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# **Risk Management Scope for Gas Oils and Kerosenes with Uses in Products Available to Consumers Group**

Environment and Climate Change Canada

Health Canada

May 2024



## Summary of Proposed Risk Management

This document outlines the risk management options under consideration for substances contained in the Gas Oils and Kerosenes with Uses in Products Available to Consumers Group (herein abbreviated as GOKUPAC), which have been proposed to be harmful to human health, but not to the environment in Canada.

In particular, the Government of Canada is considering:

- Regulatory or non-regulatory measures to help reduce dermal and/or inhalation exposures of the general population to GOKUPAC substances in subgroup 1 (C9-C25 aliphatic hydrocarbons) and subgroup 2 (C9-C16 aromatic hydrocarbons) from certain do-it-yourself (DIY) and other household products available to consumers including automotive products, construction adhesives, surface polish and cleaners, stains, coatings and paint products, to levels that are protective of human health;
- Measures to help reduce dermal and/or inhalation exposures of the general population to GOKUPAC substances in subgroup 1 (C9-C25 aliphatic hydrocarbons) from certain cosmetics such as skin moisturizers, deodorants/antiperspirants, hair products, hair removal products, makeup products, and perfumes to levels that are protective of human health by describing GOKUPAC substances in subgroup 1 (C9-C25 aliphatic hydrocarbons) as prohibited or restricted ingredients on the Health Canada's Cosmetic Ingredient Hotlist; and
- Measures to help reduce dermal exposures of the general population to GOKUPAC substances in subgroup 1 (C9-C25 aliphatic hydrocarbons) from certain natural health products and non-prescription drugs such as sunscreen products, sun protection factor (SPF) liquid foundation and body lotion, to levels that are protective of human health by describing GOKUPAC substances in subgroup 1 (C9-C25 aliphatic hydrocarbons) as restricted ingredients on the Natural Health Products Ingredients Database (NHPID).

To inform risk management decision-making, information on the following topics should be provided (ideally on or before July 3, 2024), to the contact details identified in section 8 of this document:

- Current quantities (kilograms) and concentrations (percent weight per weight) of the 16 GOKUPAC substances that are in products available to consumers;

- Changes in the use patterns for products containing any of the 16 GOKUPAC substances from previous data collection initiatives (noted in section 4.2 of this document);
- Existing, potential alternative or replacement substances to the 16 GOKUPAC substances for use in cosmetics, natural health products, non-prescription drugs, and in certain other products available to consumers, as noted in section 5 of this document;
- Socio-economic and technical impacts if the import and/or use of the 16 GOKUPAC substances were prohibited or restricted in certain consumer applications in Canada, specifically in cosmetics, natural health products, non-prescription drugs, and certain other products available to consumers where they have been identified as a concern;
- Purpose/function of the 16 GOKUPAC substances in cosmetics, natural health products, non-prescription drugs, and certain other products available to consumers;
- The minimum concentration of the 16 GOKUPAC substances in certain cosmetics, natural health products, non-prescription drugs, and certain other products available to consumers that will maintain performance function;
- Detailed compositional information (for example, analytical or spectral characterization) of the 16 GOKUPAC substances in certain cosmetics, natural health products, non-prescription drugs, and certain other products available to consumers;
- Best practices currently implemented in industry to minimize consumer exposure to the 16 GOKUPAC substances in end-use products;
- Identification of standard procedures and analytical methods available for the testing of 16 GOKUPAC substances in cosmetics, natural health products, non-prescription drugs, and certain other products available to consumers; and
- Information pertaining to the interchangeability of other Gas Oils and Kerosenes substances (including other Gas Oils and Kerosenes previously addressed under the Chemicals Management Plan, the CMP) as a replacement for subgroup 1 and 2 substances in cosmetics, natural health products, non-prescription drugs, and certain other products available to consumers.

The risk management options outlined in this Risk Management Scope document may evolve through consideration of assessments and risk management options or actions published for other CMP substances as required to ensure effective, coordinated, and consistent risk management decision-making.

**Note:** The above summary is an abridged list of options under consideration to manage these substances and to seek information on identified gaps. Refer to section 3 of this document for more complete details in this regard. It should be noted that the proposed risk management options may evolve through

consideration of additional information obtained from the public comment period, literature and other sources.

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# 1. Context

The *Canadian Environmental Protection Act* (CEPA) (Canada 1999) provides the authority for the Minister of the Environment and the Minister of Health (the Ministers) to conduct assessments to determine if substances are toxic to the environment and/or harmful to human health as set out in section 64 of CEPA<sup>1,2</sup>, and if so to manage the associated risks. The 16 substances, listed in Annex A and referred to throughout this document as the “GOKUPAC Group” or the “GOKUPAC substances”, are part of the Government of Canada’s Chemicals Management Plan (CMP).

## 2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment of the GOKUPAC Group in Canada. A notice summarizing the scientific considerations of the draft assessment for these substances was published in the *Canada Gazette*, Part I, on July 3, 2024 (ECCC, HC 2024). For further information, refer to the [draft assessment for the GOKUPAC Group](#).

