Consultation document on proposed new risk management actions for 2-butanone, oxime

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1. Purpose

The purpose of this document is to consult with interested stakeholders on proposed new risk management for 2-butanone, oxime (butanone oxime) in certain products available to consumers, particularly, paints and coatings; stains and finishes; and adhesives and sealants. New risk management actions are being proposed as a result of a performance measurement evaluation, published in 2020, that determined the risks of butanone oxime are not effectively managed at this time.

2. Background

Screening assessment

2-Butanone, oxime (CAS RN 96-29-7), commonly known as butanone oxime or methyl ethyl ketoxime (MEKO), is a human-made substance used widely as an anti-skinning agent, which prevents the drying and formation of a skin on the surface of paint and coating products. It is used in the formulation of alkyd paints, varnishes, stains, finishes, coatings, adhesives and sealants for both industrial and consumer use (Canada 2010a). In the screening assessment, published by Environment and Climate Change Canada and Health Canada (Canada 2010a) (the Departments), non-cancer effects were considered critical for risk characterization, which included effects on the nasal cavity, spleen, liver, and kidney as well as hematological effects.

Potential carcinogenicity was also considered in the screening assessment, as increased incidences of tumours were observed at moderate and high concentrations. Although the mode of induction of tumours was not fully elucidated, the tumours observed were not considered to have resulted from direct interaction with genetic material. As a result, a threshold approach was used to assess risk to human health, and non-cancer effects were used to quantitatively characterize risk from short-term, infrequent exposures (Canada 2010a).

The screening assessment under the CMP in 2010 concluded that butanone oxime may have been entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. It was therefore concluded that butanone oxime meets the criterion in paragraph 64(c) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 2010a). Subsequently, butanone oxime was added to Schedule 1 to CEPA 1999 by order in the *Canada Gazette* on December 21, 2011 (Canada 2011).

The most significant route of human exposure to butanone oxime identified in the screening assessment was via inhalation during and immediately following application of certain products available to consumers (Canada 2010a). Risk from dermal exposure during use of some products was also determined to be a concern. The proposed risk management approach, published in 2010, outlined the proposed actions to prevent or control the risks posed by exposure to butanone oxime. The human health objective was to minimize human exposure to the extent practicable, and the risk management objective was to reduce exposure

to butanone oxime (Canada 2010b). In 2014, a code of practice was published to address these objectives.

The Code of Practice

The Code of Practice for 2-Butanone, oxime (Butanone oxime Associated with the Interior Application of Consumer Alkyd Paint and Coating Products) (Health Canada 2014) (the Code) was implemented to reduce exposure of Canadians to butanone oxime from certain products and applies to any person who manufactures, imports, or sells interior or dual-use consumer alkyd paint and coating products containing butanone oxime as well as those responsible for labelling these products. The objective of the Code is "to help reduce inhalation exposure to butanone oxime by the general public during and immediately following interior application of consumer alkyd paint and coating products" (Health Canada 2014). The Code identifies 3 recommended practices to reduce exposure of the general public to butanone oxime:

1. to reduce the concentration of butanone oxime in consumer interior and dual-use alkyd paints and coatings to the lowest level technically and economically feasible (the Code does not specify target concentrations);
2. to incorporate the labelling statement, "use only in a well-ventilated area", on all applicable consumer interior and dual-use alkyd paints and coatings; and
3. to implement a consumer education program that will inform consumers of behaviours that will help to achieve well ventilated conditions during and immediately following interior application of all applicable consumer interior and dual-use alkyd paints and coatings.

The Code includes a commitment by the Minister of Health to evaluate the progress achieved toward reducing inhalation exposure to butanone oxime 5 years after its publication.

Performance Measurement Evaluation

In 2019, a performance measurement evaluation (PME) of butanone oxime was initiated to determine if the risk management, namely the Code, was meeting its objective "to help reduce inhalation exposure to butanone oxime by the general public during and immediately following interior application of consumer alkyd paint and coating products". The PME, published in 2020, determined that there has not been significant adoption of the Code, nor significant progress to reduce

exposure of the general public to butanone oxime. Specifically, concentrations of butanone oxime in consumer interior and dual-use (interior/exterior) alkyd paints and coatings have not decreased, and there were varied degrees of implementation of the recommended labelling and consumer education practices. Although efforts were made to implement certain recommended practices from the Code, based on the information available it was concluded in the PME report that risks from butanone oxime are not effectively managed at this time (Health Canada 2020).

