Risk Management Scope

for

Phenol, 2-(1-methylpropyl)-4,6-dinitro-

(Dinoseb)

Chemical Abstracts Service Registry Number 88-85-7

Environment and Climate Change Canada

Health Canada
June 2018

Summary of proposed risk management

This document outlines the proposed risk management options for phenol, 2-(1-methylpropyl)-4,6-dinitro- (commonly known as dinoseb or DNBP). In particular, the Government of Canada is proposing to consider the implementation of regulatory or non-regulatory controls to prevent or minimize the release of dinoseb to the environment from the industrial use of this substance.

Moreover, because certain data gaps remain, the following information should be provided on or before **July 30, 2018** to the contact details identified in section 8 of this document to inform risk management decision-making:

1. Presence of dinoseb in the Canadian environment, especially surface water and wastewater/biosolids;
2. Procedures and analytical methods for the sampling of dinoseb in wastewater and biosolids
3. Efficiency of wastewater treatment methods in removing dinoseb from wastewater;
4. Potential alternative substances to dinoseb in the use as a polymerization retarder or alternative production processes in the production of styrene monomer, associated costs of replacement and technical implications;
5. Best management practices in place at styrene monomer production facilities including handling, storage practices and industrial waste water treatment systems in place; and
6. Changes in use patterns from data collection initiatives (noted in section 4.1 of this document).

Note: The above summary is an abridged list of information sought to inform the risk management decision-making process. 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 during the public comment period, from other sources, and from the information presented herein.

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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[1] to the environment and/or harmful to human health[2], and if so to manage the associated risks.

As part of the third phase of the Chemicals Management Plan (CMP3), the ministers are assessing and will manage, where appropriate, the potential health and ecological risks associated with approximately 1550 substances (Canada, 2016). Phenol, 2-(1-methylpropyl)-4,6-dinitro-, Chemical Abstracts Service Registry Number (CAS RN) 88-85-7, referred to throughout this document as "dinoseb", is included in CMP3.

2. Issue

Health Canada (HC) and Environment and Climate Change Canada (ECCC) conducted a joint scientific assessment of phenol, 2-(1-methylpropyl)-4,6-dinitro-, Chemical Abstracts Service Registry Number (CAS RN) 88-85-7. A notice summarizing the draft screening assessment for dinoseb was published by HC and ECCC in the Canada Gazette, Part I, on **July 30, 2018** (Canada, 2017a) (Canada, 2017b). For further information on the proposed screening assessment conclusion for dinoseb, refer to the draft screening assessment, available from: https://canada.ca/en/environment-climate-change/services/evaluating-existing-substances/screening-assessment-dinoseb.html.

[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 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.

2.1 Draft screening assessment conclusion

On the basis of the information available, the draft screening assessment proposes that dinoseb meets the criteria under paragraph 64(a) of CEPA as it is 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 (Canada, 2017a). However, dinoseb did 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. The draft screening assessment also proposes to conclude that dinoseb 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 a danger in Canada to human life or health. Dinoseb is proposed to meet the persistence criteria, but not the bioaccumulation criteria, as defined in the Persistence and Bioaccumulation Regulations of CEPA (Canada, 2000) (Canada, 2017a).

The exposure source of concern, identified in the draft screening assessment, is based on the potential release of dinoseb from its use as a polymerization retarder in the production of styrene monomer. As such, this document will focus on this application of concern (detailed in section 5.2)

2.2 Proposed recommendation under CEPA

When a substance is found to meet one or more of the criteria under section 64 of CEPA, the ministers can (1) take no further action with respect to the substance, (2) recommend the addition of the substance to the Priority Substances List for further assessment, or (3) recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act.

On the basis of the proposed conclusion of the draft screening assessment, the ministers propose to recommend adding dinoseb to the List of Toxic Substances, Schedule 1 of CEPA (Canada, 2017b). The ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment and Risk Management Scope (RM Scope). If the ministers finalize the recommendation to add dinoseb to Schedule 1, risk management instrument(s) will be proposed and finalized within a set period of time, as outlined in sections 91 and 92 of CEPA (refer to section 8 of this document for targeted publication timelines applicable to this substance).

