaths during 14 days of observation. Varying degrees of diarrhea were noted (Elder 1984).
Acute	Surrogate substances	Oral and dermal LD₅₀ >5000 mg/kg-bw for the oral and dermal routes of exposure. No clinical signs of oral toxicity, and little to no irritation noted for dermal exposures. No systemic effects. Test substances included microcrystalline waxes, petrolatum/paraffin mixtures and USP white mineral oils (CONCAWE 1999; Elder 1984; US EPA 2006).
Acute	Microcrystalline wax	Oral LD₅₀ = 10 000 mg/kg-bw. A 20% solution in corn oil was given by stomach tube to 5 rats. There were 3 deaths, and hard wax was found in the stomach. No adverse effects were observed at 4640 mg/kg-bw (Elder 1984).
Repeat dose	Surrogate substances	Oral In orally exposed F344 rats, mineral oil and paraffin wax hydrocarbons accumulated in various organs, and a mitral valve and hepatic inflammatory response was seen, as well as mesenteric lymph node microgranulomas (BIBRA 1992, 1993, 1999; Scotter et al. 2003; Griffis et al. 2010; Miller et al. 1996). However, these effects were shown to be essentially limited to the F344 rat and to be reversible (Trimmer et al. 2004). Therefore, the F344 rat is not considered a good model for assessing possible health effects in humans from oral exposure to mineral hydrocarbons (Carlton et al. 2001; Miller et al. 1996).

Endpoint	Substance	Effect levels ^a / Results
Reproductive and developmental	Surrogate substances	Dermal Dermal exposure of rats to three lubricating oil basestocks from gestational days 0–19 at up to 2000 mg/kg-bw did not result in developmental effects (CONCAWE 1997). Oral No teratogenicity was seen when highly refined white oil was administered (as vehicle control) by gavage at 5 mL/kg-bw per day from GD 6–19 (McKee et al. 1987a). Administration at the same level for 13 weeks (as vehicle control) to males and females had no effect on breeding or the numbers or survival of offspring (McKee et al. 1987b).
Carcinogenicity	8009-03-8	Oral Petrolatum was fed at 5% in the diet to FDRL rats (50 per sex per grade) for two years. Groups received a blend of 5 or 6 different marketplace samples of one of three grades of petrolatum: grade A (“snow white,” meeting USP XVI specifications with blended UV₂₉₀ = 0.136), grade B (“white,” meeting USP XVI specifications with blended UV₂₉₀ = 0.424) or grade C (“yellow,” meeting NF XI specifications with blended UV₂₉₀ = 1.48). Two hundred rats served as control. Periodic measurements of food utilization and body weight gain, blood, serum and urine analysis, survival rates, and extensive necropsy and gross and histological organ examination of rats that died, and of 10 representative rats from each group at the end of the two-year study, did not reveal exposure-related changes. However, enlarged livers were seen in 13 and 7 rats receiving grades A and B, respectively. Lung congestion was also seen in 28 and 16 rats receiving grades A and B, respectively. Sporadic increased incidence of mammary adenocarcinoma (3% in control females vs. 4% in Group A females, and 8% in both of Groups B and C females) was observed, but was not considered by the authors to be related to test substance. A chronic oral NOAEL of approximately 3100 mg/kg-bw per day was calculated based on mean food consumption and

Endpoint	Substance	Effect levels ^a / Results
		body weights at 12 weeks (Oser et al. 1965). Dermal NF grade amber petrolatum, containing over 14 ppm PAHs (Lijinsky et al. 1963), was applied as a 15% solution in isooctane (60 µL) twice weekly to the skin of 40 male and 30 female Swiss mice for two years. Three of the 70 mice developed a total of 5 tumours, of which 3 regressed, leaving 2 mice with a single tumour each. Two mice of 100 in the control group developed tumours that did not regress. It was concluded that this sample of petrolatum was not carcinogenic. Aromatic extracts from this sample of amber petrolatum were carcinogenic in mice when tested at a 50-fold concentration at 20 µL per application. It was indicated that this petrolatum sample would not pass purity standards for food use (Lijinsky et al. 1963, 1966). Petrolatum (derived from solvent-extracted residual oil; CAS RN 64742-01-4) was applied at 25 mg (830 mg/kg-bw^b) to the shaved interscapular region of male C3H/HeJ mice twice weekly for 80 weeks. Two trials with test groups of 25 and 50 mice were conducted. The test substances did not produce any skin tumours in either group as measured by papillomas persisting for at least 1 week and reaching at least 1–3 mm in size. Survival to 60 weeks was 50% in the group of 50, and 76% in the group of 25 (Kane et al. 1984). Subcutaneous injection 50 Swiss-Webster mice per sex per group received 100 mg of one of three grades of petrolatum via i.p. injection in the interscapular region, and were observed for 18 months. Growth and food efficiency at 12 weeks was normal, and no short-term effects were noted. Liver weights at 9 months were higher than normal in all test substance groups, but were highest in the control group that received stripped lard. Chronic inflammatory or fibrotic changes were noted in some animals, consistent with the presence of foreign material. There was no increased

