Risk Management Scope

for

Methyl Acetate

(Acetic acid, methyl ester)

Chemical Abstracts Service Registry Number (CAS RN):

[79-20-9]

Environment and Climate Change Canada

Health Canada

March 2022

Summary of Proposed Risk Management

This document outlines the risk management options under consideration for methyl acetate, which has been proposed to be harmful to human health under section 64(*c*) of the *Canadian Environmental Protection Act*, 1999 (CEPA) because it is 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 (Canada 2022). Specifically, the assessment proposes that exposure of the general population to methyl acetate, in particular through its use in aerosol adhesive and paint or coating remover or stripper products (referred to as paint remover in this document), poses a risk of harm to human health due to its potential to cause developmental toxicity.

Methyl acetate was assessed under the Chemicals Management Plan (CMP) of CEPA, as one of fourteen substances within the Esters Group. In addition to methyl acetate, this group includes triacetin; methyl hexanoate; propyl acetate; isobutyl acetate; methyl dodecanoate; docusate sodium; methyl butanoate; dimethyl glutarate; tetradecyl tetradecanoate; 2,2,4-trimethyl-1,3-pentanediol diisobutyrate; texanol; C14-22 monoglycerides; and 2-methoxypropyl acetate.

The assessment additionally proposes that while exposure of the general population to 2-methoxypropyl acetate is not of concern at current levels, this substance is considered to have a health effect of concern on the basis of its potential for developmental toxicity. Therefore, there may be a concern for human health if exposures to 2-methoxypropyl acetate were to increase.

Accordingly, this document outlines the risk management options under consideration for methyl acetate, which has been proposed to be harmful to human health.

In particular, the Government of Canada is considering:

- Measures to help reduce consumer exposure to methyl acetate from the use of aerosol adhesives and paint remover products.

Any information which could inform risk management decision-making should be provided (ideally on or before May 18, 2022), to the contact details identified in section 8 of this document.

The risk management options outlined in this risk management scope 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 this substance 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.

Table of Contents

1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Government of 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[1,2], and if so to manage the associated risks.

The substance acetic acid, methyl ester, Chemical Abstracts Service Registry Number (CAS RN[3]) 79-20-9, referred to throughout this document as methyl acetate, is included in the assessment of the Esters Group, as part of the CMP (Canada 2017).

2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment relevant to the evaluation of 14 substances, referred to collectively in the assessment as the Esters Group, to determine whether these substances present or may present a risk to the environment or to human health in Canada. A notice summarizing the scientific considerations of the draft screening assessment for these substances was published in the *Canada Gazette*, Part I, on March 19, 2022 (Canada 2022). For further information, refer to the draft screening assessment for the Esters Group.

2.1 Draft Screening Assessment Conclusion

Health Canada and Environment and Climate Change Canada conducted a joint screening assessment of fourteen substances referred to collectively as the Esters Group. Of the fourteen substances, one substance was identified as a priority for the assessment on the basis of other human health concerns. The

[1] 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.*

[2] A determination of whether one or more of the criteria of section 64 are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and 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.

[3] CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information 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.

other thirteen of the fourteen substances were subsequently determined to be of low concern. A notice summarizing the scientific considerations of the draft screening assessment for this substances was published in the *Canada Gazette*, Part I, on March 19, 2022 (Canada 2022).

On the basis of the information available, the draft screening assessment proposes that methyl acetate is toxic under paragraph 64(*c*) of CEPA as it is 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 (Canada, 2022).

It is also proposed that methyl acetate is 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 under paragraphs 64(*a*) and (*b*) of CEPA (Canada 2022).

In addition, the draft screening assessment proposes that methyl acetate meets the criteria for persistence but does not meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* of CEPA (Government of Canada, 2000).

The exposure source of concern identified in the draft screening assessment is inhalation exposure to methyl acetate from use of aerosol adhesives and paint or coating remover or stripper products (referred to as paint remover in this document). As such, this document will focus on these exposure sources of concern (refer to section 5).

