



Government
of Canada

Gouvernement
du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

2-Butanone, oxime

(butanone oxime)

Chemical Abstracts Service Registry Number (CAS RN):
96-29-7

Environment Canada
Health Canada

March 2010

Canada

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This proposed risk management approach document builds on the previously released risk management scope document for butanone oxime, and outlines the proposed control actions for this substance. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

SUMMARY OF RISK MANAGEMENT

1. Restrict the concentration of butanone oxime in indoor alkyd paints available to consumers.
2. Add butanone oxime to the *Environmental Emergency Regulations*.

Note: This summary is an abridged list of the instruments and tools proposed to risk manage this substance. Please see section 9.1 of this document for a complete explanation of the proposed risk management.

1. ISSUE

1.1 Categorization and the Challenge to Industry and Other Interested Stakeholders

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (the Ministers) to categorize substances on the *Domestic Substances List* (DSL). Categorization involves identifying those substances on the DSL that, in accordance with the criteria at section 73 of the Act, a) are considered to be persistent (P) and bioaccumulative (B), based on the criteria set out in the *Persistence and Bioaccumulation Regulations*, and “inherently toxic” (iT) to humans or other organisms; or b) may present, to individuals in Canada, the greatest potential for exposure (GPE). In addition, the Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria. The assessment further determines whether the substance meets one or more of the criteria of section 64 of the Act.¹

In December 2006, the Challenge identified 193 chemical substances through categorization which became high priorities for assessment due to their hazardous properties and their potential

¹ 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 the use of consumer products. A conclusion under CEPA 1999 is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Controlled Products Regulations*, which is part of the regulatory framework for the Workplace Hazardous Materials Information System [WHMIS] for products intended for workplace use.

to pose risks to human health and the environment. In February 2007, the Ministers began publishing, for industry and stakeholder comments, profiles of batches containing 12 to 19 high-priority substances. New batches are released for comments every three months.

Information-gathering authority in section 71 of CEPA 1999 is being used under the Challenge to gather specific information where it is required. The information that is collected through the Challenge is used to make informed decisions and appropriately manage any risks that may be associated with these substances.

The substance 2-Butanone oxime, Chemical Abstracts Service Registry Number (CAS RN)² 96-29-7, referred to throughout this document as “butanone oxime,” is included in Batch 7 of the Challenge under the Chemicals Management Plan.

1.2 Final Screening Assessment Report Conclusion for Butanone Oxime

A notice summarizing the scientific considerations of a final screening assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for butanone oxime on March 6, 2010, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that butanone oxime is entering or may be entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

On the basis of the potential inadequacy of the margins between estimated exposures to butanone oxime and critical effect levels, it is concluded that butanone oxime is a substance that may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

It is therefore concluded that butanone oxime does not meet the criteria in paragraphs 64(a) and 64(b) of CEPA 1999, but it does meet the criterion in paragraph 64(c) of CEPA 1999.

The final screening assessment report also concluded that butanone oxime meets the criteria for persistence, but does not meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of butanone oxime in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for butanone oxime, refer to the final screening assessment report, available at <http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-7/index-eng.php>.

² 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.

1.3 Proposed Measure

As a result of a screening assessment of a substance under section 74 of CEPA 1999, the substance may be found to meet one or more of the criteria under section 64 of CEPA 1999. The Ministers can propose to take no further action with respect to the substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substance to the Schedule 1 of the Act. Under certain circumstances, the Ministers must make a specific proposal to recommend the implementation of virtual elimination. In this case, the Ministers proposed to recommend the addition of butanone oxime to Schedule 1. As a result, the Ministers will develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.

Butanone oxime is not subject to the virtual elimination provisions under CEPA 1999 and will be managed using a life-cycle approach.

2. BACKGROUND

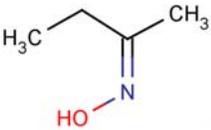
2.1 Substance Information

Butanone oxime is part of the chemical grouping discrete organics and the chemical sub-grouping oximes, or more specifically, ketoximes.

Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure and the molecular mass for butanone oxime.

Table 1. Identity of butanone oxime

CAS RN	96-29-7
DSL name	2-Butanone, oxime
NCI names	Butanone oxime (EINECS, PICCS) 2-Butanone, oxime (AICS, ASIA-PAC, PICCS, SWISS, TSCA) Butan-2-one oxime (ENCS, PICCS) 2-Butanonoxime (PICCS) Methyl ethyl ketone oxime (PICCS) Methyl ethyl ketoxime (PICCS) Oxime 2-butanone (ECL)
Other names	Aron M 1, 2-Butoxime, Ethyl methyl ketone oxime, Ethyl methyl ketoxime, Exkin 2, Exkin II, Hiaron M 1, MEK-oxime, MEKO, Mekor 70, NSC 442, NSC 65465, Troykyd AntiSkin B
Chemical group (DSL stream)	Discrete organics

Major chemical class or use	Oximes
Major chemical subclass	Ketoximes (short-chain)
Chemical formula	C ₄ H ₉ NO
Chemical structure	
SMILES	N(O)=C(CC)C
Molecular mass	87.12 g/mol

Abbreviations: AICS, Australian Inventory of Chemical Substances; ASIA-PAC, Asia-Pacific Substances Lists; CAS RN, Chemical Abstracts Service Registry Number; DSL, Domestic Substances List; ECL, Korean Existing Chemicals List; EINECS, European Inventory of Existing Commercial Chemical Substances; ENCS, Japanese Existing and New Chemical Substances; NCI, National Chemical Inventories; PICCS, Philippine Inventory of Chemicals and Chemical Substances; SMILES simplified molecular input line entry specification; SWISS, Swiss Giftlist 1 and Inventory of Notified New Substances; and TSCA, Toxic Substances Control Act Chemical Substance Inventory).
Source: NCI 2006

3. WHY WE NEED ACTION

3.1 Characterization of Risk

Evaluation of risk to human health involves consideration of data relevant to estimation of exposure (non-occupational) of the general population, as well as information on health hazards.

Carcinogenicity was considered in the health effects assessment for butanone oxime, as the substance had been classified as carcinogenic by the European Commission. As discussed under the Health Effects Assessment section of the final screening assessment report, increased incidences of liver tumours were observed in rat and mouse lifetime studies, and there was also an increased incidence of mammary gland tumours in female rats. However, these were seen only at mid and/or high concentrations of butanone oxime. Consideration of the available information on genotoxicity indicates that butanone oxime is not likely to be genotoxic. Accordingly, although the mode of induction of tumours is not fully elucidated, the tumours observed are not considered to have resulted from direct interaction with genetic material. Therefore, a threshold approach is used to assess risk to human health (Canada 2010).

With respect to non-cancer effects, the lowest-observed-adverse-effect concentration (LOAEC) for chronic inhalation exposures was 53 mg/m³, based on degeneration of the olfactory epithelium in the nasal cavities of both mice and rats, liver cell hypertrophy and necrosis in mice, and histopathological effects in the spleen of rats observed in lifetime studies with these species. For subchronic exposures, the lowest inhalation LOAEC was 36 mg/m³, based on degeneration of the olfactory epithelium in the nasal cavity of mice observed in a 13-week inhalation study. Likewise, for short-term exposures, the lowest inhalation LOAEC was 107 mg/m³, based on degeneration of the olfactory epithelium of the nasal cavity of mice exposed to a butanone oxime exposure regime of 6 hours/day, 5 days/week, for 1, 2 or 4 weeks. The occurrence of toxicological sequelae following 5 exposures (30 total hours of exposure) is relevant for the acute exposure risk assessment. For acute exposures, an inhalation LOAEC of 190 mg/m³ was determined based on decreased body weight gain in rats in a 4-hour inhalation study. The changes in body weight gain were not noted at critical effect levels in short-term inhalation

studies. However, an analysis of the change in the dose-response curve over time (190 mg/m³ acutely, 107 mg/m³ after 5 days and 36 mg/m³ after subchronic exposure) suggests that the body weight gain deficits occur in the appropriate dose range following acute exposure (Canada 2010).

