

Draft Screening Assessment

Assessment of Seven Hydrocarbon-based Substances

Chemical Abstracts Service Registry Numbers

74-86-2

8002-53-7

64742-40-1

68476-03-9

68477-26-9

68956-70-7

73138-45-1

**Environment and Climate Change Canada
Health Canada**

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Synopsis

Pursuant to sections 68 or 74 of the Canadian Environmental Protection Act, 1999 (CEPA), the Minister of the Environment and the Minister of Health have conducted a draft screening assessment of seven hydrocarbon-based substances. Substances in this group were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA or were considered a priority on the basis of other human health concerns. The Chemical Abstracts Service Registry Numbers (CAS RN¹), their Domestic Substances List (DSL) names and their common names are listed in the table below.

Seven hydrocarbon-based substances

CAS RN	DSL name	Common name
64742-40-1 ^a	Neutralizing agents (petroleum), spent sodium hydroxide	Spent sulphidic caustic
68477-26-9 ^{a,b}	Wastes, petroleum	Slop oil
68956-70-7 ^{a,b}	Petroleum products, C ₅₋₁₂ , reclaimed, wastewater treatment	Naphtha waste
74-86-2 ^b	Ethyne	Ethyne (Acetylene)
8002-53-7 ^a	Montan wax	Montan Wax
68476-03-9 ^a	Fatty acids, montan-wax	Montan-wax fatty acids
73138-45-1 ^{a,b}	Fatty acids, montan-wax, ethylene esters	Montan-wax fatty acids ethylene esters

^a This CAS RN is a UVCB (unknown or variable composition, complex reaction products, or biological materials).

^b This substance was not identified under subsection 73(1) of CEPA but was included in this draft screening assessment as it was considered a priority on the basis of other human health concerns.

Spent sulphidic caustic, slop oil and naphtha waste are by-products or wastes generated by the petroleum industry which are recycled or reclaimed to a large extent by refineries. No information on the quantity of these petroleum refinery wastes generated in Canada was identified; however they are all high production volume

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substances in the United States (US). Portions of these wastes that are not recycled or reclaimed or sold to industrial users are either treated and disposed of, or shipped offsite to provincial and territorial licenced waste disposal facilities, where they may be further processed. They are not used in products available to consumers and are not expected to be released to the environment. Accordingly, exposures to the environment and to the general population from these wastes are not expected and the potential risk to the environment and human health is expected to be low.

Ethyne is produced from the conversion of methane under high heat in the presence of oxygen. Ethyne is also manufactured by reacting calcium carbide and water, or may be incidentally produced as a co-product during the cracking of natural gas liquids, naphtha, or gas oil. No information on the quantity of ethyne manufactured in Canada was identified; however it is a high production volume chemical in the US. The primary uses of ethyne are as a raw material for the production of other chemicals (e.g., 1,4-butanediol, acetylenic alcohols, ethyl and methyl vinyl ethers) in closed systems, followed by use as a fuel for welding, cutting, and heat treating metals. Based on its use in closed industrial environments or as a fuel operating in high temperature combustion conditions, exposure to the environment and to the general population is expected to be minimal. On the basis of its minimal exposure to the environment and to the general population, as well as its low estimated ecotoxicity and human toxicity, the potential risk to the environment and human health from ethyne is expected to be low.

Montan wax is a solid wax originating from lignite coal. It has similar properties and uses to the petroleum wax petrolatum, but has a non-petroleum source. In addition to crude montan wax, this assessment considers refined (bleached or deresined) montan wax and its components montan-wax fatty acids, and montan-wax fatty acids ethylene esters. Refined montan wax is used in products available to consumers including cosmetics, automotive products, household cleaning products and food packaging materials. Montan wax is expected to be released to wastewater from these uses, and subsequently partition to sediments and biosolids, due to its low water solubility. Experimental and modelled toxicity data indicates that montan wax is considered to be of low ecological hazard. Additionally repeat-dose animal studies indicate low toxicity to humans. Given the low environmental and human health hazards associated with these substances, the potential risk to the environment and human health from these waxes is considered to be low.

Considering all available lines of evidence presented in this draft screening assessment, there is low risk of harm to organisms and the broader integrity of the environment from spent sulphidic caustic, slop oil, naphtha waste, ethyne, montan wax, montan-wax fatty acids and montan-wax fatty acids ethylene esters. It is proposed to conclude that sulphidic caustic, slop oil, naphtha waste, ethyne, montan wax, montan-wax fatty acids and montan-wax fatty acids ethylene esters 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.