### 2.1 Draft Assessment Conclusion

On the basis of the information available, the draft assessment proposes that the 16 substances in the GOKUPAC Group (as listed in Annex A) are toxic under section 64(c) of CEPA, as they are entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. However, it is proposed to conclude that these 16 substances 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

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<sup>11</sup> Section 64 of CEPA: *For the purposes of [Parts 5 and 6 of CEPA], except where the expression “inherently toxic” appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that*

- (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;*
- (b) constitute or may constitute a danger to the environment on which life depends; or*
- (c) constitute or may constitute a danger in Canada to human life or health.*

<sup>2</sup> 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 products used by consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazard Product Regulations*, which are a part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion on the basis of the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

or may constitute a danger to the environment on which life depends under paragraphs 64(a) or 64(b) of CEPA. (ECCC, HC 2024).

The exposures of concern for the general population identified in the draft assessment are dermal and/or inhalation exposures to the 16 GOKUPAC substances in certain cosmetics, natural health products, non-prescription drugs, and other products available to consumers including certain DIY and household products. As such, this document will focus on these exposures and sources (refer to section 5).

## 2.2 Proposed Recommendation under CEPA

CEPA sets out a 2-track approach for managing risks.

Under sub-section 77(3), the Ministers are required to propose recommending the addition of a substance that poses the highest risk, as defined in paragraph (a), (b) or (c), to Part 1<sup>3</sup> of Schedule 1 of the Act and, in developing a proposed regulation or instrument respecting preventive or control actions, to give priority to the total, partial or conditional prohibition of activities in relation to the substance or to the release of the substance into the environment.

For other substances recommended for addition to Part 2 of Schedule 1 of the Act, the Ministers shall give priority to pollution prevention, and this could include regulatory or non-regulatory measures [such as prohibition if warranted].

On the basis of the findings of the draft assessment conducted pursuant to CEPA, the Ministers propose to recommend that the 16 substances in the GOKUPAC

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<sup>3</sup> Under subsection 77(3), a substance must be recommended for addition to Part 1 of Schedule 1 to the Act when the substance is determined to be toxic and the ministers are satisfied that:

- a. the substance may have a long-term harmful effect on the environment and
  - i. is inherently toxic to human beings or non-human organisms, as determined by laboratory or other studies,
  - ii. is persistent and bioaccumulative in accordance with the regulations,
  - iii. is present in the environment primarily as a result of human activity, and
  - iv. is not a naturally occurring radionuclide or a naturally occurring inorganic substance;
- b. the substance may constitute a danger in Canada to human life or health and is, in accordance with the regulations, carcinogenic, mutagenic or toxic for reproduction; or
- c. the substance is, in accordance with the regulations, a substance that poses the highest risk.

GOKUPAC subgroups 1, and 2 are proposed not to meet the criteria per sub-section 77(3) for addition to Part 1 of Schedule 1 of the Act.



Group, as listed in Annex A, be added to Part 2 in Schedule 1 of the Act<sup>4</sup>. Addition of a substance to Schedule 1 to CEPA enables the Government to propose certain risk management measures under CEPA to manage potential ecological and human health risks associated with the substance.

Until regulations specifying criteria for the classification of substances that pose the highest risk or that are carcinogenic, mutagenic or toxic to reproduction are available, the 16 GOKUPAC substances are proposed to be recommended for addition to Part 2 of Schedule 1. Following the availability of the aforementioned criteria, the substance may be moved to Part 1 of Schedule 1, if applicable.

The Ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft assessment for the GOKUPAC Group and this Risk Management Scope document.

If the Ministers finalize the recommendation to add the 16 GOKUPAC substances to Part 2 of Schedule 1, risk management instruments must be proposed within 24 months from the date on which the Ministers recommended that the 16 GOKUPAC substances be added to Schedule 1 to CEPA, and will be finalized within 18 months from the date on which the risk management instruments are proposed, as outlined in sections 91 and 92 of CEPA (refer to section 8 for publication timelines applicable to this group of substances).

## **3. Proposed Risk Management**

### **3.1 Proposed Human Health Objectives**

Proposed human health objectives are quantitative or qualitative statements of what should be achieved to address human health concerns.

The proposed human health objective is to reduce exposure of the general population to the 16 substances in subgroups 1 and 2 of the GOKUPAC Group to levels that are protective of human health.

### **3.2 Proposed Risk Management Objectives**

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulation(s), instrument(s)

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After an assessment of a given substance under Part 5 of CEPA, other than section 83, the Ministers shall propose one of the following measures: take no further action with respect to the substance, add the substance to the List referred to in section 75.1 of the Act (unless the substance is already on that List), recommend the addition of the substance to Part 1 of the list of toxic substances in Schedule 1 to CEPA (for substances that pose the highest risk) or recommend the addition of the substance to Part 2 of the list of toxic substances in Schedule 1 to CEPA (for other CEPA-toxic substances).

and/or tool(s) for a given substance or substances. In this case, the proposed risk management objectives for the GOKUPAC Group are:

- To reduce dermal and/or inhalation exposures of the general population to GOKUPAC substances in subgroup 1 (C9-C25 aliphatic hydrocarbons) and subgroup 2 (C9-C16 aromatic hydrocarbons) from certain DIY and other household products available to consumers, including automotive products, construction adhesives, surface polish and cleaners, stains, coatings and paint products, to levels that are protective of human health;
- To reduce dermal and/or inhalation exposures of the general population to GOKUPAC substances in subgroup 1 (C9-C25 aliphatic hydrocarbons) from certain cosmetics such as skin moisturizers, deodorant/antiperspirants, hair products, hair removal products, makeup products, and perfumes to levels that are protective of human health; and
- To reduce dermal exposures of the general population to GOKUPAC substances in subgroup 1 (C9-C25 aliphatic hydrocarbons) from certain natural health products and non-prescription drugs such as sunscreen products, SPF liquid foundation and body lotion to levels that are protective of human health.