3. New risk management

As a result of the PME report conclusion (Health Canada 2020), the Government of Canada is proposing new risk management to reduce general population exposure to butanone oxime. In order to effectively manage the risks of this substance several important elements related to the risk management of butanone oxime have been revisited including, the objectives of risk management, the scope of products to be risk managed, and the determination of concentration limits protective of human health. The risk management objectives have been updated to ensure that the rationale for applying new risk management is in step with current information, policies, and approaches. In addition, the scope of risk management actions has been reviewed to ensure all sources of butanone oxime are considered in new risk management actions. The changes to these risk management elements for butanone oxime are expected to result in more effective management of risks and enhanced protection of Canadians.

4. Updated human health and risk management objectives

The updated objectives for managing the risks of butanone oxime are proposed in order to align with current information, policies and approaches under the Chemicals Management Plan. The Government of Canada is proposing to update the human health and risk management objectives as follows:

Human health objective

In the 2010 risk management approach, the human health objective was to minimize human exposure to the extent practicable (Canada 2010b).

The updated human health objective for butanone oxime is to reduce general population exposure to this substance to levels that are protective of human health.

Risk management objective

The 2010 risk management objective was to reduce exposure to butanone oxime (Canada 2010b).

The updated risk management objective is to reduce concentrations of butanone oxime in paints and coatings; stains and finishes; and adhesives and sealants available to consumers to levels that are protective of human health for the general population.

5. Sources of exposure of concern – product categories to be risk managed

In support of the updated human health and risk management objectives, Health Canada has reviewed the products identified in the screening assessment as containing butanone oxime that could be of concern to human health. While alkyd paints and coatings were identified in the screening assessment as the greatest source of exposure of concern, other types of products available to consumers (including but not limited to those for which exposure was quantitatively characterized in the screening assessment) were found to have margins of exposure that were not adequately protective of human health. For that reason, the Government of Canada is considering expanding the products targeted for risk management action beyond the interior and dual-use alkyd paints and coatings addressed by the Code, in order to be protective of human health. Products containing butanone oxime for which exposure either via inhalation or via inhalation and dermal routes were determined to be of concern include:

- paints and coatings (including primers)
- stains and finishes (including varnish and polyurethane)
- silicone sealants
- gasketing adhesives

As such, the proposed new risk management aims to reduce exposures of the general population to butanone oxime from these product types including interior, dual-use, and exterior products, to levels that are protective of human health. Risk management may also include these product categories more broadly (e.g. all sealants and adhesives) depending on information received during the public comment period or through other information gathering; or to prevent exposure to butanone oxime from becoming a concern in additional product sub-categories.

6. Proposed concentration limits for identified products of concern

To support development of the new proposed risk management for butanone oxime, the Government of Canada has developed proposed concentration limits for the products of concern. These limits are the highest concentrations of butanone oxime in the specified products which are not expected to result in a concern for human health based on their intended consumer use.

The proposed concentration limits for interior and dual-use products were developed based on the critical effect level of 107 mg/m^3 at which nasal lesions were observed in mice after short-term inhalation exposure to butanone oxime (Canada 2010a), and the estimated inhalation exposure of the Canadian general population from indoor use of these products.

Potential risk via the dermal route was characterized using the critical effect level of 180 mg/kg-bw/day at which effects on the red blood cells of rabbits were observed after acute dermal exposure to butanone oxime (Canada 2010a), and the estimated dermal exposure of the Canadian general population from use of the specified products. The proposed concentration limits for indoor and dual-use products are considered to be protective of health effects from exposures to butanone oxime via the inhalation and dermal routes from their intended consumer use.

For exterior use-only products, the proposed concentration limits were developed based on potential risk in consideration of the dermal route only given the uncertainty associated with estimating inhalation exposures in an outdoor setting. The inhalation exposure from the use of products outdoors is generally expected to be lower than from indoor use. However, there is uncertainty whether the proposed concentration limits for the specified exterior use-only products are sufficiently protective of health effects via the inhalation route. Additional information on outdoor air concentrations of butanone oxime during the use of exterior use-only products for various sized projects would help reduce this uncertainty. The potential use of exterior use-only products indoors containing butanone oxime at concentrations above the proposed limits for indoor and dual-use products would not be protective of health effects via the inhalation route.