On the basis of the information presented in this draft screening assessment, it is proposed to conclude that spent sulphidic caustic, slop oil, naphtha waste, ethyne, montan wax, montan-wax fatty acids and montan-wax fatty acids ethylene esters 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 proposed to conclude that spent sulphidic caustic, slop oil, naphtha waste, ethyne, montan wax, montan-wax fatty acids, and montan-wax fatty acids ethylene esters do not meet the criteria set out in section 64 of CEPA.

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1. Introduction

Pursuant to sections 68 or 74 of the Canadian Environmental Protection Act, 1999 (CEPA) (Canada 1999), the Minister of Environment and the Minister of Health have conducted a draft screening assessment of seven hydrocarbon-based substances to determine whether these substances present or may present a risk to the environment or to human health. The substances in this group were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA or were considered a priority based on other human health concerns (ECCC, HC [modified 2007]).

This draft screening assessment contains three petroleum unknown or variable composition, complex reaction products, or biological materials (UVCB) wastes, one discrete substance (ethyne) that is similar to petroleum hydrocarbons and may be derived from petroleum substances, a lignite coal-derived UVCB wax and two of its fatty acid and fatty acid ester components that are used in a similar manner as the petrolatum petroleum waxes. These seven substances are addressed individually within this assessment.

While the seven substances are being addressed in this assessment, they lack similarities that would support a group approach to exposure, hazard and risk characterization; thus, their exposure and hazard profiles are assessed in five separate chapters. Only the three montan waxes have been combined into a single chapter.

This draft screening assessment includes consideration of information on chemical properties, environmental fate, hazards, uses and exposures, including additional information submitted by stakeholders. Relevant data were identified up to February 2017. Empirical data from key studies as well as some results from models were used to reach proposed conclusions. When available and relevant, information presented in assessments from other jurisdictions was considered.

This draft screening assessment was prepared by staff in the CEPA Risk Assessment Program at Health Canada and Environment and Climate Change Canada and incorporates input from other programs within these departments.

This draft screening assessment focuses on information critical to determining whether substances meet the criteria as set out in section 64 of CEPA by examining scientific

information and incorporating a weight-of-evidence approach and precaution². The draft screening assessment presents the critical information and considerations upon which the proposed conclusion is made.

2. Spent sulphidic caustic

2.1 Substance Identity

Neutralizing agents (petroleum), spent sodium hydroxide (CAS RN³ 64742-40-1), referred to hereafter as spent sulphidic caustic, is a UVCB; it consists predominantly of water and contains sodium hydroxide and organic and inorganic sodium salts. It is produced during the treatment of light petroleum fractions with a dilute caustic solution to remove sulphur compounds. The predominant source of this substance is the Merox® regeneration unit of refineries. During this treatment, the majority of the caustic solution is returned to the treatment unit. However, in order to prevent sulphides and other extractable constituents from concentrating within the caustic solution to a point where it cannot be used, a portion of the caustic solution is periodically removed. The portion removed is referred to as the spent sulphidic caustic (API 2009).

Spent sulphidic caustic contains relatively high amounts of sodium sulphide and sodium mercaptides. Other components found in lower concentrations include phenols, amines, and other organic compounds. The most commonly identified mercaptans are C1-C6 mercaptans (methyl to hexyl mercaptans), which are produced in varying proportions depending on the refinery streams being treated (API 2009).

A typical spent sulphidic caustic solution from a petroleum refinery has a pH of 13 to 14, and may contain up to 14% (w/w) sodium hydroxide, so it is highly alkaline and corrosive (API 2009). In addition, the spent solution may contain approximately 5 to

² A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and the use of products available to consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the Hazardous Products Regulations, which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

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20% of a heterogeneous oil mixture. Other measurements of physical and chemical properties cannot reliably be made due to its highly variable composition (API 2009).

2.2 Sources and Uses

Spent sulphidic caustic is generated at some Canadian refineries (personal communication, email with attachments from Canadian Fuel Association (CFA) to Ecological Assessment Division, Environment and Climate Change Canada (ECCC), dated April 11, 2016; unreferenced). Spent sulphidic caustic can be recycled to recover the sodium hydroxide and the individual organic constituents (identified under different CAS RNs than the spent sulphidic caustic), which can then be used as feedstocks for the manufacture of a number of products (API 2009). In the US, approximately 400 000 lb/year (~180 metric tonnes/year) of spent sulphidic caustic is used in the pulp and paper industry (API 2009). Similarly, the Canadian forest products industry also uses spent sulphidic caustic (FPAC 2005) in the production of sulphate (Kraft) pulp for use in the manufacture of paper products (EPPI 2016).