The assessment additionally proposes that while exposure of the general population to 2-methoxypropyl acetate is not of concern at current levels, this substance is considered to have a health effect of concern on the basis of its potential for developmental toxicity. Therefore, there may be a concern for human health if exposures to 2-methoxypropyl acetate were to increase.

2.2 Proposed Recommendation under CEPA

On the basis of the findings of the draft screening assessment conducted under CEPA, the ministers propose to recommend that methyl acetate be added to the List of Toxic Substances in Schedule 1 of the Act[4].

The ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment and risk

[4] When a substance is found to meet one or more of the criteria under section 64 of CEPA, the ministers can propose to take no further action with respect to the substances, add the substance to the Priority Substances List for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act.

management scope in the preparation of the final screening assessment and risk management approach, if required.

If methyl acetate is concluded to meet one or more of the criteria under section 64 of CEPA at the time of the final screening assessment, and the ministers finalize the recommendation to add this substance to Schedule 1, risk management instrument(s) will be proposed within 24 months from the date on which the final screening assessment is published. The instrument(s) will be finalized within 18 months from the date on which the risk management instrument(s) are proposed (refer to section 8 for publication timelines applicable to this substance).

3. Proposed Risk Management

3.1 Proposed Human Health Objective

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

For methyl acetate, the proposed human health objective is focused on addressing the exposure source of concern outlined in section 5 of this document. As such, the proposed human health objective is to reduce exposure of the general population to methyl acetate to levels that are protective of human health.

3.2 Proposed Risk Management Objective

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instruments and/or tools for a given substance or substances.

In this case, the proposed risk management objective for methyl acetate is to reduce inhalation exposure of the general population to methyl acetate from aerosol adhesives and paint remover products.

This proposed risk management objective may be refined on the basis of consultation with stakeholders, the proposed risk management, consideration of further information received, the outcome of the final screening assessment, and socio-economic and technical considerations (outlined in section 6 of this document).

The revised human health and risk management objectives should next be presented in the risk management approach that will be published concurrently with the final screening assessment for the Esters Group, or in subsequent risk management documents (e.g., consultation document on the proposed instrument).

3.3 Proposed Risk Management Options Under Consideration

To achieve the proposed risk management objective and to work towards achieving the proposed human health objective, the proposed risk management actions being considered for methyl acetate are:

Regulatory and/or non-regulatory measures to help reduce consumer inhalation exposure to methyl acetate in aerosol adhesives and paint remover products.

Note that the proposed risk management options, described in this document, 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 be considered, along with the information presented in this document, in the instrument selection and development process[5]. The risk management options outlined in this document 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 Risk Management Information Gaps

Interested stakeholders are invited to provide further information to inform risk management decision-making regarding methyl acetate.

Should stakeholders have further information, they should provide it ideally on or before May 18, 2022 to inform the risk management decision-making process, within the timelines (and to the contact) identified in section 8 of this document.

3.5 Performance Measurement and Evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances. The aim is to determine whether human health and/or environmental objectives have been met and whether there is a need to revisit the approach to risk management for that substance, to ensure that risks are managed effectively over time. To achieve this, the Government of Canada will review the effectiveness of the risk management actions for methyl acetate.

The results of performance measurement and 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.

[5] The proposed risk management actions 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 Regulatory Management (Canada, 2012a), the Red Tape Reduction Action Plan (Canada, 2012b), and in the case of a regulation the *Red Tape Reduction Act* (Canada, 2015).

4. Background

4.1 General Information on Methyl Acetate

Methyl acetate is an organic substance that was assessed, along with 13 other ester compounds in the Esters Group by Health Canada and Environment and Climate Change Canada as part of the CMP initiative (Canada 2022).

4.2 Current Uses and Identified Sectors

Based on information submitted in response to a CEPA section 71 survey for the 2011 reporting year, methyl acetate was manufactured in a quantity of 9 600 kg and imported in a quantity of 323 602 kg in Canada.