Endpoint	Substance	Effect levels ^a / Results
		incidence of tumours relative to the control group that received stripped lard (Oser et al. 1965).
Carcinogenicity	64742-61-6	Dermal Slack wax (derived from solvent-refined heavy paraffinic distillate; CAS RN 64741-88-4) was applied at 25 mg (830 mg/kg-bw^b) to the shaved interscapular region of male C3H/HeJ mice twice weekly for 80 weeks. Two trials with test groups of 25 and 50 mice were conducted. The test substance did not produce any skin tumours in either group as measured by papillomas persisting for at least 1 week and reaching at least 1–3 mm in size. Survival to 60 weeks was 50% in the group of 50, and 96% in the group of 25 (Kane et al. 1984). Studies examining the carcinogenicity of slack wax samples prepared by the historical (obsolete) pressing method were identified (Smith et al. 1951 and Dietz et al. 1952; ECHA 1953; US EPA 2006) but are not included for summary herein.^c
Carcinogenicity	Petroleum wax	Dermal Five petroleum waxes were assessed for carcinogenicity in a skin painting study in Swiss mice (90) and rabbits (8). Wax solutions of 15% in benzene were used, resulting in repeated exposures to petroleum wax of approximately 250 mg/kg-bw for mice and 3.3 mg/kg-bw for rabbits. Desquamation and epilation were noted in the skin of both species. There were no significant differences in tumour formation between exposed and control groups, and tumours were mostly benign papillomas. Two skin papillomas were noted in one of the rabbit groups but the results are within levels seen in historical controls and therefore were considered by the authors to not be related to exposure to the test substances (Shubik et al. 1962). Oral A lifetime feeding study of different petroleum waxes used as food additives and food packaging at 5 and 10% in the diet of SD rats (100 per group) was negative for carcinogenicity (Shubik et al. 1962).

Endpoint	Substance	Effect levels ^a / Results
Carcinogenicity	White mineral oils	Oral Two food-grade white mineral oils (P70(H) and P100(H)) were tested at 60, 120, 240 and 1200 mg/kg-bw in the diet of F344 rats (50 per sex per group) in a two-year feeding study. No neoplastic lesions nor adverse health effects occurred. A NOAEL of 1200 mg/kg-bw per day was determined by the study authors (Trimmer et al. 2004). Dermal Lifetime dermal application of 0.2 mL medicinal paraffin twice weekly to male C3H/HeJ mice (n=100) did not result in the formation of skin tumours (Kane et al. 1984).
Genotoxicity: <i>in vitro</i> and <i>in vivo</i>	64743-01-7	Oxidized petroleum was tested using the ASTM E1687-98 test method and was found to not be mutagenic in bacteria (HPD 2002).
Genotoxicity: <i>in vitro</i> and <i>in vivo</i>	Surrogate substances	Genotoxicity data for white oils and highly refined base and lubricant oils (IP 346 <3% PAHs) were essentially negative (CONCAWE 1999; McKee and Przygoda 1987; McKee et al. 1990; Blackburn et al. 1984; Conaway et al. 1984). Some solvent-refined oils exhibited some mutagenicity, but severely solvent refined oils exhibit no activity (Cal EPA 2001; Mackerer et al. 2003; Venier et al. 1987).
Human studies	8009-03-8	Dermal A retrospective analysis of patch testing conducted in 79 365 humans (with European Pharmacopoeia grade petrolatum from a single German supplier, used as the vehicle control) revealed two cases (0.003%) of possible skin allergy to petrolatum. However, an “angry back” (a reaction to petrolatum vehicle in the vicinity of strong reactions to various test substances) was confirmed for one case. On follow-up testing, this patient did not react to petrolatum. The other case was likened to a reading or documentation error, as the patient also had multiple negative reactions to petrolatum. After review of the raw data, 27 cases (0.03%) were considered either likely irritant or possibly false positive reactions. The authors concluded that this brand of petrolatum

