



Government  
of Canada

Gouvernement  
du Canada

## **Risk Management Scope**

for:

**Ketones, *specifically*:**

**2-Butanone (MEK); 4-Methyl-2-pentanone (MIBK);  
2,4-Pentanedione (2,4-PD)**

**Chemical Abstracts Service Registry Number**

**(CAS RNs):**

78-93-3; 108-10-1; 123-54-6

Environment and Climate Change Canada

Health Canada

January 2019

**Canada**

## Summary of Proposed Risk Management (RM)

This document outlines the risk management option under consideration for 2-Butanone (MEK); 4-Methyl-2-pentanone (MIBK); 2,4-Pentanedione (2,4-PD), which have been proposed to be harmful to human life or health. In particular, the Government of Canada is considering the action, as below, to address health concerns:

- for Paint and Coatings Products and Do-It-Yourself (DIY) Products<sup>1</sup>
  - (a) Regulatory or non-regulatory measures to help reduce consumer exposure to MEK, MIBK, and 2,4-PD in paints / coatings products and do-it-yourself (DIY) products;

Moreover, because certain data gaps remain, information on the following items should be provided (on or before March 2019), to the contact details identified in section 8 of this document, to inform risk management decision-making:

- Ranges of concentrations of any of MEK, MIBK, and 2,4-PD in paints / coatings products and DIY products, available to consumers in Canada;
- Occurrence / content of ventilation statements on paints and coatings products and DIY products containing any of MEK, MIBK and 2,4-PD.

The risk management option outlined in this RM Scope document may evolve through consideration of assessments and RM options published for other Chemicals Management Plan (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 information gaps and uncertainties. Refer to section 3 of this document for more complete details in this regard.

### The Ketones Substance Grouping:

MEK, MIBK and 2,4-PD are three of the ten substances referred to collectively as the Ketones Group under the third phase of the Chemicals Management Plan (CMP 3).

---

<sup>1</sup> In this document, "Paints / Coatings Products" refer to Paints and Coatings Products that contain MEK, MIBK or 2,4-PD. This includes all liquid and spray paints, and all paint-type and coating-type products that contain MEK, MIBK or 2,4-PD.

In this document "Do-It-Yourself" (DIY) products include: Lacquer removers, adhesive removers, paint thinners, paint removers, adhesives and PVC cement/primer – all which may contain one or more of MEK, MIBK or 2,4-PD.

All ten substances in this assessment were identified as having low potential to cause ecological harm, based on the Ecological Risk Classification of organic substances (ERC) approach (ECCC 2016).

In addition, the seven remaining substances in this grouping, 2-Pentanone (MPK), 2-Hexanone, 5-Methyl- (MIAK), 4-Hydroxy-4-methyl-2-pentanone (DAA), 2,3-Butanedione (diacetyl), 2,3-Pentanedione (2,3-PD), 2-Butanone, 3-hydroxy-(acetoin) and 4-Methyl-3-penten-2-one (MO), are also proposed not to 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.

## Table of Contents

<b>Summary of Proposed Risk Management (RM)</b> .....	<b>2</b>
<b>1. Context</b> .....	<b>5</b>
<b>2. Issue</b> .....	<b>5</b>
2.1 Draft Screening Assessment Conclusion .....	5
2.2 Proposed Recommendation under CEPA.....	6
<b>3. Proposed Risk Management</b> .....	<b>6</b>
3.1 Proposed Human Health Objective .....	6
3.2 Proposed Risk Management Objectives and Options under Consideration..	7
3.3 Risk Management Information Gaps.....	8
<b>4. Background</b> .....	<b>8</b>
4.1 General Information on the Ketones Group.....	8
4.2 Current Uses and Identified Sectors .....	8
<b>5. Exposure Sources and Identified Risks</b> .....	<b>9</b>
<b>6. Risk Management Considerations</b> .....	<b>10</b>
6.1 Alternatives and Alternate Technologies .....	10
6.2 Socio-economic and Technical Considerations.....	11
<b>7. Overview of Existing Risk Management</b> .....	<b>11</b>
7.1 Related Canadian Risk Management Context .....	11
7.2 Pertinent International Risk Management Context .....	11
<b>8. Next Steps</b> .....	<b>12</b>
8.1 Public Comment Period .....	12
8.2 Timing of Actions.....	13
<b>9. References</b> .....	<b>14</b>

