



Government
of Canada

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**Risk Management Scope
for
methanone, diphenyl-
(Benzophenone)**

**Chemical Abstracts Service Registry Number
119-61-9**

Environment and Climate Change Canada

Health Canada

August 2018

CanadaThe wordmark for Canada, with a small red maple leaf icon integrated into the letter 'a'.

Summary of Proposed Risk Management

This document outlines the proposed risk management options for methanone, diphenyl-, commonly known as benzophenone. In particular, the Government of Canada is considering the implementation of the following risk management actions to address human health concerns:

1. Adding benzophenone as a restricted ingredient to Health Canada's Cosmetic Ingredient Hotlist; and/or applying Significant New Activity (SNAC) provisions under CEPA to benzophenone that would require any proposed new manufacture, import or use of certain cosmetic products to be subject to further assessment and potential risk management; and
2. A measure to reduce the concentration of benzophenone to a maximum of 0.1 % (w/w) or 1000 mg/kg in paint and/or coating products that are available to a consumer in Canada.

Moreover, because certain data gaps remain, information on the following items should be provided on or before October, 02, 2018, to the contact details identified in section 8 of this document, to inform risk management decision-making:

- Current quantities and concentrations of benzophenone used in paints and coatings that are available to consumers;
- Potential alternative substances to benzophenone for use in cosmetics and in paints and coatings that are available to consumers; and
- Socio-economic and technical impacts and benefits associated with the proposed risk management for benzophenone.

The risk management options outlined in this Risk Management Scope document may evolve through consideration of assessments and risk management 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 this substance and to seek information on identified information gaps and uncertainties. Refer to section 3 of this document for more complete details in this regard.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999) provides the authority for the Minister of 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.

As part of the Chemical Management Plan (CMP), the ministers are assessing and will manage, where appropriate, the potential health and ecological risks associated with approximately 1550 substances (Canada 2016). The substance methanone, diphenyl-, Chemical Abstracts Service Registry Number (CAS RN)³ 119-61-9, referred to throughout this document as benzophenone, is included in the CMP.

2. Issue

2.1 Draft Screening Assessment Report Conclusion

Health Canada and Environment and Climate Change Canada conducted a screening assessment of benzophenone in Canada. A notice summarizing the scientific considerations of the draft screening assessment for these substances

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 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, and products available to 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.

³ CAS RN: 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.

was published in the *Canada Gazette*, Part I, on August 04, 2018 (Canada 2018).

Based on the information available, the draft screening assessment proposes that benzophenone is harmful to human health under section 64(c) of CEPA because it is 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 2018).

It is proposed that benzophenone 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 sections 64(a) or (b) of CEPA, respectively (Canada 2018).

The exposure sources of concern identified in the draft screening assessment are dermal exposures to benzophenone from the use scenarios of nail polish and interior paint (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 on the draft screening assessment for benzophenone, refer to [benzophenone dSAR](#).

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 benzophenone be added to the List of Toxic Substances in Schedule 1 of the Act⁴.

The ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment report and Risk Management Scope document in the preparation of the final screening assessment report and, if required, the Risk Management Approach document. If benzophenone 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 recommend the addition of benzophenone to Schedule 1 to CEPA, risk management instrument(s) will be proposed within 24 months from the date on which the final screening assessment is published, and finalized within 18 months from the date on which the risk management instrument(s) are proposed.

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 substance, 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. 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.

The proposed human health objective for benzophenone is to reduce exposure of the general population to benzophenone to levels that are protective of human health.

3.2 Proposed Risk Management Objective and Options under Consideration

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulation(s), instrument(s) and/or tool(s) for a given substance or substances.

In this case, the proposed risk management objectives for benzophenone are to reduce dermal exposure to the sources of greatest concern, specifically cosmetic products containing benzophenone, as well as paint and coating products containing benzophenone that are available to consumers.