The lowest oral LOAEL for short-term and subchronic exposures was 10 mg butanone oxime/kg-bw per day, based on histopathological effects in the spleen and liver of adult rats observed in both a one-generation and a two-generation reproduction study (and in the kidney in the one-generation study) and based on signs of anemia in adult female rabbits observed in a range-finding developmental study (Springborn Laboratories 1990; Derelanko et al. 2003). For acute exposures, an oral lowest-observed-effect level (LOEL) of 300 mg/kg-bw was determined based on transient neurotoxic effects in rats, and a dermal LOAEL of 180 mg/kg-bw was determined based on methemoglobin production and splenic erythrophagocytosis in a 24-hour rabbit study (Canada 2010).

Due to the lack of empirical data on concentrations in several media, estimates of daily intake for the general population were not derived. Thus, margins of exposure could not be derived for comparisons between critical effect levels based on repeated daily exposures to butanone oxime and upper-bounding estimates of daily intake (Canada 2010).

Exposure to butanone oxime is most likely to occur through use of consumer products. Based on product scenario modelling using ConsExpo (2007), the highest consumer product exposure estimate was from inhalation during use of alkyd paints and coatings, resulting in a range of 73–223 mg/m³. Using the Wall Paint Exposure Assessment Model (WPEM 2001), an 8-hour average exposure estimate of 195 mg/m³ was derived for alkyd paints. Comparison of these conservative estimates with the acute to short-term critical effect levels for inhalation exposure (107–190 mg/m³) results in margins of exposure of 0.5–2.6 (Canada 2010).

Acute dermal exposures during use of alkyd paints and coatings were estimated to be 0.01–0.15 mg/kg-bw. As these estimates were based on an absorption factor of 29%, the same absorption factor was applied to the acute dermal critical effect level of 180 mg/kg-bw (as this was based on external application to rabbits), which results in 52 mg/kg-bw. Thus, comparison of these conservative estimates with the adjusted acute critical effect level for dermal exposure results in margins of exposure of about 350–5200 (Canada 2010).

In light of the uncertainties in the databases on exposure and effects, it is considered that estimated margins of exposure for these consumer product scenarios (all estimated margins of exposure based on inhalation exposure, and the margins of exposure based on dermal exposure) may not be adequately protective of human health for non-cancer effects (Canada 2010).

4. CURRENT USES AND INDUSTRIAL SECTORS

The most prevalent use of butanone oxime is as an anti-skinning agent in the formulation of alkyd paints, primers, varnishes and stains. It acts to prevent oxidative drying and formation of hard, gelatinous films on the surface of the paint product in the container. Canadians will most

likely be exposed to butanone oxime through the use of such products in and around their household.

To a lesser extent, the substance has also been reported in Canada in a number of pesticide products, namely wood preservatives and antifouling marine paints, as well as in some adhesives, silicone sealants and printing inks. Furthermore, butanone oxime is used as a corrosion inhibitor in industrial boilers and industrial water treatment systems, and serves as a blocking agent in the manufacturing process of urethane polymers. There is no significant exposure to butanone oxime via these uses for the general Canadian population. Additionally, human exposure through any quantity released to the environment from the waste sector has not been identified and is not expected.

According to the information submitted under section 71 of CEPA 1999, butanone oxime was not manufactured by any company in Canada at quantities greater than or equal to 100 kg in the 2006 calendar year. According to the information submitted under section 71 of CEPA 1999, approximately 500 000 kg of the substance were imported into Canada in 2006 and approximately 120 000 kg of the substance were used in Canada the same year.