## 1. Context

The *Canadian Environmental Protection Act, 1999* (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 harmful or dangerous to the environment and human health as set out in section 64 of CEPA<sup>2,3</sup>, and if so, to manage the associated risks.

## 2. Issue

### 2.1 Draft Screening Assessment Conclusion

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment relevant to the evaluation of Ketone substances including: MEK, MIBK, and 2,4-PD 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 January 19, 2019 (Canada 2019). Based on the information available, the draft screening assessment proposes that MEK, MIBK, and 2,4-PD are toxic under section 64c of CEPA because they are 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 (Canada 2019).

MEK and 2,4-PD are proposed to meet the persistence criteria but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

MIBK is proposed to not meet the persistence or bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

The exposure sources of concern, identified in the draft screening assessment (Canada 2019) for MEK, MIBK and 2,4-PD, are based on the release and

---

<sup>2</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>3</sup> A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, 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 *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.

inhalation of MEK, MIBK and 2,4-PD during the use of certain paints / coatings products and DIY products.

This document will therefore focus on these application and exposure sources of concern (refer to section 5). Of note, the proposed risk management options described in this document (and the proposed conclusion outlined in the draft screening assessment) are preliminary and may be subject to change. For further information, refer to the draft screening assessment for the Ketones

## **2.2 Proposed Recommendation under CEPA**

Based on the findings of the draft screening assessment conducted as per CEPA the Ministers propose to recommend that MEK, MIBK and 2,4-PD be added to the List of Toxic Substances in Schedule 1 of the Act<sup>4</sup>.

The Ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment and RM Scope document. If the ministers finalize the recommendation to add MEK, MIBK and 2,4-PD to Schedule 1, risk management instruments must be proposed and finalized within a set period of time, 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 Objective**

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

For MEK, MIBK and 2,4-PD, the proposed objective is focused on addressing the risks / exposure sources 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 MEK, MIBK and 2,4-PD to levels that are protective of human health.

The proposed human health objective may next be revised in the RM Approach document that will be published concurrently with the final screening assessment for these substances, or in subsequent risk management documents (e.g. consultation document on proposed instrument), as the case may be.

---

<sup>4</sup> 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.

## 3.2 Proposed Risk Management Objectives and Options under Consideration

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instrument(s) and/or tool(s) for a given substance or substances. In this case, the proposed risk management objective for the protection of human health is to:

- Reduce the concentrations of MEK, MIBK and 2,4-PD, in certain paints / coatings products and certain DIY products available to consumers in Canada, such as lacquer removers, adhesive removers, paint thinners, paint removers, adhesives and PVC cement/primer – all which may contain one or more of MEK, MIBK or 2,4-PD.

The proposed risk management objective may next be revised in the RM Approach document that will be published concurrently with the screening assessment for these substances, or in subsequent risk management documents (e.g. consultation document on proposed instrument), as the case may be.

### 3.2.1 Risk Management Options under consideration for Paints / Coatings Products and DIY Products

To achieve the proposed risk management objective and to work towards achieving the proposed human health objective, the following risk management option is under consideration for MEK, MIBK and 2,4-PD:

#### 3.2.1.1 Measures to reduce exposure

The regulatory or non-regulatory measures could include requirements such as:

- a) Concentration limits of MEK, MIBK, and 2,4-PD for products.
- b) Labelling, including a ventilation statement.