Exposures were estimated for product categories which had previously been quantitatively characterized in the 2010 screening assessment (Canada 2010a), as well as for additional similar products available to consumers containing butanone oxime. Additional refinements to the exposure scenarios were applied when possible based on available information and where appropriate. More details about the exposure scenarios and refinements are in appendix A.

Proposed concentration limits for the products of concern are listed in Table 1.

Table 1. Proposed concentration limits for the identified products of concern

Product type	**Proposed concentration limit (% w/w)**
Interior or dual-use non-spray paints, coatings, stains and finishes (including primers, varnish and polyurethane)	0.0032
Exterior non-spray paints, coatings, stains, and finishes (including primers, varnish and polyurethane)	0.18
Interior or dual-use spray paints and coatings	0.048
Exterior spray paints and coatings	0.55
Interior or dual-use gasketing adhesives and silicone sealants	0.20
Exterior silicone sealants	0.42

7. Proposed regulatory approach

As per the Cabinet Directive on Regulation, the Government of Canada considered both regulatory and non-regulatory actions to meet the proposed human health and risk management objectives for butanone oxime. Given the limited progress towards achieving the objective of the Code (Health Canada 2014), the Government is now proposing to pursue a regulatory approach to achieve the updated human health and risk management objectives.

Should a regulatory approach be selected, the Government may propose to develop regulations under the act that is best placed to manage the risks of general population exposure to butanone oxime. The proposed regulatory approach may include restricting the concentrations of butanone oxime in the products of concern that are available to consumers, namely paints and coatings; stains and finishes; and adhesives and sealants. The proposed concentration limits

of butanone oxime listed in Table 1 would be taken into consideration in the development of a proposed regulatory approach. This may include restrictions on the manufacture, import, sale or offer for sale of these products available to consumers. Additionally, a regulatory approach may include labelling provisions for exterior-use only paints, coatings, stains, finishes, and sealants containing butanone oxime to indicate that they are not for interior use. Following the publication of this consultation document, additional information obtained from the public comment period and from other sources, along with the information presented in this document, will be considered in the new risk management instrument development process.

Following analysis of comments submitted to the contact information found in "section 10. Next steps", work toward the development of the new risk management instrument will begin. This work will include additional opportunities for consultation.

8. Considerations

Domestic context

Existing risk management for butanone oxime in Canada related to its presence in certain types of consumer products includes the following:

The *Volatile Organic Compound (VOC) Concentration Limits for Certain Products Regulations* were published in the *Canada Gazette*, Part II, on January 5, 2022 under CEPA 1999 and apply to Canadian manufacturers and importers. They establish total VOC concentration limits for approximately 130 product categories and subcategories, including certain adhesives and sealants.

The *Volatile Organic Compound (VOC) Concentration Limits for Architectural Coatings Regulations* were published in the *Canada Gazette,* Part II, on September 9, 2009 and came into force on September 9, 2009. These regulations prevent manufacturers, importers and sellers of architectural coatings, and users of traffic marking coatings from selling and offering for sale products exceeding set VOC concentration limits.

Each of these regulations establishes a limit for the concentration of total VOCs in a certain product, but does not include a specific limit for a single VOC, such as butanone oxime. The objective of these VOC regulations is to protect the environment and health of Canadians from the effects of air pollution by reducing

VOC emissions. The concentration limits for total VOCs in both of these regulations are higher than those proposed in this consultation document and therefore are not protective for the human health effects of concern for butanone oxime.

Benefits of a regulatory approach

Should a regulatory approach be selected, it is expected to reduce health risks associated with exposure to butanone oxime by managing products available to consumers. The potential risks to human health from exposure to butanone oxime include carcinogenicity, adverse effects on organs, and adverse effects on nose tissue (Health Canada 2020a). Where possible, based on data availability, such impacts would be assessed and valued in a Regulatory Impact Analysis Statement (RIAS) as part of a proposed regulatory approach.

Impacts on potential regulatees

If a regulation is selected as the most appropriate risk management instrument, impacts on potential regulatees will be taken into account during the development of the proposed regulation for butanone oxime. As of December 2020 there were 255 manufacturers and importers that would be subject to new risk management actions (218 in paints and coatings, and 37 in adhesives and sealants), employing approximately 6,716 employees in 2020 (Statistics Canada 2020). Industry may face challenges in reducing concentrations of butanone oxime in products, or reformulating to products that do not contain butanone oxime.