Butanone oxime is an anthropogenic substance and is considered to be a high production volume (HPV) chemical by the Organisation for Economic Co-operation and Development (OECD) (OECD 2004), the U.S. Environmental Protection Agency (US EPA 2006), and the European Commission (ESIS 2006).

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

According to the information submitted under section 71 of CEPA 1999, butanone oxime was not manufactured by any company in Canada in 2006. In addition, there were no reports of any significant industrial releases of butanone oxime in the same calendar year in the section 71 responses (Environment Canada 2009). The Canadian Chemical Producers' Association (CCPA 2009) reported the release of 356 kg of butanone oxime to the environment in 2007. The reporting of industrial releases of butanone oxime to the National Pollutant Release Inventory (NPRI 2007) is not required. The total industrial releases of butanone oxime are expected to be low, and the most significant releases of butanone oxime are expected to take place at the consumer use stage (Canada 2010).

5.2 Exposure Sources

Butanone oxime is an anthropogenic substance. Based on its high vapour pressure and half-life in air, butanone oxime is expected to exist primarily as a vapour and to persist in ambient air. However, as no significant industrial releases of butanone oxime to the air were reported in 2006, the concentration of butanone oxime in ambient air is expected to be low. Modelled

estimates based on current information also predict that the concentration of butanone oxime in environmental media (air, water and soil) is low (Canada 2010).

No measured concentrations of butanone oxime in food in Canada or elsewhere were identified. Based on the uses of butanone oxime in Canada, food is unlikely to be a source of exposure (Canada 2010).

With regard to consumer products, butanone oxime is most prevalent in alkyd paints, stains, varnishes and coatings, according to information submitted under section 71 of CEPA 1999. The most likely source of exposure of concern is from the use of alkyd paint products containing butanone oxime (Canada 2010). Butanone oxime is also present in a few sealants, adhesives and fillers that are used mainly by industry, but which may also be available to the general population for home maintenance and do-it-yourself applications (Canada 2010).

Based on the available information, the most likely route of exposure to butanone oxime for the general population is likely from inhalation of indoor air immediately following the application of consumer products containing the substance. Butanone oxime is a volatile compound, and thus is not expected to remain in or on the objects onto which the products containing the substance were applied.

As the maximum concentration of butanone oxime reported in a recent United States consumer exposure study of alkyd paints was lower than the concentration resulting from the use of alkyd paints containing butanone oxime in Canada, exposure was estimated using modelling (Canada 2010).

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

Butanone oxime is subject to the *Pest Control Products Act*. It is categorized as a List 2 Formulant on the Pest Management Regulatory Agency (PMRA) List of Formulants, which was published on June 28, 2007. A List 2 designation elevates the priority for reassessment within the PMRA (Canada 2007).

6.2 Existing International Risk Management

All import, manufacture and/or use of butanone oxime must be reported under the U.S. EPA, Part 799, Identification of Specific Chemical Substances and Mixture Testing Requirements, January 2008 (USA 2008).

The use of butanone oxime in cosmetic products is prohibited by Directive 76/768/EEC of the European Commission, September 2004 (European Commission 2004), and the *Cosmetic Products (Safety) Regulations 2008* in the United Kingdom (UK 2008).

In order to meet the ecological criteria for the award of the European Union Ecolabel to indoor paints and varnishes, based on the Commission Decision of 13.8.2008, butanone oxime in alkyd paints must not exceed a limit of 0.3% (European Commission 2008).

Under the Environmental Risk Management Authority (ERMA) New Zealand, butanone oxime is considered a hazardous substance and is subject to the following controls: Classes 1 to 5 Controls, Classes 6, 8, and 9 Controls, Packaging, Disposal, Personnel Qualifications, Emergency Management, Tracking, Identification, Tank Wagon and Transportable Containers (New Zealand 2004).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

The Danish Environmental Protection Agency undertook a project to investigate the possibilities for substituting butanone oxime in air-drying coatings (Denmark 2003). The research concludes that although further work is required, success in substituting butanone oxime seems rather limited. Acetone oxime, though promising as an alternative, has a dubious health profile. Vitamin E needs to be investigated further, since it presents the best health profile of all the investigated compounds. Amino/amido compounds use might be limited due to their genotoxic potential (Denmark 2003).