Methyl acetate is primarily used as a solvent in a variety of commercial products and products available to consumers in Canada including paints and coatings, paint removers, adhesives and sealants, cleaning and furnishing care (Environment Canada 2013; SDS 2018a). Other uses reported in Canada include the manufacturing of batteries, fabric, textile and leather articles, ink, toner and colourants, paper products, and plastic and rubber materials. It is also used in cosmetics and as a formulant in pest control products in Canada. Regarding cosmetics, based on notifications submitted under the *Cosmetic Regulations* to Health Canada, it is used in products such as nail polish, nail polish remover, cleansers, exfoliants, facial masks, eye makeup, and moisturizers. Methyl acetate has been reported to occur naturally in food and may be used as flavouring agents in food in Canada (Burdock 2010). It may also be used as a component in the manufacture of food packaging materials. It is also listed in the Natural Health Products Ingredients Database (NHPID) with a non-medicinal role for use as a flavour enhancer.

5. Exposure Sources and Identified Risks

There is no evidence that methyl acetate may be associated with carcinogenic or genotoxic effects in the available empirical data for methyl acetate and its metabolites. Since methyl acetate is hydrolyzed to the main metabolite methanol, health effects data for methanol were also used to characterize methyl acetate toxicological endpoints. Potential developmental effects associated with the main metabolite, methanol, were identified to be the critical effects (Canada 2022), and the reference concentration (RfC; which is an estimate of a continuous inhalation exposure that is likely to be without an appreciable risk of deleterious effects during a lifetime) and reference dose (RfD for inhalation and oral exposure of methanol) derived by the United States Environmental Protection Agency (US EPA) were used for the purpose of characterizing the human health risk associated with methyl acetate.

Exposure of the general population to methyl acetate may occur through indoor air and its natural occurrence in food; this exposure is below the RfD for methanol (adjusted for methyl acetate) and therefore is not considered to be of concern at current levels of exposure. Inhalation exposure may also occur as a result of the use of products available to consumers, such as nail products, cleaning products, automotive products (e.g., aerosol paints, tire cleaners), adhesives (e.g., construction adhesives, aerosol adhesives for fabric and tube glues), adhesive removers, lubricants, paint removers, and floor coatings. All calculated 24-hour average air concentrations associated with the use of these products, except for aerosol adhesives for fabric and paint removers, are below the RfC for methanol which has been adjusted for exposure to methyl acetate (adjusted concentration of 46 mg/m^3). Therefore, these products are not considered to be of concern at current levels of exposure. In the case of the aerosol adhesives, at a product concentration of 40%, the estimated 24-hour average air concentration for methyl acetate is 52 mg/m^3, which is above the RfC for methanol (adjusted to methyl acetate). In the case of paint removers, at a product concentration of 70%, the estimated 24-hour average air concentrations for methyl acetate, which range from 79 to 2153 mg/m^3 depending upon the nature of the task, are above the RfC for methanol (adjusted to methyl acetate). Therefore, these products are of potential concern. Note that transient irritation and neurological effects are also associated with inhalation exposure to methanol, but these effects occur at much higher air concentrations than those associated with developmental effects.

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

There is a current movement toward the development of consumer products and products used in industrial applications with lower VOC (volatile organic compounds or organic chemicals that have a high vapour pressure at room temperature) solvent concentrations, or no VOCs at all. Similarly, several major retail chains have recently indicated their intention to remove products containing certain hazardous VOC solvents from their inventory. However, in this effort, methyl acetate had been identified in the literature as one of the lower toxicity solvents for adhesives; and therefore, potentially a safer substitute for this application (Barry et al., 2017). Nonetheless, the Government of Canada assessment of health effects associated with the use of methyl acetate in aerosol adhesives and paint remover products, indicates a concern for human health.