Paint and coating industry representatives have indicated that at low concentrations, butanone oxime may not be able to serve its purpose as an anti-skinning agent in paint products and have noted challenges in finding alternative substances to replace butanone oxime as an anti-skinning agent in paints and coatings (Health Canada 2020). These challenges include chemical incompatibility, the technical challenges of converting to waterborne paints and the fact that alternatives may not be ‘drop-in’, or one-to-one replacements for butanone oxime. These challenges also include difficulties determining whether one substance will be safer than another when used in paint products. As a result of these challenges, new risk management of products with butanone oxime concentrations could result in certain products being permanently removed from the market. Additionally, moving to alternatives may result in increased costs to consumers.

The potentially affected regulatees could experience a loss of revenue during the transition period, and incur costs linked to a proposed regulatory approach. Where possible, based on data availability, such impacts would be assessed in a RIAS as part of a proposed regulatory approach.

International context

Existing international actions for butanone oxime relate to its carcinogenic potential and current limits on VOC levels in consumer products. They include:

- The European Commission classified butanone oxime as category 1B for carcinogenicity (Presumed human carcinogen, largely based on well performed animal studies) (European Commission 2020)
- According to the generic entry 28 in Annex XVII of the REACH Regulation substances (or the substance in a mixture) with a harmonized classification as Carc. 1B are subject to a restriction preventing them from being placed on the market for the general public at concentrations ≥ 0.1% (European Commission 2006, European Commission 2008)
- In the European Union (EU), butanone oxime is prohibited from any use in cosmetics (European Commission 2009)
- In the United States (U.S.), butanone oxime is listed on the U.S. Environmental Protection Agency (EPA) National Volatile Organic Compound Emission Standards for Consumer and Commercial Products - This action promulgates national VOC emission standards for certain categories of consumer products pursuant to section 183(e) of the *Clean Air Act* (US EPA 2008)

9. Request for Information

The Departments are requesting information on the following areas that would support the development of new risk management actions for butanone oxime:

- current concentrations of butanone oxime in paints, coatings, stains, finishes, adhesives and sealants, available to consumers in Canada
- source of paints, coatings, stains, finishes, adhesives and sealants containing butanone oxime, available to consumers in Canada (for example, imported versus domestically manufactured)
- function of butanone oxime in adhesives and sealants available to consumers in Canada

- alternatives to butanone oxime in products of concern; challenges and transition costs of switching to these alternatives
- costs to Canadian manufacturers, importers and retailers of these product types, to achieve the proposed regulatory concentration limits in section 6

10. Next steps

Your comments on this consultation document and information requested above are solicited by October 13, 2022. Comments and information submissions on this consultation document should be submitted either by e-mail, or mail to the following address:

Andrew Beck
Director, Risk Management Bureau
Health Canada
Mail stop PL 4905B
Ottawa, Ontario K1A 0K9
Email: chemicalsubstanceschimiques@hc-sc.gc.ca

Please include: "Consultation Document on Proposed New Risk Management Actions for Butanone Oxime" in the subject line of your message.

The Government of Canada is committed to providing interested and affected parties with the opportunity to take part in consultations at all stages of the new risk management development. All comments submitted will be taken into consideration while developing new risk management. Following analysis of comments received, work toward the development of a new risk management instrument will begin. This work will include additional opportunities for consultation on the proposed instrument(s).

While new risk management for butanone oxime is being developed, stakeholders are encouraged to work toward adopting the recommended practices in the Code and any other strategies to reduce exposure of the public to butanone oxime. Canadians can further protect themselves by wearing gloves and ensuring well-ventilated conditions during and immediately following the use of paints and coatings; stains and finishes; adhesives and sealants, containing butanone oxime.

Confidential business information

A person who provides information to the Minister of Health must submit a written request identifying the specific information to be treated as confidential business information as well as a rationale for the request. If the Minister considers that the information does not meet the definition of confidential business information, a written notice will be given to this effect to the person who had provided the information to the Minister.

The Minister of Health will use and disclose confidential business information in respect of which a request for confidentiality has been made as permitted by law. For greater certainty, personal information as defined in section 3 of the *Privacy Act* will be used and disclosed in accordance with that Act.