Following the publication of this RM Scope 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<sup>5</sup>. The risk management options outlined in this document may evolve through consideration of assessments and risk management options published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

---

<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 Regulatory Management (TBS 2012a), Red Tape Reduction Action Plan (TBS 2012b) and the Red Tape Reduction Act (Canada, 2015).

Strategies will also be developed to demonstrate the effectiveness of the risk management option employed.

### **3.3 Risk Management Information Gaps**

At this time, additional information below is being requested from interested stakeholders to help fill information gaps and to inform risk management decision-making regarding MEK, MIBK and 2,4-PD use in Canada:

- Ranges of concentrations of any of MEK, MIBK and 2,4-PD in paint / coating products and DIY products available to Canadian consumers.
- Occurrence / content of ventilation statements on paints and coatings products and DIY products containing MEK, MIBK and 2,4-PD.

## **4. Background**

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

MEK, MIBK and 2,4-PD belong to the Ketone group of substances characterized by a carbonyl group in which the carbon atom is joined to an oxygen atom by a double bond. The other two bonds are to other carbon atoms or to hydrocarbon radicals.

MEK, MIBK and 2,4-PD, are naturally occurring organic substances in the environment in several plants and/or foods items. They are also commercially produced and MEK is produced endogenously in humans.

### **4.2 Current Uses and Identified Sectors**

According to information reported to surveys under section 71 of CEPA (Canada 2012) MEK, MIBK and 2,4-PD, were not manufactured in Canada. 1,241,783 kg of MIBK and 100,000-1,000,000 kg of 2,4,-PD were imported into Canada.

The Canadian International Merchandise Trade Database (CIMT) shows that In 2011, about 6 million kg of MEK was imported into Canada (CIMT 2011) and that between 2011 and 2016, about 4.9 million kg of MEK, on average, was imported into Canada (CIMT 2017).

#### **4.2.1 Paints / Coatings Products and Do-It-Yourself Products**

MEK, MIBK and 2,4-PD are used primarily as solvents in products available to consumers, and as solvents and additives in the manufacture of paints, coatings,



thinning lacquers, and do-it-yourself products. This includes liquid and spray paints, paint-type and coating-type products, and lacquer removers, paint thinners, and paint removers.

Other “Do-It-Yourself” (DIY) products which may contain one or more of MEK, MIBK or 2,4-PD include adhesive removers, adhesives and PVC cement/primer.

MIBK is also used in degreasing agents for bicycles, automotive scratch repair kits, and appliance touch-up floor and repair coatings, in filler/putty for automotive care and in dry erase markers.

MEK is used in adhesive and finish removers, adhesives, PVC cement or primer, as well as aerosol spray products used in automotive grease cleaners and repair products (Health Canada 2016, HPD 1993).

## 5. Exposure Sources and Identified Risks

According to the draft screening assessment, the most common exposure of the general population in Canada to MEK, MIBK and 2,4-PD is from air and food (primarily natural occurrence). These exposures are low and are not of concern. The major exposures of concern to consumers are by inhalation of emissions from certain paints / coatings products and certain DIY products which contain MEK, MIBK or 2,4-PD. Dermal and oral exposures to MEK, MIBK and 2,4-PD, may impact the overall exposures, but the major exposure of concern is by inhalation.

The purpose of the RM Scope is to present Environment and Climate Change Canada’s and Health Canada’s early proposal to manage the risks identified in the screening assessment. As such, only the exposure sources of concern are further discussed in this document. More information on other sources of exposure can be found in the screening assessment.

Exposures of concern to MEK and/or MIBK and/or 2,4-PD by inhalation, can occur in the home during painting, renovations, maintenance and repairs.

### MEK

According to the draft screening assessment, the available information on MEK indicates that the critical health effects include adverse developmental effects (increased organ weight) and decreased body weight gain.