These objectives will be refined on the basis of stakeholder consultation and new information, the outcome of the draft assessment, and socio-economic and technical considerations (refer to section 6). Revised human health and risk management objectives will be presented in the Risk Management Approach document that will be published concurrently with the final assessment for these substances.

### **3.3 Proposed Risk Management Options under Consideration**

To achieve the proposed risk management objectives and to work towards achieving the proposed human health objective, the risk management options under consideration for the GOKUPAC Group are:

- Regulatory or non-regulatory measures to help reduce dermal and/or inhalation exposures of the general population to GOKUPAC substances in subgroup 1 (C9-C25 aliphatic hydrocarbons) and subgroup 2 (C9-C16 aromatic hydrocarbons) from certain DIY and other household products available to consumers including automotive products, construction adhesives, surface polish and cleaners, stains, coatings and paint products to levels that are protective of human health;
- Measures to help reduce dermal and/or inhalation exposures of the general population to GOKUPAC substances in subgroup 1 (C9-C25 aliphatic hydrocarbons) from certain cosmetics such as skin moisturizers,

deodorant/antiperspirants, hair products, hair removal products, makeup products, and perfumes by describing GOKUPAC substances in subgroup 1 (C9-C25 aliphatic hydrocarbons) as prohibited or restricted ingredients on the Health Canada's Cosmetic Ingredient Hotlist. The Hotlist is used to communicate that certain substances may not be compliant with requirements of the *Food and Drugs Act* or provisions of the *Cosmetic Regulations*; and

- Measures to help reduce dermal exposures of the general population to GOKUPAC substances in subgroup 1 (C9-C25 aliphatic hydrocarbons) from certain natural health products and non-prescription drugs such as sunscreen products, SPF liquid foundation and body lotion to levels that are protective of human health by describing GOKUPAC substances in subgroup 1 (C9-C25 aliphatic hydrocarbons) as restricted ingredients on the NHPID.

Note that these proposed risk management options are preliminary and subject to change. Following the publication of this document, additional information obtained from the public comment period and from other sources will also be considered in the instrument selection and development process<sup>5</sup>. The risk management options may also evolve through consideration of assessments and risk management options or actions published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

### 3.4 Performance Measurement and Evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances<sup>6</sup>. The aim is to determine whether human health and/or environmental objectives have been met and whether there is a need to revisit the risk management approach for these substances, to ensure that risks are managed effectively over time. To achieve

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<sup>5</sup> The proposed risk management regulation(s), instrument(s) or tool(s) will be selected using a thorough, consistent and efficient approach and take into consideration available information in line with the Government of Canada's Cabinet Directive on Regulation (TBS 2018), the Red Tape Reduction Action Plan (TBS 2012), and in the case of a regulation the *Red Tape Reduction Act* (Canada 2015).

<sup>6</sup> Performance measurement can be performed at 2 levels:

- Instrument-based performance measurement evaluates the effectiveness of an individual instrument in meeting the specific risk management objectives that were set out when the risk management tool was designed. The results of performance measurement will help determine if additional risk management or assessment is needed (that is, evaluate whether risk management objectives have been met); and
- Substance-based performance measurement considers performance of all final risk management instruments applied to a chemical substance and relevant data or indicators of exposure to the environment or human health (that is, evaluate whether human health and/or environmental objectives have been met).

this, the Government of Canada will evaluate the effectiveness of the risk management action(s) for the GOKUPAC Group.

The Government of Canada plans to measure the effectiveness of the risk management action(s) by collecting and analyzing data to measure progress towards meeting the risk management objective(s). The results of the performance measurement evaluation will be used to inform whether further risk management action is warranted and will be made available to Canadians along with recommendations for further action, if applicable.

### **3.5 Risk Management Information Gaps**

Interested stakeholders can provide further information to inform risk management decision-making regarding the GOKUPAC Group, as identified in the draft assessment, including:

- Current quantities (kilograms) and concentrations (percent weight per weight) of the 16 GOKUPAC substances that are in products available to consumers;
- Changes in the use patterns for products containing any of the 16 GOKUPAC substances from previous data collection initiatives (noted in section 4.2 of this document);
- Existing, potential alternative or replacement substances to the GOKUPAC substances for use in cosmetics, natural health products, non-prescription drugs, and in certain other products available to consumers (noted in section 5 of this document);
- Socio-economic and technical impacts if the import and/or use of the 16 GOKUPAC substances were prohibited or restricted in certain consumer applications in Canada, specifically in cosmetics, natural health products, non-prescription drugs, and other products available to consumers where they have been identified as a concern;
- Purpose/function of the 16 GOKUPAC substances in cosmetics, natural health products, non-prescription drugs, and other products available to consumers;
- The minimum concentration of the 16 GOKUPAC substances in certain cosmetics, natural health products, non-prescription drugs, and other products available to consumers that will maintain performance function;
- Detailed compositional information (for example, analytical or spectral characterization) of the 16 GOKUPAC substances in certain cosmetics, natural health products, non-prescription drugs, and certain other products available to consumers;
- Best practices currently implemented in industry to minimize consumer exposure to any of the 16 GOKUPAC substances in end-use products;
- Identification of standard procedures and analytical methods available for the testing of the 16 GOKUPAC substances in cosmetics, natural

health products, non-prescription drugs, and other products available to consumers; and

- Information pertaining to the interchangeability of other Gas Oils and Kerosene substances (including other Gas Oils and Kerosenes previously addressed under the CMP) as a replacement for subgroup 1 and 2 substances in cosmetics, natural health products, non-prescription drugs, and other products available to consumers.