There are no uses of this substance in pesticides, natural health products, cosmetics, foods and food packaging, and other products available to the general population in Canada.

2.3 Exposure

There are three possible treatment routes for spent sulphidic caustic in Canada. Spent sulphidic caustic may be treated at refinery waste water treatment plants (WWTPs) to meet sewer discharge permit requirements if discharged into the municipal sewer system, or may be sent offsite for disposal where it needs to meet provincial/territorial licencing requirements. API (2009) reports deep well injection as another possible disposal method for spent sulphidic caustic and was identified as a method of disposal for spent sulphidic caustic for at least one refinery in Alberta (Gentsia 2010).

The Forest Products Association of Canada indicates that this substance is not released to the environment under normal operating conditions, as it is a hazardous substance that is contained and managed accordingly (FPAC 2005).

Release of spent sulphidic caustic to the environment, and resulting exposure of the general population, is expected to be limited based on the above information.

2.4 Ecological and Human Health Effects

Spent sulphidic caustic was not identified as posing a high hazard for carcinogenicity, genotoxicity, developmental toxicity, or reproductive toxicity based on classifications by other national or international agencies (API 2009). It is also not on the European Chemicals Agency's Candidate List of Substances of Very High Concern for Authorisation (ECHA [modified 2015]).

The critical effect for spent sulphidic caustic is corrosivity at the site of contact, due to its high pH. Spent sulphidic caustic is known to be highly corrosive to animals and aquatic organisms due to its pH of up to 14 (API 2009). Further characterization of health effects is not warranted at this time given that human exposure is considered to be negligible.

2.5 Risk Characterization

Ecological effects from pH are mitigated as there are set limits for the adjustment of pH in effluent from wastewater treatment systems. Release of spent sulphidic caustic is expected to be minimal such exposure to the general population and to the environment is not expected. Therefore, the potential to cause harm to the environment or to human health for the general population of Canada is expected to be low.

3. Slop oil

3.1 Substance Identity

Wastes, petroleum (CAS RN 68477-26-9), hereafter referred to as slop oil, is defined by NCI (2015) as waste products from any petroleum refinery or production process which has been dewatered. Others, such as the American Petroleum Institute, define slop oil as any petroleum product at a refinery that does not meet product specifications and cannot be used without further processing (API 2010a). It may also be referred to as petroleum wastes, petroleum refining wastes and petroleum refinery wastes (NCI 2015).

Slop oil is a UVCB with a highly variable composition, as slop oils from various refinery streams are often combined together for storage. The wastes generally contain sulphides, phenols, aliphatic and aromatic hydrocarbons, and heavy metals (API 2010a). Slop oils commonly have water and bottom sediment content ranging from 5-60% with the solids comprising around 20%, though lower values of water and bottom sediment are possible (Rhodes 1994).

3.2 Sources and Uses

Slop oil is collected at points in the refinery where wastes are generated in such a way as to eliminate the discharge of this product into wastewater (API 2010a). Slop oil is a waste product with no identified uses.

In 2016, CFA members voluntarily identified that slop oil is generated at most Canadian refining facilities (personal communication; email with attachments from CFA to Ecological Assessment Division, ECCC, dated April 11, 2016; unreferenced). While it is expected that all refineries would produce hydrocarbon wastes, such as slop oil, the

wastes may be identified under different CAS RNs than those in this draft screening assessment.

There are no uses of this substance in pesticides, natural health products, cosmetics, foods and food packaging, and other products available to the general population in Canada.

3.3 Exposure

API (2010a) indicates that slop oil with a bottom sediment and water content less than 1% can easily be re-refined in the distillation unit. Disposal methods for other slop oil compositions identified by API (2010a) include use as a fuel, deep well injection, landfilling in a regulated and approved site, or transfer off-site for hydrocarbon recovery.

Similar to management practices described in API (2010a), voluntary information collected through the CFA in 2016 (personal communication; email with attachments from CFA to Ecological Assessment Division, ECCC, dated April 11, 2016; unreferenced) indicated that, in Canada, several Canadian facilities recycled slop oil back to the refinery for re-refining. A small amount of material that cannot be recovered for re-refining goes to WWTP.