In six 7-hour TWA exposure scenarios<sup>6</sup> in the screening assessment (Canada 2019) the calculated margins of exposure (MOE) for inhalation exposure to MEK in

---

<sup>6</sup> Seven-hour time-weighted average (TWA) concentrations were derived for the product scenarios to match up with the exposure durations of the critical effects study used to characterize risk.

certain lacquer removers, adhesive removers, paint thinners, floor coatings, liquid paints (solvent rich) for truck bed, spray paints, and PVC cements/primers, were inadequate to account for uncertainties in the health effects and exposure databases.

### MIBK

The International Agency for Research on Cancer (IARC) considers MIBK to be in group 2B (“possibly carcinogenic to humans”), with “sufficient evidence” of carcinogenicity in laboratory animals. For non-cancer effects, effects on the liver and kidney as well as developmental effects were observed in laboratory studies.

The margins of exposure (MOE) with regards to MIBK for certain wood lacquers, liquid paints (solvent rich) for trucks and spray paint, in inhalation exposure scenarios<sup>7</sup> in the draft screening assessment (Canada 2019) were inadequate to account for uncertainties in the health effects and exposure databases.

### 2,4-PD

According to the draft screening assessment, critical health effects such as systemic toxicity and adverse developmental effects (reduced foetal weight, reduced foetal ossification, skeletal variations) have been associated with exposure to 2,4-PD.

The general population of Canada may be exposed to 2,4-PD from the use of a limited number of products available to consumers, such as certain specialty coating products. In one inhalation exposure scenario<sup>8</sup> of the draft screening assessment (Canada 2019), the MOE were inadequate to account for uncertainties in the health effects and exposure databases.

## **6. Risk Management Considerations**

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

Several alternatives and alternative technologies to solvent-based paints and coatings are available. These include water-based paints and coatings, plant-based paints, dry coatings and electrostatic coatings. As expected, there are pros and cons to employing these alternatives. Water-based and plant-based paints and coatings may offer lower VOCs and reduced toxicity for the consumer. However, they may require the addition of more additives, biocides and fungicides.

---

<sup>7</sup> Six-hour TWA concentrations were derived for the product scenarios to match up with the exposure durations of the critical effects study used to characterize risk.

<sup>8</sup> Six-hour TWA concentrations were derived for the product scenario to match up with the exposure durations of the critical effects study used to characterize risk

Furthermore, they would require more preparation for use and longer drying time. (Massachusetts Toxics Reduction Institute, 2016, [Alternatives to solvents based coatings](#).1993)

## 6.2 Socio-economic and Technical Considerations

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

## 7. Overview of Existing Risk Management

### 7.1 Related Canadian Risk Management Context

MEK, MIBK are VOCs and are included in the National Pollutant Release Inventory, 2016-2017, as part of the National Air Pollution Surveillance (NAPS) program.

The following are current or proposed VOC regulations which are applicable to VOC containing substances but may not be specifically applicable to controlling these substances

The [VOC Concentration Limits for Architectural Coatings Regulations](#) for coatings were published in the *Canada Gazette, Part II* on September 30th, 2009.

The proposed [VOC Concentration Limits for Certain Products Regulations](#) were first published in *Canada Gazette Part I* in 2008, and are being revised.

MEK, MIBK, 2,4-PD are regulated as dangerous goods for transportation. The *Hazardous Waste and Hazardous Recyclable Material Regulations* control the export and import of MEK and MIBK. Several Provincial and Territorial governments regulate MEK, MIBK and 2,4-PD for occupational health and safety exposure.

MEK is listed as a permitted food additive in natural extractives and in spice extracts as prescribed in Health Canada's *List of Permitted Carrier or Extraction Solvents* with a maximum residual level of 50 ppm..

### 7.2 Pertinent International Risk Management Context

The US Food and Drug Administration (FDA) recognize MEK as a food additive that may be used as carrier or extraction solvents. MEK is also permitted in other direct food additives and indirect food additives (e.g. adhesives, polymer coatings, cellophane). MIBK is a Food and Drug Administration (FDA) approved indirect food additive for adhesives, paper and paperboard, and polymers and as a direct food additive (synthetic flavour). MEK, MIBK and 2,4-PD, are all in the *Toxic Substances Control Act* inventory. Many states in the US have regulations controlling these substances as hazardous.