Stakeholders that have information to help address these gaps should provide it on or before July 3, 2024 to the address identified in section 8.

## **4. Background**

### **4.1 General Information on the GOKUPAC Group**

For the human health risk assessment, the 16 substances in the GOKUPAC Group are separated into 2 subgroups on the basis of differences in aromatic content and, by extension, their health effects (see also Annex A). These subgroups are:

- Subgroup 1: C9 to C25 predominantly aliphatic hydrocarbons (14 CAS RNs); and
- Subgroup 2: C9 to C16 predominantly aromatic hydrocarbons (2 CAS RNs).

The substances in the GOKUPAC Group are of unknown or variable composition, complex reaction products or biological materials (UVCBs). 6 CAS RNs in this draft assessment are kerosenes: 8008-20-6, 64742-14-9, 64742-47-8, 64742-81-0, 64742-94-5, and 64742-96-7 (CONCAWE 1995, 2001; API 2010a); the remaining 10 CAS RNs are gas oils. Operational definitions for all 16 GOKUPAC substances are included in Appendix A. 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 processing and blending of petroleum. Gas oils and kerosenes usually consist of variable proportions of straight and branched chain alkanes (also referred to as normal and isoparaffins), cycloalkanes (naphthenes), aromatic hydrocarbons, and alkenes. Given their complex and variable compositions, gas oils and kerosenes cannot practicably be synthesized by simply combining individual constituents and can be difficult to fully and consistently characterize.

### **4.2 Current Use(s) and Identified Sector(s)**

GOKUPAC substances are used in a variety of industrial and commercial processes and products. Use information was received in response to CEPA section 71 surveys and voluntary submissions (Environment Canada 2011a, 2011b, 2012; ECCC 2016a, 2016b).

The predominant use of gas oils in general is as intermediate blending components in the production of diesel fuels and fuel oil (API 2012a). They may also serve as blending components for other fuels such as kerosene, gasoline, and aviation fuel, which leave the facility under different CAS RNs. Some gas oils are used in the production of products available to consumers.

The predominant use of kerosenes in general in the United States is as aviation turbine fuel for civilian and military aircraft (API 2010a). It is expected that a similar usage is applicable in Canada. Kerosenes are also used as diesel fuel, domestic heating fuel and illuminating kerosene, as well as being used as solvents in the formulation of a range of products including cleaning products, insecticides, antifoaming agents and mold release agents. These kerosenes are often of a narrower distillation range than those used in fuels and are often further treated to reduce odour and aromatics content (CONCAWE 1995).

Certain gas oil and kerosene substances that were surveyed (Environment Canada 2012; ECCC 2016a, 2016b) were identified as being present in, or as having the potential to be ingredients in, products available to Canadian consumers. Further information gathering and review, including of publicly available information such as safety data sheets, indicated that the products available to consumers containing these substances that are available in Canada include lubricants, automotive products, fuels and solvents, paints and coatings, adhesives and sealants, household cleaning products, lawn and garden care products, building products, and other miscellaneous products.

Eight of the 16 GOKUPAC substances (CAS RNs 8008-20-6, 64741-44-2, 64741-77-1, 64742-46-7, 64742-47-8, 64742-94-5, 64742-96-7, and 68477-31-6) are both on the Pest Management Regulatory Agency (PMRA) List of Formulants and currently being used in pest control products in Canada (ECCC, HC 2024).

Ten of the 16 GOKUPAC substances (CAS RNs 8008-20-6, 64741-44-2, 64742-14-9, 64742-46-7, 64742-47-8, 64742-81-0, 64742-94-5, 64742-96-7, 64771-72-8, and 68477-31-6) were identified as potentially being used as a component in the manufacture of food packaging materials and/or as components of incidental food additives as solvents in food processing establishments<sup>7</sup>, including lubricants for machinery, defoamers for food pads, cleaners (which are afterwards rinsed with potable water), coating for paper, paper board, inks, interior lacquer of cans, plastic films, and vinyl gloves (ECCC, HC 2024).

3 gas oil and kerosene substances (CAS RNs 64742-46-7, 64742-47-8, and 64771-72-8) were identified as being used in a wide range of cosmetics including body moisturizers, hair products, and makeup (ECCC, HC 2024).

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<sup>7</sup> While not defined under the *Food and Drugs Act*, incidental additives may be regarded, for administrative purposes, as those substances which are used in food processing plants and which may potentially become adventitious residues in foods (for example, cleaners, sanitizers).

Distillates (petroleum), hydrotreated middle (CAS RN 64742-46-7) is listed in the NHPID as “C13-15 Alkane” with a non-medicinal role for topical use only as solvent in natural health products (NHPID [modified 2022]). It is also listed in the Licensed Natural Health Products Database (LNHPD) as being present in licensed topical natural health products (LNHPD [modified 2021]). This substance was identified as being present in NHPs such as sunscreens, body moisturizers, and facial cleansers (ECCC, HC 2024).