Exposure of the general population in Canada to this substance is not expected. Exposure of this substance to the environment is expected to be limited.

3.4 Ecological and Human Health Effects

API (2010a) considered heavy fuel oils, Fuel oil nos. 4, 5, and 6, to be the petroleum streams that most closely resemble slop oil, and thus are appropriate for read-across. Slop oils are expected to have similar toxicity. Fuel oil nos. 4 and 6 were previously assessed (Environment Canada, Health Canada 2014) and critical toxicity values for marine and freshwater aquatic organisms of 0.9 and 4.1 mg/L, respectively, were determined.

Slop oil was not identified as posing a high hazard to human health based on classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity, or reproductive toxicity. It is also not on the European Chemicals Agency's Candidate List of Substances of Very High Concern for Authorisation (ECHA [modified 2015]). Further investigation of health effects is not warranted at this time given that exposure of the general Canadian population is not expected.

3.5 Risk Characterization

Release of slop oil is expected to be minimal such that exposure to the general population is not expected, and exposure to the environment is expected to be limited.

On the basis of limited exposure, the potential to cause harm to the environment or to human health for the general population of Canada is expected to be low.

4. Naphtha waste

4.1 Substance Identity

Petroleum products, C5-12, reclaimed, wastewater treatment (CAS RN 68956-70-7), hereafter referred to as naphtha waste, is a complex combination of hydrocarbons recovered in a dilute solution from onsite waste water treatment (NCI 2015) and recycled back to the refinery (API 2010b). It consists of petroleum hydrocarbons (aliphatic and aromatic) having carbon numbers predominantly in the carbon range of C₅ through C₁₂ (API 2010b, NCI 2015); and thus is similar to naphtha refinery streams (US EIA 2010). This substance is a UVCB and may consist of normal, branched-, and cyclic alkanes; alkenes; and aromatic hydrocarbons (mainly alkylbenzenes) predominantly in the C₅-C₁₂ range (API 2010b).

4.2 Sources and Uses

Naphtha waste is recovered at petroleum facilities from the WWTP and is recycled back to the refinery for processing (API 2010b). No other uses for this substance were identified.

In 2016, CFA members voluntarily identified that naphtha waste is generated by approximately half of the respondents (personal communication, email with attachments from CFA to Ecological Assessment Division, ECCC, dated April 11, 2016; unreferenced).

There are no uses of this substance in pesticides, natural health products, cosmetics, foods and food packaging, and other products available to the general population in Canada.

4.3 Exposure

In Canada, naphtha waste is either considered to be a subset of slop oil or is added to the slop oil tank, and thus is treated similarly to slop oil described above (personal communication; email with attachments from CFA to Ecological Assessment Division, ECCC, dated April 11, 2016; unreferenced).

Based on sources and uses of naphtha waste and information on slop oil release to the environment, exposure of the general population to naphtha waste is not expected.

4.4 Ecological and Human Health Effects

Naphtha waste is considered to be similar to other naphtha streams, including gasoline, in composition. Therefore, toxicity data for gasoline and naphthas are used as read-across for this substance, as recommended by API (2010b). The volatility of naphthas means that they will likely only affect aquatic organisms for short periods of time, as gasoline will completely volatilize in less than 20 hours (Fingas 1997). Thus, short-term acute studies are more likely to reflect the effective toxicity of naphtha waste in the environment compared to longer laboratory studies.

The toxicity of naphthas and gasoline were used as read-across for light natural gas condensates in the assessment of natural gas condensates, and a critical toxicity value of 11 mg/L was determined for aquatic effects (ECCC, HC 2016a). This value is considered to be representative of the toxicity of naphtha waste as well.

Naphtha waste was not identified as posing a high hazard to human health based on classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity, or reproductive toxicity. It is also not on the European Chemicals Agency's Candidate List of Substances of Very High Concern for Authorisation (ECHA [modified 2015]). Further investigation of health effects is not warranted at this time given that exposure of the general Canadian population is not expected.

4.5 Risk Characterization

Release of naphtha waste is expected to be minimal such that exposure to the general population is not expected, and exposure to the environment is expected to be limited. Therefore, the potential to cause harm to the environment or to human health for the general population of Canada is expected to be low.

5. Ethyne

5.1 Substance Identity

Ethyne (CAS RN 74-86-2) (also known as acetylene) is a discrete substance described by the chemical formula C_2H_2 .