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

- **Cosmetics:**
 - 1) To add benzophenone as a restricted ingredient to Health Canada's Cosmetic Ingredient Hotlist, which is an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances may contravene the general prohibition found in section 16 of the *Food and Drugs Act* (F&DA), or may contravene one or more provisions of the *Cosmetic Regulations*. Section 16 of the F&DA states that "*No person shall sell any cosmetic that has in or on it any substance that may cause injury to the health of the user*". In addition, the Cosmetic Ingredient Hotlist includes certain substances that may make it unlikely for a product to be classified as a cosmetic under the F&DA. Compliance with the provisions of section 16 are monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations* of the F&DA, which requires that all

manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada; and/or

- 2) To apply Significant New Activity (SNAc) provisions under CEPA to benzophenone that would require any proposed new manufacture, import or use of certain cosmetic products be subject to further assessment and potential risk management;
- **Paints and Coatings:** To implement a measure to reduce the concentration of benzophenone to a maximum of 0.1 % (w/w) or 1000 mg/kg in paint and/or coating products that are available to a consumer in Canada. The selected measure would improve the protection of human health by facilitating a reduction in dermal exposure of the general public to benzophenone during application of consumer paint and coating products that contain benzophenone. This can be done through voluntary actions by industry such as a guideline or code of practice, or through regulatory actions under CEPA. The concentration threshold will be confirmed following further analysis on levels of benzophenone in these products.

Following the publication of this Risk Management 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(s) selection and development process⁵. 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.

3.3 Risk Management Information Gaps

In order to make informed decisions on the proposed risk management, interested stakeholders are invited to provide further information on the following:

1. Current quantities (kilograms) and concentrations (percent weight per weight) of benzophenone used in paints and coatings that are available to consumers;
2. Potential alternative substances to benzophenone for the use in cosmetics and in paints and coatings that are available to consumers ;
and
3. Socio-economic and technical impacts and benefits associated with the proposed risk management for benzophenone.

⁵ 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).

Should stakeholders have further information to help address these gaps, they are encouraged to provide it on or before October 02, 2018 to the contact identified in section 8 of this document. Such information can help inform the risk management decision-making process.

4. Background

4.1 General Information on Benzophenone

Benzophenone is an organic substance (aromatic ketone) which occurs naturally in the environment and is also synthetically manufactured (Canada 2018). It was evaluated by Health Canada and Environment and Climate Change Canada as part of the CMP.

4.2 Current Uses and Identified Sectors

Responses to a 2008 survey conducted under section 71 of CEPA indicated that between 0 to 200 kg of benzophenone were manufactured in Canada, and 35 000 to 135 000 kg of benzophenone were imported into Canada (Canada 2009).

According to notifications submitted under the *Cosmetic Regulations* to Health Canada, benzophenone is present in certain cosmetic products such as nail polishes, fragrances, makeup and hair products. Benzophenone has been identified as a component in some printing inks used in a limited number of food packaging materials that have no direct contact with food. Benzophenone may also be used as a food flavouring agent. Benzophenone is listed in the Natural Health Products Ingredients Database (NHPID) with a non-medicinal role for oral use as flavour enhancer only, as well as with a tolerable daily intake of 0.03 mg/kg bw/day consistent with the European Food Safety Authority (EFSA 2009, 2017). Although benzophenone is currently listed in the Licensed Natural Health Products Database (LNHPD) as being present in a limited number of currently licensed natural health products (NHPs); based on communications with the associated licence holders, it is rather benzophenone derivatives (i.e., benzophenone-1, benzophenone-2, or benzophenone-3) that are present in these products (LNHPD 2016; NHPID 2016). Benzophenone is permitted and used as a formulant in pest control products (Canada 2018). Non-confidential uses for benzophenone reported in the 2008 survey include its function as an additive in paints and coatings, as a fragrance ingredient, as a photosensitive substance in inks, as a toner and colourant, as a laboratory substance for medical devices, as an industrial photoinitiator, and in adhesives and sealants (Canada 2009). Based on publically-available safety data sheets, benzophenone

may also be present in stains for decks, deck crack fillers and auto-related cleaning products available to the general population of Canada (Canada 2018).

In the United States (US), the national production volume of benzophenone in 2012 was approximately 1.75 million kilograms (3.87 million pounds) (CDAT [modified 2014]). Benzophenone is also listed on the 2007 Organisation for Economic Co-operation and Development List of High Production Volume Chemicals, where it was produced or imported at levels greater than 1 million kilograms (1 000 tonnes) per year in at least one member country of the European Union (OECD, 2009). Globally, benzophenone has reported uses as an intermediate in chemical manufacturing, as an industrial photoinitiator, as an ultraviolet (UV) light absorber, as a component in certain plastics (including baby bottles and food packaging materials), as a food flavouring agent, as a fragrance and perfume fixative, as well as an additive or formulating agent in pesticides, agricultural chemicals, pharmaceuticals and cleaning products (Canada 2018).

5. Exposure Source and Identified Risk

General population exposure to benzophenone may occur from environmental media, including food. Products available to consumers, including cosmetics, and paints and coatings, are also sources of general population exposure in Canada.

