



Government
of Canada

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**Risk Management Scope for 1,2-
Benzenedicarboxylic acid, benzyl C7-9-branched
and linear alkyl esters (B79P)
Chemical Abstracts Service Registry Number
(CAS RN): 68515-40-2**

Environment and Climate Change Canada

Health Canada

October 2017

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

Summary of Proposed Risk Management

Under the Substance Groupings Initiative of the Government of Canada's Chemicals Management Plan (CMP), B79P was identified as a priority for assessment and was included in the Phthalate Substance Grouping. The draft Screening Assessment Report (dSAR) proposes that B79P is toxic under paragraph 64(a) of the *Canadian Environmental Protection Act, 1999* (CEPA).

This document outlines the risk management options under consideration for the substance B79P from the Phthalate Substance Grouping. In particular, the Government of Canada is proposing to consider:

1. Implementation of regulatory and non-regulatory controls to minimize the release of B79P to the Canadian environment.

Moreover, because certain data gaps remain, information on the following items is required to inform risk management decision-making and should be provided (on or before December 6, 2017), to the contact details identified in section 8 of this document:

1. Quantity and current use of B79P by Canadian importers of the substance and products or manufactured items containing B79P;
2. Changes to B79P use patterns and economic impacts;
3. Chemical and non-chemical alternatives to B79P; and
4. Releases of B79P to the Canadian environment, including from landfill leachate.

The risk management options outlined in this Risk Management Scope document may evolve through consideration of assessments and risk management options published for other CMP substances as required to ensure effective, coordinated, and consistent risk management decision-making.

Note: The above summary is an abridged list of options under consideration to manage B79P and to seek information on identified gaps. Refer to section 3 of this document for more complete details in this regard. It should be noted that the proposed risk management options may evolve through consideration of additional information obtained from the public comment period, literature and other sources.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999) provides the authority for the Minister of the Environment and Climate Change 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 Chemicals Management Plan (CMP), the ministers are presently working to assess and manage, where appropriate, the potential health and ecological risks associated with approximately 500 substances, in nine substance groupings, under the Substance Groupings Initiative (Canada 2011). The Substance Groupings initiative is a key element of the CMP.

The substance, 1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters, Chemical Abstracts Service Registry Number (CASRN)³ 68515-40-2 and referred to throughout this document as B79P, was included in the Phthalate Substance Grouping of the Substance Groupings Initiative of the CMP (Canada 2017).

2. Issue

Health Canada and Environment and Climate Change Canada (ECCC) conducted a joint scientific assessment of phthalates in the Phthalate Substance Grouping, including information relevant to the evaluation of B79P in Canada. A notice summarizing the scientific considerations of the draft Screening Assessment Report (dSAR) for the Phthalate Substance Grouping, including B79P, was published in the Canada Gazette, Part I, on October 7, 2017 (Canada 2017). For further information on the dSAR for the Phthalate Substance Grouping, including B79P, refer to <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=516A504A-1>.

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 used by consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazard Product Regulations*, which are a part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion on the basis of criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

³ Chemical Abstracts Service Registry Number (CASRN). 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 report 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.

Additional information is also available in the State of Science Report: Phthalate Substance Grouping Medium-Chain Phthalate Esters, refer to <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=4D845198-1>.

2.1 Draft Screening Assessment Report conclusion

Based on information examined in the dSAR, it is proposed to conclude that B79P meets the criteria under paragraph 64(a) of CEPA as it is entering or may enter 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. It is also proposed to conclude that B79P does not meet the criteria under paragraph 64(b) of CEPA as it is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends (Canada 2017).

The dSAR determined that B79P does not meet the criteria for persistence and does not meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA (Canada 2000).

Key lines of evidence for B79P presented in the dSAR relate to high measured and predicted ecotoxicity potential as well as measured presence of the substance in some Canadian industrial and municipal wastewater samples collected by ECCC's CMP Monitoring and Surveillance Program in 2014-2016. The calculated risk quotient of 0.95 indicates potential risk to aquatic organisms at current exposure levels in Canada (Canada 2017). As such, this document will focus on this risk of concern (refer to section 5.2).

Based on the information presented in this dSAR, it is proposed that B79P does not meet the criteria under paragraph 64(c) of CEPA as it is 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.

Note that the proposed conclusions outlined in the dSAR are preliminary and may be subject to change.