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.

In this case, the proposed environmental objective would be to prevent the presence of dinoseb in the aquatic environment to the greatest extent practicable. This objective may be quantitatively defined to achieve and maintain the lowest environmental levels possible. Predicted no-effect concentrations (PNECs) may be used as ultimate goals to work towards but interim levels may also be set, for the media of interest (e.g., water).

The only Canadian environmental concentration data identified for dinoseb was from a sampling campaign that took place from 2003 to 2005 on surface waters in Quebec, that found no presence of dinoseb in the samples taken (Environment Canada, 2011). These samples were taken to determine the presence and levels of substances used as pesticides in the Canadian aquatic system and not in the context of the use of dinoseb in the chemical sector. Stakeholders that may have analytical methods or results to share are encouraged to contact ECCC on or before **July 30, 2018** (via the contact details identified in section 8 of this document).

3.2 Proposed risk management objective

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 given substance(s) to work towards meeting the proposed environmental objective.

In this case, the proposed risk management objective would be to reduce the releases of dinoseb to surface water from the chemical sector, such that levels are protective to the environment and are technically and economically feasible. This objective may be quantitatively defined to ensure that practices in place are protective of the environment at existing and new facilities in the chemical sector.

3.3 Proposed risk management options

To achieve the proposed risk management objective and to work towards achieving the proposed environmental objective, the proposed risk management options under consideration for dinoseb include the implementation of regulatory or non-regulatory controls to minimize releases of dinoseb to the Canadian environment.

Note that the proposed risk management options 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 in the instrument selection and development process[3]. The risk

[3] 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 (Canada, 2012a), the Red Tape

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.

Of note, other activities to track commercial use patterns associated with styrene monomer production, or more broadly with additives in the chemical sector may be considered in the future. Furthermore, these substances are intended to be submitted to the 2017 Identification of Risk Assessment Priorities (IRAP)[4] review for further consideration.

3.4 Risk management information gaps

Interested stakeholders are currently invited to provide information, such as outlined below, to inform risk management decision-making regarding dinoseb:

1. Presence of dinoseb in the Canadian environment, especially surface water, and wastewater/biosolids;
2. Procedures and analytical methods for the sampling of dinoseb in wastewater and biosolids
3. Efficiency of wastewater treatment methods in removing dinoseb from wastewater;
5. Potential alternative substances to dinoseb in the use as a polymerization retarder or alternative production processes in the production of styrene monomer, associated costs of replacement and technical implications;
6. Best management practices in place at styrene monomer production facilities including handling, storage practices and industrial waste water treatment systems in place; and
7. Changes in use patterns from data collection initiatives (noted in section 4.1 of this document).

Stakeholders are invited to provide this information on or before **July 30, 2018** to the contact identified in section 8 of this document.

4. Background

Historically, dinoseb was imported into Canada for use as an herbicide, specifically, as pre-emergent or contact sprays, and as a desiccant. It was available commercially for these purposes as an aqueous solution and also as an

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Reduction Action Plan (Canada, 2012b), and in the case of a regulation the Red Tape Reduction Act (Canada, 2017c).

[4] Information on the IRAP review can be found at the following address: https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/identification-risk-assessment-priorities.html

emulsifiable concentrate (Hazardous Substances Database, 2003). The registration of all non-essential pesticidal (in this case, herbicidal) uses of dinoseb was suspended by Agriculture Canada in 1990 when health concerns about dinoseb were raised. No further uses were registered after December 31, 2000. The use of dinoseb as an herbicide has been prohibited as of December 31, 2001 (PMRA, 2000).

4.1 Current uses and identified sectors

The only current use of dinoseb in Canada is as a polymerization retarder in the production of styrene monomer. Information obtained under the Export Notification provisions of the Rotterdam Convention, and from follow-up discussions with industry, indicates that dinoseb was imported into Canada in 2015 in a quantity between 100 000 and 1 000 000 kg.

