

# Risk Management Approach for

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

# Chemical Abstracts Service Registry Number (CAS RN):

88-85-7

Environment and Climate Change Canada

Health Canada

February 2021

## **Summary of Proposed Risk Management**

This document outlines the proposed risk management actions for dinoseb, which has been found to be harmful to the environment.

In particular, the Government of Canada is proposing to implement an environmental performance agreement (EPA), which is proposed to include provisions to adhere to a code of practice or best management practices. If this is not feasible, a pollution prevention planning Notice under section 56 of the Canadian Environmental Protection Act, 1999 (CEPA) may be considered.

Moreover, because certain data gaps remain, the following information should be provided (ideally on or before April 7, 2021), to the contact details identified in section 8 of this document, to inform risk management decision-making:

- Presence of dinoseb in the Canadian environment, especially surface water and in wastewater/biosolids; and
- Changes in use patterns from data collection initiatives (noted in section 4.1 of this document).

The risk management actions outlined in this Risk Management Approach document may evolve through consideration of assessments and risk management options or actions 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 actions proposed to manage this substance 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 action(s) 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 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<sup>1,2</sup>, and if so, to manage the associated risks.

As part of the third phase of the Chemicals Management Plan (CMP), the ministers are assessing and managing, where appropriate, the potential health and ecological risks associated with approximately 1550 substances (Government of Canada, 2016). The substance phenol, 2-(1-methylpropyl)-4,6-dinitro-, Chemical Abstracts Service Registry Number (CAS RN³) 88-85-7, referred to throughout this document as dinoseb, is included in the third phase of the Chemicals Management Plan (CMP) (Government of Canada, 2016).

#### 2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint assessment relevant to the evaluation of dinoseb in Canada. A notice summarizing the scientific considerations of the Screening Assessment for dinoseb was published in the *Canada Gazette*, Part I, on February 6, 2021 (Canada, 2021b). For further information on the Screening Assessment for dinoseb, refer to the <u>Screening Assessment for Dinoseb</u>.

<sup>&</sup>lt;sup>1</sup> 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

 <sup>(</sup>a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

<sup>(</sup>b) constitute or may constitute a danger to the environment on which life depends; or

<sup>(</sup>c) constitute or may constitute a danger in Canada to human life or health.

<sup>&</sup>lt;sup>2</sup> 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 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 the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

<sup>&</sup>lt;sup>3</sup> 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.

### 2.1 Screening Assessment Report Conclusion

On the basis of the information available, the Screening Assessment concludes that dinoseb is toxic under section 64 of CEPA because 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 (Canada, 2021a).

The Screening Assessment also concludes that dinoseb meets the criteria for persistence and does not meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* under CEPA (Government of Canada, 2000).

The exposure source of concern, identified in the 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 (refer to section 5.2).

While exposure of the general population to dinoseb is not of concern for human health at current levels, this substance is associated with human health effects of concern. An analysis of information related to current and potential future uses of this substance suggest that it is unlikely that exposure will increase to levels of concern to human health.

#### 2.2 Recommendation under CEPA

On the basis of the findings of the screening assessment, the ministers recommend that dinoseb be added to the List of Toxic Substances in Schedule 1 of the Act<sup>4</sup>.

The ministers have taken into consideration comments made by stakeholders during the 60-day public comment period on the draft Screening Assessment for dinoseb (Canada, 2018a) and its associated Risk Management Scope document (Canada, 2018b).

If the ministers finalize the recommendation to add dinoseb to Schedule 1, the Government of Canada plans to propose risk management instrument(s) within 24 months from the date on which the Screening Assessment is published, and finalize risk management instrument(s) within 18 months from the date on which the risk management instrument is proposed.

<sup>&</sup>lt;sup>4</sup> 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.

## 2.3 Public Comment Period on the draft Screening Assessment and the Risk Management Scope

The draft Screening Assessment for dinoseb and its associated Risk Management Scope document summarizing the proposed risk management options under consideration at that time were published in June 2018. Industry and other interested stakeholders were invited to submit comments on both documents during a 60-day comment period.

Comments received on the draft Screening Assessment and the Risk Management Scope document were taken into consideration in the development of this document. A summary of responses to public comments received is available from the <u>Summary of public comments received on the screening assessment report for dinoseb</u>.

## 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 dinoseb, the proposed objective is focused on addressing the exposure source of concern outlined in section 5 of this document. As such, the proposed environmental objective for dinoseb is to ensure that levels of dinoseb in the aquatic environment are below dinoseb's predicted no-effect concentration (PNEC) for aquatic organisms, 0.17 µg/L (1.7 x 10<sup>-4</sup> mg/L).