Regarding paint removers, various manufacturers offer alternative products such as water-based products that do not contain methyl acetate nor other solvents associated with toxicity issues. In order to determine the most suitable risk management measure, Health Canada will discuss with stakeholders possible product modifications and potential alternatives to methyl acetate in paint remover products. These discussions will take into consideration the avoidance of using any alternative substance that could have a negative impact on human health.

6.2 Socio-economic and Technical Considerations

Socio-economic factors will be considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objectives(s). Socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Regulatory Management* (Canada 2012) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action* (Canada 2007).

7. Overview of Existing Risk Management

7.1 Related Canadian Risk Management Context

Domestically, the risk management actions are as follows:

- In Canada, the safety of chemicals used in food packaging materials is subject to the provisions of Division 23 of the *Food and Drug Regulations* and section 4(1)(a) of the *Food and Drugs Act*.

- In Canada, the safety of food flavouring agents is subject to the provisions of section 4(1)(a) of the *Food and Drugs Act.*

- Canadian implementation of the International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use Guidance Q3C(R6): Impurities: Listing of methyl acetate under Guideline for Residual Solvents as a Class 3 solvent (low toxic potential).

- The NHPID lists methyl acetate with a non-medicinal role for use as a flavour enhancer. However, methyl acetate is not listed in the Licensed Natural Health Products Database as being present in currently licensed natural health products in Canada.

- *Pest Control Products Act* – Methyl acetate is permitted as a formulant in registered pest control products in Canada.

- *Transportation of Dangerous Goods Regulations* including Amendment SOR/2017-253 (*Transportation of Dangerous Goods Act*) lists methyl acetate as a Class 3 (Flammable and combustible liquids). This schedule lists the safety specifications for transport of this substance and other dangerous goods by land or water.

- The proposed *Volatile Organic Compound Concentration Limits for Certain Products Regulations* were published in the *Canada Gazette*, Part I, on July 6, 2019 under CEPA and would apply to Canadian manufacturers and importers. Once finalized, they will establish VOC concentration limits for approximately 130 product categories and subcategories, including paint or

coating removers or strippers, graffiti removers, paint thinners, etc. The regulations would set a VOC concentration limit for the total amount of VOCs in a certain product **but would not** capture methyl acetate, which is an excluded VOC under item 65 of Schedule 1 of CEPA.

7.2 Pertinent International Risk Management Context

Internationally, the pertinent risk management actions are as follows:

United States (US):

- *The Federal Food, Drug and Cosmetic Act (FD&C Act)* - Methyl acetate is a food additive permitted for direct addition to food for human consumption as a synthetic flavoring substance and adjuvant in accordance with certain conditions (21 CFR 172.515); methyl acetate is an indirect additive for use only as a component of adhesives (21 CFR 175.105).

- Cosmetic Ingredient Review Expert Panel funded by the US. Personal Care Products Council - concluded that methyl acetate "is safe in present practices of use and concentration".

- *The Federal Insecticide, Fungicide, and Rodenticide Act* - Methyl acetate is an inert ingredient in pesticides, which is approved for non-food use.

- *The Clean Air Act* - National VOC emission standards for certain categories of consumer products - Reactivity Factors provided for methyl acetate in National Volatile Organic Compound Emission Standards for Aerosol Coatings (National VOC Compound Emission Standards for Consumer and Commercial Products 40 CFR 59).

- Methyl acetate is subject to the US EPA National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry (SOCMI) (40 CFR 63) (similar to 40 CFR 60 below).

- Methyl acetate is subject to various US federal codes for shipping/transportation (33 CFR 154, 46 CFR 150, 46 CFR 30, 49 CFR 172).

- Methyl acetate is subject to standards of performance for equipment leaks of VOC in the SOCMI (40 CFR 60.489 (US EPA)).

European Union (EU)

- The EU permits methyl acetate to be used as a flavouring agent in food (EU Food Flavourings Database), and is listed in the Register of Flavouring Substances pursuant to Article3(1) of Regulation EC No. 2232/96 (28 Oct 1996) that lays out a procedure for flavouring substances used or intended for use in or on foodstuffs.