According to the draft screening assessment of benzophenone, the exposure sources of concern were dermal exposure to benzophenone from the use scenarios of nail polish and interior paint (Canada 2018). Dermal exposures were estimated to be 0.043–0.085 mg/kg bw/event from the use of nail polish containing 5 % benzophenone and 0.067 mg/kg bw/event from the use of interior paint containing 0.3 % benzophenone.

Benzophenone has been reviewed by the International Agency for Research on Cancer (IARC, 2013) and EFSA (2009, 2017). These reviews provide a basis for the health effects characterization in the draft screening assessment. Based on the available information, a derived benchmark dose for a 10 % effect (BMDL₁₀) of 3.1 mg/kg bw/day for non-cancer kidney effects and of 19 mg/kg bw/day for kidney cancer derived by EFSA (2009) from the chronic oral carcinogenicity study in rats were selected as the most appropriate points of departure to characterize risks from chronic daily dermal exposure (Canada 2018). To characterize risk of benzophenone associated with short-term dermal exposure, the no-observed-adverse-effect level (NOAEL) of 5 mg/kg bw/day for maternal health effects associated with early termination of pregnancy and reductions in maternal body weight from the oral developmental toxicity study was used for adults, and the NOAEL of 20 mg/kg bw/day for non-cancer kidney and liver

effects from a 28-day oral toxicity study was used for children and teens in light of the absence of short-term toxicity investigations. A dermal absorption value of 44 % for benzophenone, determined in monkeys under unoccluded conditions, was applied to the dermal estimates for route to route extrapolation from the dermal to oral route (Canada 2018).

Margins of exposure comparing effect levels observed in laboratory animals and estimates of dermal exposure from the use scenarios of nail polish and interior paint are considered as potentially inadequate to address uncertainties in the health effects and exposure databases for benzophenone (Canada 2018).

The calculated margins of exposure for all other scenarios assessed, including from environmental media, food, plastic uses and from other products available to consumers, were considered adequate to address uncertainties in the health effects and exposure databases (Canada 2018). Therefore, risk management for these scenarios is not being proposed at this time.

6. Risk Management Considerations

6.1 Alternatives

Alternative cosmetic products are available that do not use benzophenone. For products that use benzophenone as a UV absorber (i.e. to protect formulations from UV damage), substances are available with a similar function to protect against UVA and UVB damage.

The paint, coating and solvent industry adopts two stabilization methods to protect products from light damage. The first method is using competitive UV absorbers, such as benzophenone, in the wavelength range 290-350 nm and the second method is using radical scavengers to trap radicals formed during polymer degradation (Freitag and Stoye, 2008). There are substances with similar functions to benzophenone that may be used to protect products from light damage; however, their feasibility as alternatives is currently unknown.

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

Food and Drugs Act (F&DA)

Food: The safety of chemicals used in food packaging materials is subject to the provisions of section 4(1)(a) of the F&DA and Division 23 of the *Food and Drug Regulations*. Any food packaging assessments of benzophenone as a component in some printing inks used in a limited number of materials to package food have determined that risk from potential dietary exposure to benzophenone from those uses is not of concern. Benzophenone is not currently included on Health Canada's lists of permitted food additives; therefore, it is not an approved food additive in foods sold in Canada.

Cosmetics: Benzophenone is present in cosmetics based on notifications submitted under the *Cosmetic Regulations*; it is not currently included on Health Canada's Cosmetic Ingredient Hotlist.

Natural Health Products: NHPs are regulated under the *Natural Health Products Regulations*. Oral use of benzophenone as a non-medicinal ingredient for the purpose of flavour enhancer in NHPs is permitted in Canada, with a tolerable daily intake of up to 0.03 mg/kg bw/day. Benzophenone, as opposed to some of its derivatives, is not listed as a medicinal ingredient in the Health Canada's Sunscreen Monograph (Canada 2013).

Medical Devices: Any potential use of benzophenone as a component of medical devices is subject to biocompatibility testing as part of the assessment of device safety and effectiveness as per the *Medical Devices Regulations* of the F&DA (Canada 2018).

Pest Control Products Act (PCPA)

The currently registered uses of benzophenone as a formulant in pest control products are regulated under the *Pest Control Products Act*.