"Confidential business information," with respect to a person to whose business or affairs the information relates, means business information:

(a) That is not publicly available;

(b) In respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available; and

(c) That has actual or potential economic value to the person or their competitors because it is not publicly available and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors.

11. References

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Appendix A. Exposure scenarios and refinements

Input parameters and assumptions for exposure scenarios that were used in the derivation of concentration limits and previously characterized in the 2010 screening assessment (that is, for interior and dual-use alkyd products: coating, high solid paint, solvent-rich paint, aerosol paint; interior and dual-use gasketing adhesive and silicone sealant) are found in appendix 1 of that report (Canada 2010a). However, it should be noted that updated ConsExpo Web 2020 defaults (for example, mass transfer co-efficient) were used for derivation of concentration limits where applicable. The exposure scenarios for the additional, similar products available to consumers containing butanone oxime are described below. Scenario input parameters and assumptions are based on recommended defaults from the ConsExpo Paint Products Fact Sheet (Bremmer and van Engelen 2007) and the ConsExpo Do-It-Yourself Products Fact Sheet (ter Burg et al. 2007) unless noted otherwise. Although there are different exposure scenarios for different types of paints, coatings and finishes (for example, non-spray alkyd coatings, high solid paints, solvent rich paints, stains, varnishes, polyurethane), one concentration limit is proposed given the similarity between these products and their derived concentration limits. For the same reason, one concentration limit is proposed for interior or dual-use gasketing adhesives and silicone sealants.

ConsExpo Web (2020) was used to characterize inhalation exposures. The critical effect level for the inhalation route (107 mg/m^3) was derived from a toxicological study in which animals were exposed on an intermittent basis (6/24 hours per day, 5/7 days a week for 1 week) (Canada 2010a). To address the differences in exposure duration between the critical effects study and the actual use pattern of the products available to consumers containing butanone oxime, both the critical effect level and the exposure concentrations were adjusted to more accurately characterize potential risk. The critical effect level was adjusted to a daily exposure (107 mg/m^3 x 5/7 = 76.4 mg/m^3) and inhalation exposure concentrations were converted to 6-hour time-weighted average concentrations (TWAs), where TWA = mean event concentration × hours of exposure per day in the exposure scenario / hours of exposure per day in the toxicological study. The term “day” is defined as those days in which the test item was administered (that is, on the day of exposure).

Dermal exposures were characterized using the relevant algorithms in ConsExpo Web (2020) for estimating exposure from use of paints, coatings and joint sealants.

Table A-1. Parameters used in estimating exposure to butanone oxime from use of additional, similar products available to consumers

Exposure scenario	Model parameters and assumptions
Interior or dual use stains and finishes (including varnish and polyurethane) (scenario assumes application using a brush and/or roller on a floor in a small room)	For inhalation exposure: Model: Exposure to vapour – evaporation Frequency: 1/year (professional judgement) Exposure duration: 165.5 min (Westat 1987) Molecular weight matrix: 3000 g/mol Product amount: 956 g (Westat 1987) Room volume: 20 m^3 Ventilation rate: 0.6 changes per hour Release area mode: Increasing Release area: 8.2 m^2 (professional judgement, area of the floor = 20 m^3 ÷ 2.4 m walls) Application duration: 117 min (Westat 1987)
Exterior paints, coatings, stains and finishes (including primers, varnish and polyurethane) (scenario assumes application on a deck using a brush and/or roller)	For dermal exposure: Contact rate: 30 mg/min Release duration: 240 min (professional judgement, based on increased surface area in comparison to ConsExpo solvent rich and high solid paint scenarios) Body weight: 70.9 kg (Health Canada 1998)
Exterior spray paints and coatings (scenario assumes application of 2 coats on 1 side of a standard-size front door)	For dermal exposure: Contact rate: 100 mg/min Release duration: 23 min (based on the ratio of application duration to surface area in the ConsExpo spray paint scenario) Body weight: 70.9 kg (Health Canada 1998)
Exterior silicone sealants (scenario assumes application to exterior of residential windows)	For dermal exposure: Contact rate: 50 mg/min Release duration: 60 min (US EPA 2019, 2020) Body weight: 70.9 kg (Health Canada 1998)