5. Exposure sources and identified risks

Dinoseb is expected to persist in air and water; persistence in soil and sediment is also likely, but less certain. It has a low potential to bioaccumulate in aquatic organisms but is highly hazardous to various forms of aquatic organisms, as well as to birds and mammals. This means there would be effects at low levels of exposure. It also binds to proteins and DNA, has effects on reproduction (embryotoxicity), as well as survival and growth. Empirical studies, in vitro assays, and modelling all indicate the potential for adverse effects in aquatic organisms at low concentrations. For further information on the proposed screening assessment conclusion for dinoseb, refer to the draft screening assessment, available from: https://canada.ca/en/environment-climate-change/services/evaluating-existing-substances/screening-assessment-dinoseb.html.

The quantity of dinoseb imported into Canada is significant (between 100 000 and 1 000 000 kg in 2015). Information on its use as a polymerization retarder in the production of styrene monomer indicates potential for releases into the Canadian environment through water.

5.1 Environmental presence

Dinoseb does not naturally occur in the environment, but could be present due to its past use as a pesticide. The environmental sampling campaign in Quebec found no presence of dinoseb in the surface water samples taken (Environment Canada, 2011).

No other information on concentrations of dinoseb in the environment in Canada has been identified.

5.2 Releases and exposure of concern in Canada

The current predicted environmental concentration (PEC) of dinoseb in Canadian surface water has been estimated by an exposure scenario based on assumed releases of dinoseb from its use as a polymerization retarder in the production of styrene monomer. Once released to water, dinoseb is expected to primarily remain in that medium due to its water solubility and overall persistence in that medium. Therefore, the assessment primarily focused on the aquatic ecosystem.

Releases of concern would be the result of industrial activities using dinoseb and related processes. Off-site wastewater treatment was reported, but removal efficiency of dinoseb in wastewater is unknown and generally estimated to be ineffective for conventional biological sewage treatment processes (Canada, 2017a).

6. Risk management considerations

6.1 Alternatives

Other chemical substances are available as alternatives to dinoseb in its application as a polymerization retarder in the production of styrene monomer. However, there are data gaps on the implications associated with the substitution of these alternatives in the manufacturing process. Stakeholders are invited to provide this information on or before **July 30, 2018.**

6.2 Technical considerations

The removal efficiencies of different wastewater treatments for dinoseb are unknown. It is anticipated that wastewater conventional biological treatment techniques (equivalent to secondary treatment) would not be effective for removing dinoseb (Canada, 2017a)and may create the need for pre-treatment or more advanced and adapted removal techniques (e.g., activated carbon filtration, advanced oxidation pre-treatments, nanofiltration, or membrane bioreactors). Industrial wastewater treatment processes may be better suited to remove dinoseb from the wastewater stream. This should not prevent the use of other best management practices in lieu of or in addition to wastewater treatment (such as, but not limited to, recycling and re-use in the process, or better disposal means, where possible).

6.3 Socio-economic context

Socio-economic factors, such as incremental costs associated with improving removal efficiency of industrial wastewater treatments for dinoseb, as well as incremental costs associated with alternative substances and manufacturing processes, will be considered in the selection process for the regulatory and/or non-regulatory controls to minimize release of dinoseb to the Canadian environment, and in refining the risk management objective. Socio-economic

factors will also be considered in the development of the instrument(s) as identified in the Cabinet Directive on Regulatory Management[5].