5.2 Sources and Uses

Ethyne is produced at a yield of approximately 25% when converted from methane in the presence of oxygen (Dow 2015). Ethyne is also manufactured by reacting calcium carbide and water (MSDS 2016). It may be incidentally produced as a co-product (from

1.0 to 2.5 weight percent) during the cracking of natural gas liquids, naphtha, or gas oil (Dow 2015).

No information on the quantity of ethyne manufactured in Canada was identified. Ethyne is an HPV substance in the US, with approximately 50 000 tonnes produced in 2012, and between 100 000 and 1 000 000 tonnes per year produced in the EU (US EPA 2016, ECHA 2017a).

The primary uses of ethyne is as a raw material for the production of other chemicals (e.g., 1,4-butanediol, acetylenic alcohols, ethyl and methyl vinyl ethers) in closed systems, followed by use as a fuel for welding, cutting, and heat treating metals (Dow 2015). Other reported uses include the manufacture of polymers and semiconductors, lubricants and greases, certain plastics, electronic electrical and optical equipment. Ethyne has also been identified as being used in organic synthesis, molecular manufacturing, calibration, laboratory and medical gasses, and plant cultivation (ECHA 2017a,b, MSDS 2016, Linde 2017)

There are no reported uses of this substance in pesticides, natural health products, cosmetics, foods and food packaging, and other products available to the general population in Canada.

5.3 Exposure

Ethyne is used mainly in the chemical manufacturing industry in closed systems. In outdoor/indoor environments, ethyne is found as a component of automotive emissions. Small amounts of ethyne are also produced in burning agricultural wastes and other plant material (Warneck 1999). If released to the atmosphere, ethyne will slowly photodegrade with exposure to sunlight; it has an estimated half-life in air of about 13 days (AOPWIN 2010). Ethyne was subject to outdoor air monitoring between 2001-2009 in Ontario and had an average concentration over nine years of 380 parts per trillion (ECCC 2009). Indoor and outdoor air monitoring studies were also recently performed in Edmonton (Health Canada 2013), Halifax (Health Canada 2012), Regina (Health Canada 2010b), and Windsor (Health Canada 2010a). The mean concentrations and minimum and maximum ranges of concentration of ethyne from sampling over 24 hour periods were determined for summer and winter conditions. For summer conditions, the highest mean ethyne concentration indoors measured in these four cities is $2.0 \mu\text{g}/\text{m}^3$ (minimum and maximum values 0.0 to $79.2 \mu\text{g}/\text{m}^3$) and the highest mean ethyne concentration outdoors measured in these four cities is $0.723 \mu\text{g}/\text{m}^3$ (minimum and maximum values 0.5 to $5.0 \mu\text{g}/\text{m}^3$). For winter conditions, the highest mean ethyne concentration indoors measured in these four cities is $8.7 \mu\text{g}/\text{m}^3$ (minimum and maximum values 0.2 to $1045.2 \mu\text{g}/\text{m}^3$) and the highest mean ethyne concentration outdoors measured in these four cities is $2.1 \mu\text{g}/\text{m}^3$ (minimum and maximum values 0.3 to $11.0 \mu\text{g}/\text{m}^3$). These values are in the parts per billion range, with the highest observed maximum in the ~ 1 ppm range.

There are no additional known uses of ethyne in products available to consumers (Dow 2015); and therefore exposures from products are not expected.

Ethyne has a high vapour pressure and is a gas under almost all environmental conditions (Dow 2015). While it has high solubility in water (1200 mg/L) (EPI Suite c2000-2012), it quickly volatilizes from water with an estimated half-life of 0.5 hours in a river or 49 hours in a lake (EPI Suite c2000-2012).

5.4 Ecological and Human Health Effects

No reliable empirical ecotoxicity data was included in previous assessments of this substance (ACC 2005, US EPA 2008).

Ethyne was not identified as posing a high hazard to human health based on classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity, or reproductive toxicity. It is also not on the European Chemicals Agency's Candidate List of Substances of Very High Concern for Authorisation (ECHA [modified 2015]). Similar to the saturated short-chain alkanes ethane, propane, and butane previously evaluated (ECCC HC, 2017), adverse effects from ethyne are only seen at very high concentrations, above the lower explosive limit of 25000 ppm. Human and animal studies have demonstrated that anesthetic or narcotic effects may arise from exposure to high concentrations of ethyne (in the range of 33 000 to 35 000 ppm), or with very high concentrations (about 40 000 ppm), asphyxiation may occur (ECHA 2017a, HSDB 2017, ACC 2005).