Endpoint	Substance	Effect levels ^a / Results
		(purified white petrolatum of pharmaceutical quality meeting pharmacopeia requirements) therefore cannot be considered an allergen (Schnuch et al. 2006). Other studies of individuals with petrolatum sensitivity were identified and reviewed (Dooms-Goossens and Degreeef 1983; Marzulli and Maibach 2008; Ulrich et al. 2004).
Human studies	Microcrystalline wax	Dermal Twenty-five volunteers were exposed via their forearms to a lipstick formulation containing 15% microcrystalline wax. Exposures were with occlusion every 2 days for 10 days. Volunteers were then exposed to 10% sodium lauryl sulfate and then challenged with the test substance. Dermal sensitization did not occur (Elder 1984).

^a LD₅₀, median lethal dose; LC₅₀, median lethal concentration; 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.

^b Assuming average mouse body weight of 30 grams.

^c Samples of petrolatum and waxes produced in the mid-20th century via the “pressing” method could contain higher levels of PAHs and are not considered here as they are not representative of the current marketplace.

Appendix F. Compositional Testing of Products Available to the Consumer

Table F.1. Compilation of high resolution testing results for 16 PAHs from 20 Canadian products containing petrolatum

PAH species	Concentration range ^{a,b} (ppb)	Median concentration ^c (ppb)	B[a]P equivalents ^d (ppb)	Log K _{ow} ^e
naphthalene	ND – 75.4	5*	0.005	3.37
acenaphthylene	ND – 1.92	0.5*	0.0005	N/A
acenaphthene	ND – 15	5*	0.005	4.0
fluorene	ND – 16	2.5*	0.0025	4.2
phenanthrene	ND – 70	2.5*	0.0025	4.57
anthracene	ND – 24	2.5*	0.025	4.54
fluoranthene	ND – 42	2.5*	0.0025	5.22
pyrene	ND – 28	2.5*	0.0025	5.0
benz[a]anthracene	ND	0.5*	0.05	5.91
chrysene	ND – 19.1	5*	0.05	5.86
benzo[b+j]fluoranthene	ND – 147	5*	0.5	5.8
benzo[k]fluoranthene	ND – 2.36 ^f	0.5*	0.05	6.0
benzo[a]pyrene	ND – 30.1 ^g	5*	5	6.4
indeno[1,2,3-cd]pyrene	ND – 15.2	5*	0.5	N/A
dibenz[a,h]anthracene	ND – 9.69 ^f	0.5*	2.5	5.8
benzo[ghi]perylene	ND – 69	5*	0.05	6.9

^a Health Canada, unpublished (compositional analyses conducted in 2013-2014). Results given as µg PAH per kg product (parts per billion).

^b "ND" indicates not detected at the Limit of Detection (LoD) of 0.5 or 1 ppb (in liquid products) or 5 or 10 ppb (in gel/solid products).

^c asterisks indicate that the median value had to be selected from a measure of the LoD (i.e., the majority of the products did not contain a majority of the PAHs); when PAHs were primarily not detected, the median was considered to be ½ of the highest LoD (gel/solid products); this measure was also used when lower levels were detected in liquid products but not detected in gel products. In two cases where only one product contained the PAH of interest, ½ the highest LoD below the concentration detected was considered the median. No product contained a detectable level of benzo[a]anthracene, and therefore ½ the lowest LoD was used.

^d B[a]P equivalents were calculated based on the assigned median concentration and using PAH potency equivalence conversion factors from Nisbet and LaGoy, 1992 (Appendix G); this approach assumes that the mechanism of action for each PAH is the same as B[a]P. After scaling each PAH based on its potency relative to B[a]P, values are summed to obtain total B[a]P equivalents, considered to represent the potential toxicity of a sample. Using the considerations described here, the median B[a]P equivalents, across 20 petrolatum-containing products, is 9 parts per billion.

^e From Sangster 1989.

^f Only one product contained a detectable level of benzo[k]fluoranthene or dibenz[a,h]anthracene.

^g B[a]P was not detected in 16 products.

Appendix G. Potency Equivalence Factors for Certain PAH Species

Table G.1. Potency equivalence factors for 16 PAH species measured in the compositional testing of petrolatum-containing products

PAH Species	Relative B[a]P potency ^a
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

^a adapted from Nisbet and LaGoy, 1992