7. Overview of existing risk management

7.1 Related Canadian risk management context

Dinoseb and its salts and esters are listed in Annex III of the Rotterdam Convention for pesticide uses making them subject to the prior informed consent (PIC) procedure (UNEP, 2010). Canada is a Party to the Rotterdam Convention and does not consent to the import of these substances for their pesticide use. The Convention and its PIC procedure do not explicitly apply to exports of these substances for other uses, such as industrial uses. Under Article 12 of the Rotterdam Convention, Parties must send an export notification to importing Parties before exporting any substance they (the exporting Parties) have banned or severely restricted. As such, ECCC receives export notifications from some Parties who have banned or severely restricted the industrial use of these substances and export them to Canada, or who have chosen to go beyond the requirements of the Convention itself and notify of these exports on a voluntary basis. ECCC has received, since 2013, notifications about intended exports of dinoseb to Canada for its industrial uses falling under “dinoseb and its salts and esters”.

The use of dinoseb as an herbicide has been prohibited in Canada as of December 31, 2001, by Health Canada, Pest Management Regulatory Agency (PMRA, 2000).

Dinoseb has Canadian water quality guidelines for the protection of agricultural uses of 16 µg/L for irrigation water (46 µg/L for cereals, tame hays and pastures, 93 µg/L for legumes, and 16 µg/L for other crops), and 150 µg/L for livestock water (Canadian Council of Ministers of the Environment, 1999a). The Canadian water quality guideline for the protection of aquatic life is 0.05 µg/L[6] for fresh water (Canadian Council of Ministers of the Environment, 1999b).

Dinoseb was included in the Guidelines for Canadian Drinking Water established by the Federal-Provincial-Territorial Committee on Drinking Water in 1996; however, this guideline was archived since dinoseb is no longer registered for use as a pesticide in Canada and it is no longer found in Canadian drinking water supplies “at levels that could pose a risk to human health” (Federal-Provincial-Territorial Committee on Drinking Water of the Federal-Provincial-Territorial Committee on Health and the Environment, 2014).

[5] Government of Canada’s Cabinet Directive on Regulatory Management (Canada, 2012a), Red Tape Reduction Action Plan (Canada, 2012b), Red Tape Reduction Act (Canada, 2017c)

[6] This value and the PNEC were derived from the same study, but different assessment factors were applied

No specific risk management measure for dinoseb, in the context of its current use as a polymerization retarder in the production of styrene monomer, has been found.

Transportation of dinoseb is subject to the Transportation of Dangerous Goods Act and regulations, administered by Transport Canada (Canada, 1992).

Lastly, dinoseb, if intended to be disposed of or recycled, is covered by the Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations (Canada, 2005) and Interprovincial Movement of Hazardous Waste Regulations administered by ECCC (Canada, 2002).

7.2 Pertinent international risk management context

Canada is mostly aligned with the international community on regulation of this chemical in that Canada is a Party to the Rotterdam Convention. It is important to note, however that several countries including the US are not a party to the Rotterdam Convention and as such have no obligations to notify Canada under this convention. Furthermore, existing risk management measures taken internationally on dinoseb are related to its use as a pesticide rather than as an additive in the chemical sector.

Internationally, dinoseb is a restricted chemical under Annex III chemicals of the Rotterdam Convention: subject to prior informed consent procedure (PIC) (UNEP, 2010). PIC regulation administers the import and export of certain hazardous chemicals and places obligations on companies who wish to export these chemicals to non-EU countries. It implements, within the European Union, the Rotterdam Convention on prior informed consent procedure for certain hazardous chemicals and pesticides in international trade.

In the US, dinoseb is on the Environmental Protection Agency (EPA) list of banned or severely restricted pesticides (US EPA, 2016a). In addition, it is a registered pesticide under The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (US EPA, 2016b). The Safe Drinking Water Act (SDWA) in the US specifies the maximum contaminant level (MCL) for dinoseb at 7 µg/L (US EPA, 2017a).In Canada, guidelines are archived for parameters that are no longer found in Canadian drinking water supplies (Federal-Provincial-Territorial Committee on Drinking Water of the Federal-Provincial-Territorial Committee on Health and the Environment, 2014) (but previously the drinking water guideline for dinoseb was 10 µg/L (Federal-Provincial-Territorial Committee on Drinking Water of the Federal-Provincial-Territorial Committee on Health and the Environment, 2010 (archived)). Dinoseb is listed in the Toxic Release Inventory (TRI) with a de minimis of 1.0% (US EPA, 2017b), while it is not reportable to the National Pollutant Release Inventory (NPRI) in Canada.