Distillates (petroleum), hydrotreated light (CAS RN 64742-47-8) is listed in the NHPID as “C13-14 Alkane” with a non-medicinal role for topical use only as solvent in natural health products (NHPID [modified 2022]). It is listed in the LNHPD as being present in licensed topical natural health products and was identified as being present in NHPs that are sunscreens (LNHPD [modified 2021]; ECCC, HC 2024).

Petroleum is listed in the NHPID with a non-NHP role since it is not a naturally occurring substance falling under Schedule 1 of the *Natural Health Products Regulations*. It is also listed in the NHPID as a homeopathic substance (for example, EHP\_Petroleum) which uses kerosene (CAS RN 8008-20-6) as a source material (NHPID [modified 2022]). Assuming the ingredient “petroleum” therefore falls under the CAS RN 8008-20-6, this substance is considered to be included in the LNHPD and was identified as being present as a medicinal ingredient in a number of natural health products licensed as homeopathic medicines (LNHPD [modified 2021]; ECCC, HC 2024).

CAS RN 64742-47-8 is currently being used as a non-medicinal ingredient in one non-prescription drug that is a sunscreen.

## **5. Exposure Sources and Identified Risks**

### **5.1 Subgroup 1 (C9 to C25 predominantly aliphatic hydrocarbons)**

The draft assessment identified general population exposures of concern to subgroup 1 GOKUPAC substances from the use of certain cosmetics, natural health products, non-prescription drugs, and other do it yourself (DIY) and household products available to consumers.

For the subgroup 1 substances, systemic effects on hematological parameters and spleen and adrenal weights were considered to be the critical effects following short- and long-term dermal exposures. Developmental neurotoxicity was considered to be the critical effect following short- and long-term oral and inhalation exposures. A comparison of the associated critical effect levels to the exposure estimates from some cosmetics, natural health products, a non-prescription drug,

automotive products, cleaning products, DIY products, paints and coatings, and other household products available to consumers in Canada resulted in margins of exposure (MOEs) that are considered to be potentially inadequate to address uncertainties in the health effects and exposure data used to characterize risk.

Exposure to substances in the GOKUPAC Group may occur from the use of various products available to consumers, such as cosmetics, DIY products (for example, adhesives, automotive products, lubricants, paints and coatings), household cleaning products, and other miscellaneous products. Depending on the product, exposures of concern may occur via the dermal and/or inhalation route. Table 1 summarizes the exposures of concern for subgroup 1 GOKUPAC substances.

**Table 1. Products in subgroup 1 (C9 to C25 predominantly aliphatic hydrocarbons) with exposures of concern**

<b>Product</b>	<b>Dermal Exposure</b>	<b>Inhalation Exposure</b>
Moisturizers including face sprays and masks, after hair-removal products, sunless tan lotions, after sun products, body packs, facial foundations, facial makeup removers, hair conditioning products, hair colours, hair styling products, massage oils, spray perfumes, deodorants/antiperspirants, waterless hand cleaners, and genital products	Y	N
Hair conditioner, leave-on (cream or semi-solid cream)	Y	Y
Moisturizers, sunscreens (NHPs and an NPD product), and liquid foundation with SPF	Y	N
Automotive products (vehicle cleaners and polishes [including engine, exterior, and interior])	Y	Y
Cleaning products (household cleaning products [including firearm, furniture, and surface	Y	Y



cleaners and polishes] and adhesive removers)		
DIY products (lubricants, adhesives, and paint thinners)	Y	Y
Other household products (fabric and leather protectants and air fresheners)	Y	Y
Paints and coatings (paints [including spray, automotive, and primer] and wood stains and coatings [including varnish and wax])	Y	Y

Abbreviations: Y, yes; N, no; NHP, natural health product; NPD, non-prescription drug; SPF, sun protection factor

Due to similarities in the expected health effects and physical-chemical properties of all the substances in subgroup 1, it is expected that these substances could be used interchangeably in products available to consumers and would all pose the same potential risk. Therefore, the risk characterization in the draft assessment applied to all subgroup 1 substances and resulted in MOEs that are considered to be potentially inadequate for all subgroup 1 substances. Potential exposures from the use of products that could be used concurrently (for example, cosmetics, automotive products) were not aggregated, as risk concerns were identified for individual scenarios. However, individuals who use multiple products containing these substances could be exposed to higher levels of GOKUPAC substances and could therefore be at higher risk.

No other sources of exposure of concern were identified for subgroup 1 GOKUPAC substances.

## 5.2 Subgroup 2 (C9 to C16 predominantly aromatic hydrocarbons)

The draft assessment identified general population exposures of concern to subgroup 2 GOKUPAC substances from the use of certain products available to consumers. Depending on the product, exposures of concern may occur via the dermal and/or inhalation route. For subgroup 2 substances, exposure from the dermal and inhalation routes were combined for risk characterization purposes.

For the subgroup 2 substances, maternal and fetal toxicity was considered to be the critical effect following long-term oral exposure, short-term dermal exposure, and short- and long-term inhalation exposures. A comparison of the associated critical effect level to the exposure estimates from automotive products, paints and coatings, and other household products available to consumers in Canada resulted

in MOEs that are considered to be potentially inadequate to address uncertainties in the health effects and exposure data used to characterize risk.