2.2 Proposed recommendation under CEPA

Based on the findings of the dSAR conducted as per CEPA, the ministers propose to recommend that B79P be added to the List of Toxic Substances in Schedule 1 of the Act⁴.

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

The ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the dSAR and Risk Management Scope document. If the Ministers finalize the recommendation to add B79P 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 environmental objective

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

For B79P, the proposed objective is focused on addressing the potential risk to aquatic organisms in Canada outlined in section 5 of this document.

As such, the proposed environmental objective for B79P is to reduce the concentration of B79P in the ambient aquatic environment to levels below the predicted no-effects concentration of 4.0 µg/L⁵.

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 regulations, instrument(s) and/or tool(s) for a given substance or substances. In this case, the proposed risk management objective for B79P is to achieve the lowest level of release of the substance, which is technically and economically feasible, into the Canadian environment.

This objective will be refined based on consultation with stakeholders, the proposed risk management, consideration of further information received, the outcome of the final Screening Assessment Report (fSAR), and socio-economic and technical considerations (as outlined in section 6 of this document). Revised environmental and risk management objectives should next be presented in the Risk Management Approach document that will be published concurrently with the fSAR for the Phthalate Substance Grouping (including B79P), or in subsequent risk management documents (e.g. consultation document on proposed instrument).

To achieve the proposed risk management objective and to work towards achieving the proposed environmental objective, the risk management option under consideration for B79P is the implementation of regulatory and non-

⁵ As identified in the Draft Screening Assessment Report for the Phthalate Substance Grouping (Canada 2017)

regulatory controls to minimize the release of B79P to the Canadian environment.

Note that the proposed risk management options, described in this document, are preliminary and subject to change. Following the publication of this document, additional information obtained from the public comment period and from other sources will be considered, along with the information presented in this document, in the instrument selection and development process⁶. The risk management options outlined in this document may also 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

Interested stakeholders are invited to provide further information, such as may be outlined below, to inform risk management decision-making regarding B79P:

1) Quantity and current use of B79P by Canadian importers of the substance and products or manufactured items containing B79P:

- Details on the uses of B79P in different products, such as adhesive, coating and sealant materials, automotive parts, cable and wire insulation, construction materials, inks and printing products, electrical and electronic products and textiles, including:
 - The quantity of B79P used in these applications;
 - The concentration of B79P used in these applications; and
 - A description of the specific uses of this substance for these applications.

2) Changes to B79P use patterns and economic impacts:

- Anticipated economic impacts if the import and/or use of B79P is prohibited or restricted in Canada; and
- Ongoing or anticipated changes in use of B79P, whether in response to:
 - Market forces;
 - Shifts to alternative substances (please provide commercial name), alternative systems and approaches; and
 - Other reasons (please provide information on these reasons).

3) Chemical and non-chemical alternatives to B79P:

- Details on chemical alternatives and/or technologies to B79P and their feasibility, as applicable to Canadian importers for use in:

⁶ 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), the Red Tape Reduction Action Plan (TBS 2012b), and in the case of a regulation the *Red Tape Reduction Act* (Canada, 2015a).

- Adhesives, coatings and sealants in auto manufacturing and other applications;
- Automotive parts;
- Cable and wire insulation;
- Construction materials;
- Inks and printing products;
- Electrical and electronic products; and
- Textiles.

Should stakeholders have further information to help address these gaps, they should provide it to the contact identified in section 8 of this documentation or before December 6, 2017 to inform the risk management decision-making process).

In addition, due to data gaps related to B79P in landfill leachate, the Government of Canada proposes to undertake surveillance in order to characterize potential releases from this source.

4. Background

4.1 General information on B79P

The phthalate ester B79P is a diester of benzenedicarboxylic acid, comprised of a benzene ring with two side-chain ester groups. B79P belongs to the medium-chain phthalates subgroup and is considered to be a substance of *Unknown or Variable Composition, Complex Reaction Products or Biological Materials* (UVCB), as it is characterized by alkyl-chain ester side groups that can vary in length from 7 to 9 carbon atoms and in the degree of branching (Canada 2015b).

4.2 Current uses and identified sectors

In Canada, B79P is listed on the Domestic Substances List (DSL).

Based on the results of an industry survey conducted in 2013 under section 71 of CEPA, B79P was not reported to be manufactured in Canada above the reporting threshold⁷ in 2012, but was both imported and exported in the range of 100 to 1,000 tonnes (Canada 2015b).