MEK, MIBK and 2,4-PD are all in the REACH List of Registered Substances. As well, they are all listed in the in the Register of Flavouring Substances with a procedure for flavouring substances used or intended for use in or on foodstuffs

For MEK, in the UK, occupational exposure limits of 200 ppm (8-hr TWA reference period) and 300 ppm (15 minute reference period) are available. Australia has listed MEK in the Poisons Standard (the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) with conditions for its use in preparations. It is also listed in the Australian Customs as a poison to be controlled. MEK is on Australia's National Pollutant Inventory.

## 8. Next Steps

### 8.1 Public Comment Period

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). Please submit additional information and comments prior to March 20, 2019. 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 Screening Assessment Report. 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  
Chemicals Management Division  
Gatineau Quebec K1A 0H3  
Tel: 1-800-567-1999 | 819- 938-3232  
Fax: 819-938-3231  
Email: [eccc.substances.eccc@canada.ca](mailto:eccc.substances.eccc@canada.ca)

Companies who have a business interest in MEK, MIBK, or 2,4-PD, are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding MEK, MIBK, or 2,4-PD and may be contacted for further information.

## 8.2 Timing of Actions

<b>Action</b>	<b>Date</b>
Electronic consultation on the Risk Management Scope document	January 19, 2019 to March 20, 2019
Submission of additional studies or information on MEK, MIBK and 2,4-PD	on or before March 20, 2019
Publication of responses to public comments on the draft screening assessment and Risk Management Scope document	on or before March 20, 2020
Publication of the final screening assessment and, if required, the Risk Management Approach document	on or before March 20, 2020
Publication of responses to public comments on the Risk Management Approach document, if applicable, and publication if required, of the proposed instrument(s)	At the latest, 24 months from the publication of the final screening assessment
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)

## 9. References

Canada. 1999. [Canadian Environmental Protection Act, 1999](#). S.C., 1999, ch. 33. Canada Gazette. Part III. vol. 22, no. 3.

Canada. 2000. *Canadian Environmental Protection Act, 1999: [Persistence and Bioaccumulation Regulations](#)*, P.C. 2000-348, 23 March 2000, SOR/2000-107

Canada. 2011. *Canadian Environmental Protection Act, 1999: [Announcement of planned actions to assess and manage, where appropriate, the risks posed by certain substances to the health of Canadians and the environment](#)*. Canada Gazette, Part I, vol. 145, no. 41 – October 8, 2011, p. 3125-3129.

Canada. 2015. [Red Tape Reduction Act](#).

Treasury Board of Canada Secretariat. 2012. [Red Tape Reduction Action Plan](#).

Canada. 2019. Dept. of the Environment, Dept. of Health. [Draft Screening Assessment for the Ketones](#).

Canada. 2016. [Science approach document: ecological risk classification of organic substances](#).

Massachusetts Toxics Reduction Institute, 2016, [Alternatives to solvents based coatings](#). 1993

Massachusetts Toxics Reduction Institute, 2016. [Paint and Coating Removal](#)

Massachusetts Toxics Reduction Institute, 2018. [Alternatives](#)

Massachusetts Office of Technical Assistance. 2016. [Water-based Paints \(PDF, 290 KB\)](#); [Less Toxic Alternatives \(PDF, 373 KB\)](#)

US Coatings, 2018. [Water-based coatings vs solvent-based coatings](#)

[TBS] Treasury Board of Canada Secretariat. 2018. [Cabinet Directive on Regulation](#).

[CIMT] Canadian International Merchandise Trade [database on the Internet]. 2017. [291412 Butanone \(methyl ethyl ketone\), 2011-2016](#).