Table 2 summarizes the exposures of concern for subgroup 2 GOKUPAC substances.

**Table 2. Products in subgroup 2 (C9 to C16 predominantly aromatic hydrocarbons) with exposures of concern**

Product	Dermal Exposure	Inhalation Exposure	Combined Exposure (Dermal and Inhalation)
Automotive products (automotive undercoating sprays)	Y	N	Y
Paints and coatings (spray paints and wood stains)	Y	Y	Y
Other household products (fabric and leather protectants)	Y	Y	Y

Abbreviations: Y, yes; N, no

Similar to subgroup 1, there are similarities in the expected health effects and physical-chemical properties of the 2 substances in subgroup 2 and it is expected that these substances could be used interchangeably in products available to consumers.

Unlike the substances in subgroup 1, no uses in cosmetics, natural health products, or non-prescription drugs were identified for subgroup 2 substances.

No other sources of exposure of concern were identified for subgroup 2 GOKUPAC substances.

## **6. Risk Management Considerations**

### **6.1 Alternatives and Alternate Technologies**

Compositional variability within and between GOKUPAC substances can lead to CAS RNs being used interchangeably in products if they meet product use specifications. While the draft assessment is on the 16 substances, it is

acknowledged that other Gas Oil or Kerosene substances with similar compositions to these 16 substances may be used as substitutes for similar uses or in products. As part of the requested information under section 3.5, efforts are being made to gain insight into the likelihood of substitution of other Gas Oil and Kerosene substances in cosmetics, natural health products, non-prescription drugs, and other products available to consumers.

## 6.2 Socio-economic and Technical Considerations

Socio-economic factors will be considered in the selection process for a regulation or instrument respecting preventive or control actions, and in the development of the risk management objective(s) as per the guidance provided in the Treasury Board document [Assessing, Selecting, and Implementing Instruments for Government Action](#) (TBS 2007). In addition, socio-economic factors will be considered in the development of regulation(s), instrument(s) or tool(s) to address risk management objective(s), as identified in the [Cabinet Directive on Regulation](#) (TBS 2018) and [Red Tape Reduction Action Plan](#) (TBS 2012) and the [Red Tape Reduction Act](#) (Canada 2015).

# 7. Overview of Existing Risk Management

## 7.1 Related Canadian Risk Management Context

Domestically, the existing risk management actions are as follows:

**Cosmetics:** None of the 16 substances in the GOKUPAC Group are on the Cosmetic Ingredient Hotlist. The Hotlist is used to communicate that certain substances may not be compliant with requirements of the *Food and Drugs Act* or provisions of the *Cosmetic Regulations*.

**Food additives and food flavouring agents:** The 16 substances in the GOKUPAC Group are not found on the *List of Permitted Food Additives*. The safety of food flavouring agents is subject to the provisions of section 4(1)(a) of the *Food and Drugs Act*.

**Food packaging and incidental additives:** 10 of the 16 GOKUPAC substances may be used in food packaging and/or as components of incidental additives (for example, lubricants and/or cleaners) used in food processing establishments (ECCC, HC 2024). The safety of chemicals used in food packaging materials and

incidental additives are subject to section 4(1)(a) of the *Food and Drugs Act*. Additionally, chemicals used in food packaging materials are subject to the provisions of Division 23 of the *Food and Drug Regulations*.

**Pest control products:** 7 substances in the GOKUPAC Group are on List 2 of Health Canada's PMRA List of Formulants. These formulants are potentially toxic, based on either structural similarity to List 1 (that is, toxic) formulants or data suggestive of toxicity. They are also considered high priority for toxicity testing. Registrants with List 2 formulants in their products are strongly encouraged to consider amending formulations by substituting more acceptable alternatives, such as those on Lists 3, 4A and 4B. One GOKUPAC substance is a List 3 formulant (Formulants That Do Not Meet the Criteria of Lists 1, 2, 4A and 4B).

**Products available to consumers:** Paint products, cleaners, and automotive care products available to consumers are subject to the *Canada Consumer Product Safety Act* and the *Consumer Chemicals and Containers Regulations, 2001* (CCCR, 2001). The CCCR, 2001 help to protect people in Canada from acute human health and physical hazards associated with chemical products available to consumers. A consumer product that meets any of the acute hazard classification criteria set out in the CCCR, 2001 must display labelling in the form of hazard symbols, hazard statements, instructions for safe use and first-aid treatments in both official languages. The label must also correctly disclose all hazardous ingredients, as defined in the Regulations. The CCCR, 2001 also sets out prohibitions on dangerous chemical products and container requirements such as child-resistant containers for certain hazard sub-categories. While none of the 16 GOKUPAC substances proposed to be toxic from this draft assessment are listed as substances of special concern in the CCCR, 2001, all hazardous ingredients, as defined in the CCCR, 2001, must be considered when classifying a product.

Certain products may also be subject to the *Volatile Organic Compound (VOC) Concentration Limits for Certain Products Regulations*. The regulations establish maximum VOC concentration limits and emission potentials for the manufacture and import of over 130 categories and subcategories of products.

**Environment:** GOKUPAC substances are subject to the *Regulations Respecting Reduction in the Release of Volatile Organic Compounds (Petroleum Sector)*. These regulations apply to industrial releases, not consumer products. They require the implementation of comprehensive leak detection and repair programs at Canadian petroleum refineries, upgraders and certain petrochemical facilities.