In the US, The Code of Federal Regulation (CFR), title 21: Food and Drugs, Part 165: Beverages, 165.110 Bottled water, specifies a 0.007 mg/L allowable level for pesticides and other synthetic organic chemicals (SOCs) (United States, 2017a). The CFR, title 40: Protection of the Environment, Part 268: Land disposal restrictions (United States, 2012), specifies the water-waste standard for dinoseb as 0.066 mg/L and for non-water standard as 2.5 mg/kg (United States, 2017b). The reportable quantity for dinoseb under Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) is 1000 lb (US EPA, 2016). Dinoseb was removed from the chemicals identified for Tier 1 screening under the Endocrine Disruptor Screening Program (EDSP) (2013) with the rationale that the pesticide is not in use anymore (United States, 2013). Dinoseb is listed as a hazardous substance under the Superfund Amendments and Reauthorization Act (SARA) (United States, 2011), and a hazardous constituent under the Resource Conservation and Recovery Act (RCRA) (United States, 2012). Finally, dinoseb was listed under the California Proposition 65 in 1989 for male developmental effects (California, 2017). As a whole, Canada aligns with the United States on dinoseb.

In the European Union (EU), dinoseb, its acetate and salts are banned in pesticides in the active substance regulation because they have been found in animal studies to result in high risks of birth defects, male sterility, and high acute toxicity (European Union, 2016). Dinoseb is subject to Classification and Labelling (CLP) regulation (2008): All chemicals that are exported have to comply with rules on packaging and labeling. Dinoseb has a warning label: Do not transport with food and feedstuffs, Marine pollutant (ECHA, 2017a). Furthermore, it is listed on the Candidate List of substances of very high concern for Authorisation under REACH (2012) because of its possible toxicity for reproduction (ECHA, 2017b). Dinoseb is also listed in Substances Prohibited in Cosmetic Products (2009) (European Union, 2009). In the EU, dinoseb is prohibited in cosmetic products, whereas in Canada, it is not listed under the Cosmetic Hot List. Canada aligns to a certain extent with the EU on dinoseb.

Dinoseb has been assessed by the Organisation for Economic Co-operation and Development (sponsoring country Japan) in 2007 and it was concluded that the chemical is a candidate for further work indicating a hazard to the environment (OECD, 2007).

In Australia, an assessment on dinoseb has been conducted by the Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and found that it is not in use in the country (NICNAS, 2017).

8. Next steps

8.1 Public comment period

Stakeholders are invited to submit comments on the content of this RM Scope or other information (such as outlined in section 3.4 of this document) that would help to inform decision-making for these substances. Please submit additional information and comments prior to **July 30, 2018**. If needed, the RM Approach, which will outline and seek input on the proposed risk management instrument(s) moving forward, will be published at the same time as the final screening assessment. At that time, there will be a further opportunity for public comment on the RM Approach only. Comments and information submissions on the RM 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
E-mail: eccc.substances.eccc@canada.ca

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

8.2 Timing of actions

Actions	Date
Electronic consultation on the draft screening assessment and RM Scope for dinoseb	June 2 to July 30, 2018
Submission of public comments and additional information on dinoseb	On or before July 30, 2018
Publication of responses to comments on the draft screening assessment and RM Scope for dinoseb	No later than the time of publication of the final screening assessment
Publication of the final screening assessment and, if required, the RM Approach for dinoseb	2019 (tentative)
Publication of responses to public comments on the RM Approach for dinoseb, if applicable	No later than the time of publication of the proposed instrument
If required, consultation and publication of the proposed instrument(s) in accordance with section 91 of CEPA	Within 24-month from the publication of the final screening assessment and RM Approach
Publication of the final instrument(s), if required, in accordance with section 92 of CEPA	Within 18-month from the publication of the proposed instrument

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