- Methyl acetate is listed in the European Commission's database for information on cosmetic substances and ingredients (CosIng) with primarily solvent and perfuming agent functions, in Section 1, Annex I (Cosmetic Ingredients other than Perfume and Aromatic Raw Material) of Commission Directive 2006/257/EC, an amendment of Section 5a of Commission Directive 76/768/EEC which establishes the inventory and common nomenclature of ingredients used in cosmetic products.

- EU Regulation No. 2017/53, regarding Regulation (EC) No. 1831/2003 concerning the authorisation of methyl acetate as a feed additive for all animal species. The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds' is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

- Methyl acetate is included of Annexes A and B to Council Directive 94/55/EC on the transport of dangerous goods by road, and in Annexes A and B to Council Directive 96/49/ with regard to the transport of dangerous goods by rail.

7.3 Risk Management Alignment

There is limited risk management alignment between Canada, the U.S. and the EU, as Canada appears to be the first jurisdiction to propose preventive or control actions to address exposure of the general population to methyl acetate specifically from paint remover products. While methyl acetate is suspected of being of concern in other jurisdictions, no restrictions or controls have yet been applied to paint remover products.

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 section 3.4. Please submit additional information and comments prior to May 18, 2022.

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

Comments and information submissions on the risk management scope should be submitted to the address 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

Companies who have a business interest in methyl acetate are encouraged to identify themselves as stakeholders. The stakeholders will be informed of future decisions regarding methyl acetate and may be contacted for further information.

Following the public comment period on the risk management approach, the Government of Canada will initiate the development of the specific risk management actions, where necessary. Comments received on the risk management approach will be taken into consideration in the selection or development of these actions. Consultation will also take place as actions are developed.

8.2 Timing of Actions

Electronic consultation on the draft screening assessment and risk management scope: March 19, 2022 to May 18, 2022. This should include the submission of public comments, additional studies [and/or] information on methyl acetate.

Publication of responses to public comments on the draft screening assessment and risk management scope: concurrent to the publication of the screening assessment and, if required, the risk management approach.

Publication of responses to public comments on the risk management approach, if applicable and if required, the proposed instrument(s): At the latest, 24 months from the date on which the ministers recommended that methyl acetate be added to Schedule 1 of CEPA.

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

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

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

Burdock GA. 2010. Fenaroli's handbook of flavor ingredients. 6th ed. Orlando (FL): Burdock Group.

Barry CP, Morose GJ, Begin K, Atwater M, Hansen CJ. 2017. The identification and screening of lower toxicity solvents for contact adhesives. International Journal of Adhesion and Adhesives 78:174-181.

Canada. 2007. Treasury Board of Canada Secretariat. 2007. Assessing, Selecting, and Implementing Instruments for Government Action.

Canada. 2012. Treasury Board of Canada Secretariat. *Cabinet Directive on Regulatory Management*.

Canada, Department of the Environment, Department of Health. 2022. Draft Screening Assessment for the Esters Group.

Environment Canada. 2013. DSL Inventory Update data collected under the *Canadian Environmental Protection Act, 1999*, section 71: Notice with respect to certain substances on the Domestic Substances List. Data prepared by: Environment Canada, Health Canada; Existing Substances Program.

Government of Canada. (1999). *Canadian Environmental Protection Act, 1999*. S.C., 1999, c. 33. Retrieved October 13, 2017, from *Canada Gazette*. Part III. vol. 22, no. 3 [PDF].

Government of Canada. (2016). *Canadian Environmental Protection Act, 1999*: Announcement of planned actions to assess and manage, where warranted, the risks posed by certain substances to the health of Canadians and the environment. Retrieved October 13, 2017, from *Canada Gazette*, Part I, vol. 150, no. 25. June 18, 2016, p. 1989-1994.