#### **Other related risk management actions:**

Several of the GOKUPAC substances are noted in various provincial and/or territorial occupational health and safety/exposure standards.

## 7.2 Pertinent International Risk Management Context

### United States

**Food packaging and incidental additives:** One CAS RN (8008-20-6) is subject to the US Food and Drug Administration Regulations under Part 175 Indirect Food Additives: Adhesives and Components of Coatings, Part 176 Indirect Food Additives: Paper and Paperboard Components, and Part 177 Indirect Food Additives: Polymers. One CAS RN (64742-47-8) is listed under the Inventory of Effective Food Contact Substance Notifications (US eCFRa,b).

**Pest control products:** In the United States, 3 CAS RNs (8008-20-6, 64742-94-5, and 68477-31-6) are permitted for conventional chemical use as active ingredients. 8 GOKUPAC substances are listed as inert ingredients, permitted for a combination of food, non-food and fragrance uses in pest control products. No specific limits were placed on any of the listed substances (US eCFRc).

**Environment:** The United States Environmental Protection Agency also has a Proposed Rule for reporting under the National Emission Standards for Hazardous Air Pollutants (US eCFRd) for 3 GOKUPAC substances.

### Europe

**Cosmetics:** 8 GOKUPAC substances are prohibited for use in cosmetics if the substance does not have a known refining history, or the originating material from which it is produced is a carcinogen. One of those GOKUPAC substances (CAS RN 64741-77-1) is prohibited with no exceptions (EC 1223/2009).

**Food additives and flavouring agents:** The 16 GOKUPAC substances are not found in the European Union additives database.

**Pest control products:** None of the 16 GOKUPAC substances are listed as active substances under the *Biocidal Products Regulation*, EU 528/2012. Petroleum oils are not approved under EC 1107/2009 (Regulation concerning the placing of plant protection products on the market) as an active substance in pesticides.

A single substance (CAS RN 64742-46-7) is approved under EC 1107/2009 until December 31, 2023, when its inclusion under this regulation expires. It is listed as paraffin oil in the active substances database. No risk management actions for the remaining 15 GOKUPAC substances were identified.

## **8. Next Steps**

### **8.1 Public Comment Period**

Industry and other interested stakeholders are invited to submit comments on the content of this Risk Management Scope or other information that would help to inform decision-making (such as outlined in sections 3.2, 3.3 and/or 3.5). Please submit additional information and comments prior to July 3, 2024.

The Risk Management Approach document, which will outline and seek input on the proposed risk management instrument(s), will be published at the same time as the final assessment. At that time, there will be further opportunity for consultation.

Comments and information submissions on the Risk Management Scope should be submitted via the address, telephone/fax number or email provided below:

Environment and Climate Change Canada  
Gatineau, Quebec K1A 0H3  
Telephone: 1-800-567-1999 (in Canada) or 819-938-3232  
Fax: 819-938-5212  
Email: [substances@ec.gc.ca](mailto:substances@ec.gc.ca)

Companies who have a business interest in GOKUPAC substances considered in the draft assessment report are encouraged to identify themselves as stakeholders. The stakeholders will be informed of future decisions regarding the GOKUPAC Group and may be contacted for further information.

When the first regulation or instrument respecting preventive or control actions is published in relation to the 16 GOKUPAC substances, a statement outlining the estimated timeframe for the development of subsequent proposed regulations or instruments will be made available.

### **8.2 Timing of Actions**

Electronic consultation on the draft assessment report and Risk Management Scope: May 4, 2024 to July 3, 2024. This should include the submission of public comments, additional studies and/or information on GOKUPAC substances.

Publication of responses to public comments on the draft assessment and Risk Management Scope: concurrent to the publication of the final assessment and, if required, the Risk Management Approach document.

Publication of responses to public comments on the Risk Management Approach, if applicable and if required, and the proposed instrument(s): At the latest, 24 months from the date on which the Ministers recommended that the GOKUPAC Group, as listed in Annex A, be added to Schedule 1 of CEPA.

Consultation on the proposed instrument(s), if required: 60-day public comment period starting upon publication of each proposed instrument.

Publication of the final instrument(s), if required: At the latest, 18 months from the publication of each proposed instrument.

These are planned timelines and are subject to change. Please consult the [schedule of risk management activities and consultations](#) for updated information on timelines.

## 9. References

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[EU] European Union, 2009. Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food. [Accessed August 15, 2021].

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# ANNEX A.

## Substances in the GOKUPAC Group by Subgroup

**Table A-1. Subgroup 1: C9-C25 predominantly aliphatic hydrocarbons**

<b>CAS RN*</b>	<b>Domestic Substances List name</b>
8008-20-6	Kerosene (petroleum)
64741-44-2	Distillates (petroleum), straight-run middle
64741-77-1	Distillates (petroleum), light hydrocracked
64741-85-1	Raffinates (petroleum), sorption process
64741-91-9	Distillates (petroleum), solvent-refined middle
64742-13-8	Distillates (petroleum), acid-treated middle
64742-14-9	Distillates (petroleum), acid-treated light
64742-38-7	Distillates (petroleum), clay-treated middle
64742-46-7	Distillates (petroleum), hydrotreated middle
64742-47-8	Distillates (petroleum), hydrotreated light
64742-79-6	Gas oils (petroleum), hydrodesulfurized
64742-81-0	Kerosine (petroleum), hydrodesulfurized
64742-96-7	Solvent naphtha (petroleum), heavy aliph.
64771-72-8	Paraffins (petroleum), normal C5-20