5.5 Risk Characterization

Ethyne is not expected to be released to water. Ethyne has been detected in air monitoring studies; however, its environmental concentration is in the parts per billion to parts per trillion range. Health effects were only observed above the lower explosive limit. Modelled environmental toxicity indicates that this substance is considered to be of low ecological hazard. Therefore, the potential to cause harm to the environment or to human health for the general population of Canada is expected to be low.

6. Montan wax, Fatty acids, montan-wax, and Fatty acids, montan-wax, ethylene esters

6.1 Substance Identity

Montan wax (CAS RN 8002-53-7) is a natural wax extracted from lignite or brown coal (NCI 2015; Wei et al 2014). Montan wax differs from petroleum waxes in that it contains a large proportion of oxygen-containing compounds, whereas petroleum waxes are comprised predominantly of nonpolar hydrocarbons (Wolfmeier et al. 2012).

Crude montan wax is a solid material comprised of wax (50-80%), resins (20-40%), and asphaltic material (10-20%) (Matthies 2001, Wei et al. 2014). The direct use of crude montan wax is limited and further refining of the crude wax is undertaken before it is used in marketplace products (Wolfmeier et al. 2012, Wei et al. 2014). The first step in refining montan wax is the removal of the resin fraction (Wolfmeier et al. 2002, Wei et al. 2014). Deresined montan wax can be used in some applications, though the majority undergoes further refining, such as oxidative bleaching followed by derivatization (Wolfmeier et al. 2012, Wei et al. 2014). Oxidative bleaching results in a mixture of mainly montan wax fatty acids (Wolfmeier et al. 2012) which might be reported under a different CAS RN (i.e., CAS RN 68476-03-9; montan-wax fatty acids). However, CAS RN 8002-53-7 can also refer to bleached montan wax (NCI 2015); thus, this draft screening assessment will consider crude, deresined, and bleached montan wax.

Wax fraction constituents of montan wax include acids, alcohols, esters and hydrocarbons, with carbon chain lengths ranging from approximately 16 to 34 carbon molecules, though predominantly in the C₂₈ to C₃₀ range (Wolfmeier et al. 2012). The resin fraction is complex and not well-characterized, containing a variety of substances including triterpenes, diterpenoid acids and their esters, diterpenoid alcohols and their esters, steroids, alkanes and aromatic compounds (Wolfmeier et al. 2012, Wei et al. 2014).

The montan wax fatty acids (CAS RN 68476-03-9) and montan wax fatty acids ethylene esters (CAS RN 73138-45-1) are components of montan wax. Montan wax fatty acids, are long chain straight carboxylic acids with carbon range of C₂₂ to C₃₄. Montan wax fatty acids, ethylene esters is identified as ethylene glycol monomontanate or 2-hydroxyethyl octasosanoate with a molecular weight of 468.8 g/mol. These esters are partly isolated and purified products from montan wax (EFSA 2013).

6.2 Sources and Uses

Montan wax is mainly produced in Germany, the US, Ukraine, Russia and China (Wolfmeier et al 2002). The montan-wax fatty acids, and montan-wax fatty acids ethylene esters are not manufactured in Canada (ECCC 2016) but are imported in the range of 100 – 1000 kg and 20 000 kg, in 2011, respectively. These substances have a variety of uses, including in plastics and rubber materials (ECCC 2016). The major use of refined montan wax is in car polishes/waxes and automotive after-market products such as cleaners, with approximately one third of the total world production reported as being used for this (Carmel 2010, ECCC 2016). Other reported industrial uses in Canada from a voluntary survey and a mandatory section 71 survey under CEPA (ECCC 2015, ECCC 2016) include in gypsum product manufacturing, as an additive in rubber in the automotive industry, in architectural finishes and industrial coatings, and in protective and marine coatings.

Montan wax may also be used in food packaging in Canada. This includes in laminated films, colour concentrates, polypropylene/polyethylene trays, PVC containers, and PET films (personal communication, email from the Foods Directorate, Health Canada (HC)

to the Existing Substances Risk Assessment Bureau, HC, dated Dec. 8, 2016; unreferenced). It is listed in the Natural Health Products Ingredients Database with a non-medicinal role for topical use only up to 25% as binder or viscosity increasing agent – non-aqueous; however, it is not listed in the Licensed Natural Health Products Database (Health Canada 2016) as being present in currently licensed natural health products in Canada. Based on notifications submitted under the Cosmetic Regulations to Health Canada, montan wax is used in certain cosmetic products in Canada with an upper concentration of 10% in make-up and 3% in body moisturiser (personal communication, email from the Consumer Product Safety Directorate, HC to the Existing Substances Risk Assessment Bureau, HC, dated Dec. 8, 2016; unreferenced). Montan wax was reported to be used in products with maximum use concentration of 11% by the United State Food and Drug Administration (FDA) in 2002 (CIR 1984, 2005).