7.2 Alternative Technologies and/or Techniques

No information on alternative technologies was submitted, nor have any been identified.

7.3 Socio-economic Considerations

Socio-economic factors have been considered in the selection process for a regulation and/or instrument 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 regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (Treasury Board of Canada Secretariat 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

Socio-economic considerations for butanone oxime:

- The revenue of the Paint and Coating Manufacturing Industry (NAICS 325510) was approximately \$2.6 billion in 2007, with 283 establishments employing approximately 6259 employees (Statistics Canada 2009).
- In 2008, Canadian annual exports of Paint and Coating Manufacturing products decreased to \$399 million from \$433 million in 2004. During the same period, Canadian annual imports fell from \$1 billion to \$917 million (Industry Canada 2009).

7.4 Children's Exposure

The Government of Canada considered, where available, risk assessment information relevant to children's exposure to this substance. As part of the Challenge, the Government asked industry and interested stakeholders to submit any information on the substance that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked through a questionnaire if any of the products containing the substance were intended for use by children. Given the information received, it is proposed that no risk management actions to specifically protect children are required for this substance at this time.

8. PROPOSED OBJECTIVES

8.1 Human Health Objectives

A human health objective is a quantitative or qualitative statement of what should be achieved to address human health concerns identified during a risk assessment.

The proposed human health objective for butanone oxime is to minimize human exposure to the extent practicable.

8.2 Risk Management Objectives

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management regulations, instrument(s) and/or tool(s).

The proposed risk management objective for butanone oxime is to reduce exposures.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Regulations

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation*³ and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the two proposed risk management regulations were selected using a consistent approach, and took into consideration the information that was received through the Challenge and other information available at the time.

³ Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal".

In order to achieve the risk management objective and to work towards achieving the human health objective, the risk management being considered for butanone oxime is to **restrict the concentration of butanone oxime in indoor alkyd paints available to consumers.**

In addition, the federal government has assessed butanone oxime in the event that it were to enter the environment as a result of an environmental emergency and has concluded that the substance meets one of the criteria set out in section 200 of CEPA 1999. Therefore, the government intends to **propose adding butanone oxime to the *Environmental Emergency Regulations* with a proposed threshold of 6800 kg set through the Risk Evaluation Framework for sections 199 and 200 of CEPA 1999** (Environment Canada 2002).

9.2 Implementation Plan

The proposed regulation or instrument respecting preventative or control actions in relation to butanone oxime will be published in the *Canada Gazette*, Part I, no later than February 2012, as per the timelines legislated in CEPA 1999.

10. CONSULTATION APPROACH

The risk management scope document for butanone oxime, which summarized the proposed risk management under consideration at that time, was published on September 5, 2009. Industry and other interested stakeholders were invited to submit comments on the risk management scope document during a 60-day comment period. Comments received on the risk management scope document were taken into consideration in the development of this proposed risk management approach document.

Consultation for the proposed risk management approach documents will involve publication on March 6, 2010, and a 60-day public comment period.

The primary stakeholders include

- paints and coatings industry
- environmental non-governmental organizations

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed risk management approach document	March 6, 2010, to May 5, 2010
Response to comments on the proposed risk management approach document	No later than the time of publication of the proposed instrument
Consultation on the draft instrument	Fall–winter

	2010–2011
Publication of the proposed instrument	No later than March 2012
Formal public comment period on the proposed instrument	No later than spring 2012
Publication of the final instrument	No later than September 2013

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Please submit comments prior to May 5, 2010, since the risk management of butanone oxime will be moving forward after this date. During the development of regulations, instrument(s) and tool(s), there will be opportunity for consultation. Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Chemicals Management Division
Gatineau, Quebec K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 819-953-7155
Email: Existing.Substances.Existantes@ec.gc.ca

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