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

**Table A-2. Subgroup 2: C9-C16 predominantly aromatic hydrocarbons**

<b>CAS RN*</b>	<b>Domestic Substances List name</b>
64742-94-5	Solvent naphtha (petroleum), heavy arom.
68477-31-6	Distillates (petroleum), catalytic reformer fractionator residue, low-boiling

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**Table A-3. *Domestic Substances List* (DSL) names and definitions of the 16 substances in the GOKUPAC Group (NCI 2015)**

CAS RN	DSL Name	Definition
8008-20-6	Kerosene (petroleum)	A complex combination of hydrocarbons produced by the distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C9 through C16 and boiling in the range of approximately 180°C to 300°C (356°F to 572°F).
64741-44-2	Distillates (petroleum), straight-run middle	A complex combination of hydrocarbons produced by the distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C11 through C20 and boiling in the range of 205°C to 345°C (401°F to 653°F).
64741-77-1	Distillates (petroleum), light hydrocracked	A complex combination of hydrocarbons from distillation of the products from a hydrocracking process. It consists predominantly of saturated hydrocarbons having carbon numbers predominantly in the range of C10 through C18, and boiling in the range of approximately 160°C to 320°C (320°F to 608°F).
64741-85-1	Raffinates (petroleum), sorption process	A complex combination of hydrocarbons remaining after removal of normal paraffins in a selective adsorption process. It consists predominantly of branched chain and cyclic hydrocarbons having carbon numbers predominantly in the range of C5 through C25 and boiling in the range of approximately 35°C to 400°C (95°F to 752°F).
64741-91-9	Distillates (petroleum), solvent-refined middle	A complex combination of hydrocarbons obtained as the raffinate from a solvent extraction process. It consists predominantly of aliphatic hydrocarbons having carbon numbers predominantly in the range of C9 through C20 and boiling in the range of approximately 150°C to 345°C (302°F to 653°F).
64742-13-8	Distillates (petroleum), acid-treated middle	A complex combination of hydrocarbons obtained as a raffinate from a sulfuric acid treating process. It consists of hydrocarbons having carbon numbers predominantly in the range of C11 through C20 and boiling in the range of approximately 205°C to 345°C (401°F to 653°F).
64742-14-9	Distillates (petroleum), acid-treated light	A complex combination of hydrocarbons obtained as a raffinate from a sulfuric acid treating process. It consists of hydrocarbons having carbon numbers predominantly in the range of C9 through C16 and boiling in the range of approximately 150°C to 290°C (302°F to 554°F).
64742-38-7	Distillates (petroleum), clay-treated middle	A complex combination of hydrocarbons resulting from treatment of a petroleum fraction with natural or modified clay, usually in a percolation process to remove the trace amounts of polar compounds and impurities present. It consists of hydrocarbons having carbon numbers predominantly in the range of C9 through C20 and boiling in the range of approximately 150°C to 345°C (302°F to 653°F).

CAS RN	DSL Name	Definition
64742-46-7	Distillates (petroleum), hydrotreated middle	A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C11 through C25 and boiling in the range of approximately 205°C to 400°C (401°F to 752°F).
64742-47-8	Distillates (petroleum), hydrotreated light	A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C9 through C16 and boiling in the range of approximately 150°C to 290°C (302°F to 554°F).
64742-79-6	Gas oils (petroleum), hydrodesulfurized	A complex combination of hydrocarbons obtained from a petroleum stock by treating with hydrogen to convert organic sulfur to hydrogen sulfide which is removed. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C13 through C25 and boiling in the range of approximately 230°C to 400°C (446°F to 752°F).
64742-81-0	Kerosine (petroleum), hydrodesulfurized	A complex combination of hydrocarbons obtained from a petroleum stock by treating with hydrogen to convert organic sulfur to hydrogen sulfide which is removed. It consists of hydrocarbons having carbon numbers predominantly in the range of C9 through C16 and boiling in the range of approximately 150°C to 290°C (302°F to 554°F).
64742-94-5	Solvent naphtha (petroleum), heavy arom.	A complex combination of hydrocarbons obtained from distillation of aromatic streams. It consists predominantly of aromatic hydrocarbons having carbon numbers predominantly in the range of C9 through C16 and boiling in the range of approximately 165°C to 290°C (330°F to 554°F).
64742-96-7	Solvent naphtha (petroleum), heavy aliph.	A complex combination of hydrocarbons obtained from the distillation of crude oil or natural gasoline. It consists predominantly of saturated hydrocarbons having carbon numbers predominantly in the range of C11 through C16 and boiling in the range of approximately 190°C to 290°C (374°F to 554°F).
64771-72-8	Paraffins (petroleum), normal C <sub>5-20</sub>	A complex combination of normal paraffins obtained by a selective adsorption process using a solid adsorbent such as a molecular sieve. It consists of straight chain saturated hydrocarbons having carbon numbers predominantly in the range of C5 through C20 and boiling in the range of 35°C to 345°C (95°F to 653°F).
68477-31-6	Distillates (petroleum), catalytic reformer fractionator residue, low-boiling	The complex combination of hydrocarbons from the distillation of catalytic reformer fractionator residue. It boils approximately below 288°C (550°F).