Montan wax fatty acids, and montan-wax fatty acids ethylene esters are used in food packaging in Canada. They have been used as components in laminated films, colour concentrates for PET resins, PVC tubing and hoses for food transportation, and PET containers (personal communication, email from the Foods Directorate, Health Canada (HC) to the Existing Substances Risk Assessment Bureau, HC, dated Dec. 8, 2016; unreferenced). These substances may also be used as a protective layer on fruit skins and coating on food; however, this use has not been reported in Canada (personal communication, email from the Foods Directorate, Health Canada (HC) to the Existing Substances Risk Assessment Bureau, HC, dated May 25, 2016; unreferenced). The montan-wax fatty acids ethylene ester is used in cosmetics (personal communication, email from the Consumer Product Safety Directorate, Health Canada (HC) to the Existing Substances Risk Assessment Bureau, HC, dated April 22, 2016; unreferenced). The two substances have not been reported to be used in natural health products and drugs in Canada (personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada (HC) to the Existing Substances Risk Assessment Bureau, HC, dated April 28, 2016; unreferenced). They can be used as a formulant in some pesticides (personal communication, email from the Pesticide Management Regulatory Agency, Health Canada (HC) to the Existing Substances Risk Assessment Bureau, HC, dated May 9, 2016; unreferenced).

6.3 Exposure

Due to the complex interaction of components within a UVCB that impact their physical and chemical properties and behaviour, it is difficult to predict the fate of a complex substance such as montan wax. Therefore, as a general indication of the fate of montan wax, the physical and chemical properties of representative C16 to C30 structures of montan wax were examined. Components representing the predominant wax fraction in crude, deresined and bleached montan wax (which is mainly fatty acids) were chosen based on Noskova (2010)

The individual components, including the fatty acids, montan wax and fatty acid, montan wax, ethylene esters are characterized by very low water solubilities (i.e., 0.04 mg/L or less), low to moderate vapour pressures (i.e., 1.7×10^{-9} to 0.46 Pa), moderate to high Henry's law (air-water partition) constants (i.e., 2.03 to 6.8×10^8 Pa·m³/mol), high log K_{ow} values (6.7 to 16.6), and very high log K_{oc} values (i.e., 4.12 to 13.1).

In pure form, montan wax is expected to be solid at ambient temperatures, based on the melting point of the whole substance, as well as the melting points for the majority of components. Thus, if released to the environment, it is not expected to leach into the soil or dissolve in water based on its physical state, as well as low water solubilities of the representative structures. Any components that do leach from the wax are expected to sorb to sediment or soil and become immobile based on the very high log K_{oc} values, or, for many components, volatilize from moist soil surfaces given the moderate to high Henry's law constants. The potential for volatilization of some components from dry soil surfaces may also exist based on the moderate vapour pressures for the C16 to C18 saturated alcohols and C16 to C20 n-alkanes.

The refined montan wax and the montan wax fatty acids substances may enter the water via wastewater following the use of products available to the consumer containing these substances, or from use in industrial processes. If released to wastewater, it is expected to sorb to biosolids due to the very high log K_{oc} values of its components and be removed from the effluent. Montan wax may be added to soil through the application of biosolids; however, the wax fraction is expected to be biodegradable.

There will be negligible exposure to this substance for aquatic organisms if it is released in wastewater effluent due to its very low water solubility; however, there may be exposure through its sorption to sediments and particulate matter.

Exposure to the general population is only expected from the refined and purified bleached montan wax, and the fatty acids, montan wax and fatty acids, montan wax, ethylene esters. Dermal exposure may occur via the use of cosmetics and other products available to consumers such as car waxes and cleaners. Oral exposure to montan wax, montan-wax fatty acids, and montan-wax fatty acids ethylene esters may occur via food packaging however the exposure related to this use is considered negligible. Use of these substances as a coating on certain fruits has not been reported in Canada (personal communication, email from the Foods Directorate, Health Canada (HC) to the Existing Substances Risk Assessment Bureau, HC, dated May 25, 2016; unreferenced). Potential dermal exposure to fatty acid, montan-wax, ethylene esters used in plastics from leaching is also considered to be negligible.