7.2 Pertinent International Risk Management Context

7.2.1 United States

Federal Food, Drug and Cosmetic Act (FD&C Act)

Food: Benzophenone is listed as a food additive permitted for direct addition to food for human consumption as a synthetic flavoring substance and adjuvant (as specified in 21CFR 172.515; United States Food and Drug Administration [US FDA]). However, it is currently one of the seven substances included in a food additive petition submitted to the US FDA in 2015, proposing that regulations be amended to no longer authorize its use as a synthetic flavoring food additive based on the petition's assertion that data establish that these substances are carcinogenic (United States 2016). The timeline for review of this petition is not publically available. Benzophenone is also permitted for use in certain rubber articles that may come in contact with food as part of food packaging or processing (i.e. indirect food additive as listed in 21CFR 177.2600(c)(4)(iv) diphenyl ketone; US FDA). Benzophenone is not approved for use in printing inks for cardboard or paperboard food packaging materials.

Cosmetics: Benzophenone is not currently included on the US FDA's List of Prohibited and Restricted Ingredients from use in cosmetics. Benzophenone is not listed as a permitted active ingredient in sunscreen drug products (as specified in 21CFR 352; US FDA).

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

Benzophenone is listed as an inert ingredient on the US EPA's Fragrance Ingredient List, and is therefore approved for use in pesticide products as a fragrance for non-food use only. As an approved fragrance, it is subject to the requirements under the US EPA's Pesticide Fragrance Notification Pilot Program (United States 2015).

Toxic Substances Control Act (TSCA)

Benzophenone is listed on the *Toxic Substances Control Act* Inventory with a regulatory flag "T", indicating that it is a substance subject to testing requirements for high production volume chemicals (as specified in 40CFR 799; US EPA).

Other

The California Environmental Protection Agency listed benzophenone as 'Known to the State to Cause Cancer' (Proposition 65 List) in 2012, based on the International Agency for Research on Cancer (IARC) classification. IARC concluded that "*there is sufficient evidence in experimental animals for carcinogenicity of benzophenone*" based on chronic oral studies in rats and mice and classified the substance as "*possibly carcinogenic to humans*" (Group 2B); however, there were no relevant studies identified for humans.

7.2.2 European Union

Food Flavouring Substances and Food Contact Materials Regulations

Benzophenone is listed as a permitted flavouring substance used or intended for use in or on foodstuffs as specified in Regulation (EU) No. 872/2012 (European Union 2012). It is also authorized to be used as an additive or polymer production aid in food contact materials with a specific migration limit of 0.6 mg/kg food as specified in Regulation (EU) No 10/2011 (European Union 2011).

Cosmetic Products Regulations

Benzophenone is permitted for use in cosmetics as a UV absorber (i.e. protects the cosmetic product from the effects of UV light) as specified in the European Union's Commission Decision 2006/257/EC Annex 1 (European Union 2006). In the European Union, sunscreen products are regulated as cosmetics according to Regulation (EU) No. 1223/2009 (European Union 2009). Benzophenone is not included in Annex VI *List of UV Filters Allowed in Cosmetic Products*; therefore, it is not permitted as an active ingredient in sunscreens.

7.2.3 Other Jurisdictions

Benzophenone is not included on Australia's list of suncreening agents permitted as active ingredients in listed products (Australia 2016).

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 document or other information that would help to inform decision-making (such as outlined in section 3.2). Please submit additional information and comments prior to October 02, 2018. The Risk Management Approach document, if required, 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 document 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: 819-938-5212
 Email: eccc.substances.eccc@canada.ca

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

8.2 Timing of Actions

Action	Date
Electronic consultation on the Risk Management Scope document	August 04 to October 02, 2018
Submission of additional studies or information on benzophenone	on or before October 02, 2018
Publication of responses to public comments on the draft screening assessment report and Risk Management Scope document	No later than the time of publication of the final screening assessment
Publication of the final screening assessment report and, if required, the Risk Management Approach document	2019 (tentative)
Publication of responses to public comments on the Risk Management Approach document, if applicable, and publication if required, of the proposed instrument(s)	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	18 months from the publication of the proposed instrument(s)

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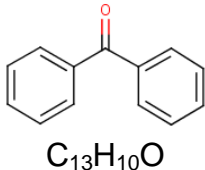
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ANNEX A. Substance Targeted for Risk Management

CAS RN	DSL name (common name; acronyms; other names)	Chemical structure and molecular formula	Molecular weight (g/mol)
119-61-9	Diphenylmethanone (Benzophenone; benzophenone; Ph ₂ CO; BZPh; Diphenyl ketone)	 C ₁₃ H ₁₀ O	182.22