The results of the section 71 survey also included information on the uses of B79P in Canada for the year 2012 (Canada 2015b). B79P was reported to be imported primarily in adhesive, coating and sealant materials, predominantly for use in the automotive sector. A small amount was also reported to be imported

⁷ Reporting threshold: a total quantity greater than 100kg of B79P, at a concentration equal to or above 0.001% by weight (w/w%) (Canada 2013)

as a component of footwear and apparel care products available to consumers (Canada 2015b).

Internationally, B79P is also used in cable and wire insulation, construction materials, inks and printing products, electrical and electronic products and textiles (Canada 2015b).

5. Exposure sources and identified risks

There are no known natural sources of B79P, and releases to the environment are associated only with anthropogenic activities (Canada 2017).

Phthalates, including B79P, are potentially released during industrial activities and could also be released during transportation and storage. Furthermore, during processing, B79P does not become chemically bound into the polymer matrix and therefore can migrate to the surface of polymer products. As such, phthalates, including B79P, could potentially be released throughout the lifecycle of products containing the substance. The rate of this migration is expected to be slow and will be counteracted by chemical and physical attractive forces which work to hold the phthalates within polymers (Canada 2017).

Based on known applications of phthalates, including B79P, in consumer and industrial products, environmental releases are expected to occur primarily to water, through off-site wastewater treatment systems (WWTS)⁸ and through disperse releases from products available to consumers. As such, the aquatic compartment is thought to be the key receiving environmental compartment for all phthalates, including B79P (Canada 2017).

Once released into the aquatic environment, B79P is expected to reside predominantly in water, with some partitioning to sediments and adsorption to particles. Phthalates biodegrade and are not expected to persist in the environment, although degradation rates vary with phthalate molecular size and physicochemical properties, substrate concentration and environmental conditions. Degradation proceeds more slowly under low oxygen conditions, such as may occur in sediment and soil, potentially increasing exposure times for organisms residing in these media. As well, information on Canadian phthalate use and release patterns suggests that exposure to phthalates in the Canadian environment may be continuous (Canada 2017).

⁸ The term “wastewater treatment system” refers to a system that collects domestic, commercial and/or institutional household wastewater and possibly industrial wastewater (following discharge to the sewer), typically for treatment and eventual discharge to the environment. Unless otherwise stated, the term wastewater treatment system makes no distinction of ownership or operator type (municipal, provincial, federal, indigenous, private, partnerships). Systems located at industrial operations and specifically designed to treat industrial effluents will be identified by the terms “on-site wastewater treatment systems” or “industrial wastewater treatment systems”.

Based on information about releases and the predicted distribution in the environment, aquatic organisms (water column and sediment) will have the highest potential for exposure. The relatively rapid biodegradation rates of phthalates indicate that exposure will be greatest for organisms inhabiting areas close to release sites. Concentrations of phthalates, including B79P, are expected to decrease with increasing distance from points of discharge (Canada 2017).

Information on phthalate concentrations, including B79P, in influents and effluents in Canada was obtained through a sampling campaign carried out by ECCO in 2014-2016. Influent and effluent of on-site WWTS from industrial facilities involved in the manufacture or use of phthalates were collected and analyzed, along with influents and effluents of the off-site WWTS where the industrial sites direct their effluents. In addition to these industrial sites and corresponding WWTS, the influents and effluents of eleven other Canadian WWTS were sampled and analyzed. This monitoring data was used to generate predicted environmental concentrations (PECs) for B79P in the receiving waters near potential discharge points (Canada 2017).

Risk quotient analyses for the aquatic medium were developed for B79P, using the derived PECs and a predicted no-effect concentration (PNEC) of 4.0 µg/L, which is based on reduced reproduction in the water flea, *Daphnia magna*. The analyses determined that B79P has the potential to cause adverse effects in populations of aquatic organisms in Canada (i.e. risk quotient of ~ 1) at current levels of exposure predicted using sampling data from WWTS effluents (Canada 2016). No risk of harm was identified (risk quotient < 1) using PECs developed for the off-site wastewater treatment facilities that receive effluents from the industrial sites involved with phthalates that were sampled (Canada 2017).