6.4 Ecological and Human Health Effects

Limited information on the ecotoxicity of montan wax was found. Unpublished industry ecotoxicity data for aquatic invertebrates and algae submitted to the European Union under the Regulation on the REACH indicate low toxicity with no-observed-effects-

concentrations (NOECs) for *Daphnia magna* and algae (*Desmodesmus subspicatus*) greater than or equal to 100 mg/L (ECHA 2017b).

Toxicity data modelled (ECOSAR 2012) on representative structures for the wax fraction, which makes up the largest proportion of crude montan wax and all of the deresined and bleached montan waxes, indicates that components of the wax fraction of montan wax are not expected to elicit acute ecological effects at saturation in water or soil.

Montan wax and the montan-wax fatty acids substances were not identified as posing a high hazard to human health based on classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity, or reproductive toxicity. These substances are also not on the European Chemicals Agency's Candidate List of Substances of Very High Concern for Authorisation (ECHA [modified 2015], EFSA 2013).

Montan wax was not mutagenic in in vitro bacterial mutation assays using *Salmonella typhimurium* and *Escherichia coli*, with and without metabolic activation (EFSA 2012).

Animal studies on montan wax reported low toxicity. In a 90-day study in the rat and in two 90-day studies in the dog, no treatment-related effects were found at doses up to 1660 mg/kg bw/day for the dog and up to approximately 4000 mg/kg bw/day for the rat (EFSA 2013). Two-year chronic toxicity studies in rats reported that doses of up to 2900 mg/kg bw/day did not lead to any sign of treatment-related toxic effects; however, the studies (conducted in the 1960s) were determined to be of poor quality (EFSA 2013).

A 90-day oral toxicity study on a group of F344 rats exposed to montan wax indicated the formation of liver granulomas and hepatocyte effects at approximately 260 mg/kg bw/day, the lowest dose tested (Ikeda et al., 2008). Similar effects were discussed in the *Petrolatum and Waxes* assessment for oral exposure of this strain of rats to white oils (ECCC, HC 2016b). For mineral oils, 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). Mineral oil-induced histological changes can also occur in the human liver and in the hepatic node and spleen; these include intra- and extracellular lipid 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). Therefore, the F344 rat study is not considered relevant to define a point of departure for risk characterization.

6.5 Risk Characterization

If released to water, montan wax and the montan-wax fatty acids substances are expected to partition to sediment; however, sediment concentrations are expected to be low due to effective removal via sorption of montan wax and the montan-wax fatty acids substances during wastewater treatment. Experimental and modelled toxicity data for crude montan wax indicates low hazard to aquatic and soil organisms.

The general population may be exposed to montan wax through food packaging, cosmetics, and other products available to the general population in Canada. The general population may be exposed to montan-wax fatty acid, ethylene esters through food packaging, cosmetics and some plastic products available to the general population in Canada. The German Federal Institute for Health, Consumer Protection and Veterinary Medicine, the US FDA and the EU, have approved montan wax for many applications, including as a component of plastics, paper and paperboard in contact with food, and for the surface treatment of citrus fruits (Matthies 2001, FDA 2016, EWF 2009).

Although the hazard database is limited, the available data indicates that these substances are considered to be of low hazard, and therefore quantitative characterization of exposure (i.e., derivation of exposure estimates) was not warranted. The potential to cause harm to the environment or to human health for the general population of Canada is expected to be low.

7. Conclusion

Considering all available lines of evidence presented in this draft screening assessment, there is low risk of harm to organisms and the broader integrity of the environment from spent sulphidic caustic, slop oil, naphtha waste, ethyne, montan wax, montan-wax fatty acids, and montan-wax fatty acids ethylene esters. It is proposed to conclude that sulphidic caustic, slop oil, naphtha waste, ethyne, montan wax, montan-wax fatty acids, and montan-wax fatty acids ethylene esters 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.

Based on the information presented in this draft screening assessment, it is proposed to conclude that spent sulphidic caustic, slop oil, naphtha waste, ethyne, montan wax, montan-wax fatty acids, and montan-wax fatty acids ethylene esters 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 proposed to conclude that sulphidic caustic, slop oil, naphtha waste, ethyne, montan wax, montan-wax fatty acids, and montan-wax fatty acids ethylene esters do not meet the criteria set out in section 64 of CEPA.

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