There is uncertainty with respect to the sources of phthalates in the aquatic environment. An analysis of locations where both industrial and municipal monitoring was available suggests that phthalate loadings from known industrial users generally accounted for less than 10% of the total phthalate loadings in off-site WWTS influents. This suggests that much of the phthalates found in the influents of off-site WWTS may be coming from other sources, such as products available to consumers, industrial sources not captured by the S.71 survey reporting requirements, or landfill leachate (Canada 2017).

Additionally, for each of the WWTS, a per capita phthalate influent loading was estimated. It was found that the average per capita loading of phthalates for a WWTS that receives landfill leachate was 2 - 9 times higher than the average per capita loading of phthalates for the WWTS that didn't receive leachate, suggesting that landfill leachate may represent a non-negligible source of phthalates in municipal WWTS influent. However, because the total quantity of phthalates entering landfills through end-of-life products, manufactured items or other materials is not known and because the concentration of phthalates in

landfill leachate were not measured, it is not presently possible to confirm or quantify the contribution of landfill leachate as a source of phthalates to WWTS influents (Canada 2017).

6. Risk management considerations

6.1 Alternatives and alternate technologies

Very little information is available with regards to alternative chemicals or technologies that are specific to B79P. However, information does exist regarding the use of alternatives to phthalates in general, for certain relevant applications.

A number of chemicals, including citrates, sebacates, adipates, and phosphates, have been identified as chemical alternative plasticizers in polyvinylchloride (PVC) applications, which traditionally rely on the use of phthalates. In addition to their application as alternative PVC plasticizers, these chemicals are also already being used in adhesives and solvents, in fixatives for cosmetic products and in inks and printing products (Lowell, 2011).

Many of these alternative chemicals are not well studied with regard to their potential effects on human health and the environment. Like phthalates, these alternative chemicals are not chemically bound to the polymer matrix and therefore can also migrate to the surface of products and manufactured items containing them (Lowell, 2011).

Additionally, there are many plastics available that do not require the addition of phthalates, for example certain petroleum-based plastics (e.g. polyurethane) and bio-based plastics (cellulose and cellulose acetate), which can be used in a wide variety of applications, including those relevant to B79P (e.g. adhesives and sealants in auto manufacturing and in construction materials and electronics).

6.2 Socio-economic and technical considerations

There is little information available about the current state of industry transition to alternative substances and/or technologies for B79P. Therefore, socio-economic factors will be considered in the development of risk management objectives and will also be considered in the selection and development of regulation(s), instrument(s) and/or tool(s) respecting preventative or control actions, 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

Currently, B79P is not subject to any substance specific risk management in Canada.

7.2 Pertinent international risk management context

7.2.1 United States

7.2.1.1 Federal level

In the United States, B79P is listed under the *Toxic Substances Control Act* (TSCA) inventory under CASRN 68515-40-2, and is flagged as a UVCB.

Currently, B79P is not subject to any substance specific risk management in the United States.

7.2.2 Europe

A registration dossier for B79P has been submitted under the European Union's Registration, Evaluation and Authorization of Chemicals (REACH).

Furthermore, B79P is currently being evaluated by Denmark under the REACH Community Rolling Action Plan (ECHA, 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 or other information that would help to inform decision-making (as outlined in sections 3.4). Please submit additional information and comments prior to December 6, 2017. 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 fSAR. 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

Companies who have a business interest in B79P are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding B79P and may be contacted for further information.

8.2 Timing of actions

Electronic consultation on the Risk Management Scope: October 7, 2017 to December 6, 2017.

Submission of additional studies or information on 1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters (B79P): on or before December 6, 2017.

Publication of responses to public comments on the draft Screening Assessment Report and Risk Management Scope: on or before October 2018.

Publication of the final Screening Assessment Report and, if required, the Risk Management Approach document: on or before October 2018.

Publication of responses to public comments on the Risk Management Approach, if applicable and if required, the proposed instrument(s): at the latest, 24-month from the publication of the final Screening Assessment Report

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

Publication of the final instrument(s), if required: at the latest, 18-month from the publication of each proposed instrument(s)

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ANNEX A. Synonyms and Trade Names

CAS RN	Domestic Substances List name (English)	Common Names / Synonyms	Chemical Formula	Acronym
68515-40-2	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	Benzyl octyl phthalate; Benzyl C7-9-branched and linear alkyl phthalates; Phthalic acid, benzyl alkyl(C7-C8) ester; benzyl octyl benzene-1,2-dicarboxylate	C ₂₃ H ₂₈ O ₄ (representative)	B79P