## 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, instruments and/or tools for a given substance or substances. In this case, the proposed risk management objective for dinoseb is to ensure that the total concentration or quantity of dinoseb released from facilities in the chemical sector is protective to the environment (i.e., below the PNEC), taking into account technical and economic feasibility and socio-economic factors.

## 3.3 Proposed Risk Management Actions

To achieve the proposed risk management objective and to work towards achieving the proposed environmental objective, the proposed risk management action being considered for dinoseb is to implement an environmental performance agreement (EPA), which is proposed to include provisions to adhere to a code of

practice or best management practices. If this is not feasible, a pollution prevention planning Notice under section 56 of CEPA may be considered.

An EPA is a voluntary and non-statutory instrument that allows parties with common goals to address a particular environmental issue. EPAs can address a wide variety of environmental issues affecting the environment and human health such as reducing the use or release of chemicals, promoting product stewardship or conserving sensitive habitats. They can be used to complement a regulation, a code of practice or a pollution prevention planning notice under CEPA.

Part 4 of CEPA gives the Minister of the Environment the authority to require the preparation and implementation of pollution prevention (P2) plans for substances listed on Schedule 1 of CEPA. The Minister of Environment can require the preparation and implementation of P2 plans by issuing a Notice under Section 56 of CEPA in the *Canada Gazette*. These Notices specify the persons or class of persons covered by the Notice; the substances or group of substances; the commercial, manufacturing, processing, or other activities covered by the Notice; the factors to be considered in preparing the plan; the time limits for preparing and implementing plans; and any administrative matter (EC 2009).

Note that the proposed risk management actions described in this document may be 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 process<sup>5</sup>. The risk management options outlined in this document may also evolve through consideration of assessments and risk management options or actions published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

#### 3.4 Performance Measurement and Evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances<sup>6</sup>. The aim is to determine whether human health and/or environmental objectives have been met and

<sup>&</sup>lt;sup>5</sup> The proposed risk management regulation(s), instrument(s) or tool(s) are 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 Regulation(Canada, 2018d), the Red Tape Reduction Action Plan (Canada, 2012b), and in the case of a regulation the *Red Tape Reduction Act* (Canada, 2015).

<sup>&</sup>lt;sup>6</sup> Performance measurement can be performed at two levels:

Instrument-based performance measurement evaluates the effectiveness of an individual instrument in
meeting the specific risk management objectives that were set out when the risk management tool was
designed. The results of performance measurement will help determine if additional risk management
or assessment is needed (i.e., evaluate whether risk management objectives have been met); and

<sup>•</sup> Substance-based performance measurement considers performance of all final risk management instruments applied to a chemical substance and relevant data or indicators of exposure to the environment or human health (*i.e.*, evaluate whether human health and/or environmental objectives have been met).

whether there is a need to revisit the risk management approach for that substance, to ensure that risks are managed effectively over time. To achieve this, the Government of Canada will review, on a regular basis, the effectiveness of the risk management action(s) for dinoseb.

The Government of Canada plans to measure the effectiveness of the risk management action(s) by collecting and analyzing data, such as data on the presence of dinoseb in industrial effluent and the compliance rate with the risk management instrument to measure progress towards meeting the risk management objective. The results of performance measurement, including sampling results of presence of dinoseb in industrial effluent, will be made publicly available.

In addition, the Government of Canada plans to collect and analyze monitoring data including data obtained from the CMP Environmental Monitoring and Surveillance Program and/or other initiatives on the presence of dinoseb in environmental media of concern (i.e. surface water) and wastewater. This data will be used to establish a baseline environmental presence and to measure progress towards meeting the environmental objective following the implementation of risk management measures.

The results of performance measurement and evaluation will be used to inform whether further risk management action is warranted and will be made available to Canadians along with recommendations for further action, if applicable.

## 3.5 Risk Management Information Gaps

Stakeholders and other interested parties are invited to provide further information, such as is outlined below, to inform risk management decision-making regarding dinoseb:

- 1. Presence of dinoseb in the Canadian environment, especially surface water and in wastewater/biosolids: and
- 2. Changes in use patterns of dinoseb from data collection initiatives (noted in section 4.1 of this document).

Should stakeholders have further information to help address these gaps, they should provide it ideally on or before April 7, 2021 to inform the risk management decision-making process, within the timelines (and 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 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 was discontinued as of December 31, 2001 (PMRA, 2000).

#### 4.1 Current Uses and Identified Sectors

Based on information available, the largest 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, and has effects on reproduction (embryotoxicity), 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 screening assessment conclusion for dinoseb, refer to the Screening Assessment for Dinoseb.

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.

Given the information available, it is proposed that there is the potential for exposure concentrations resulting from industrial activities to exceed chronic noeffect thresholds in the receiving environment, even when dinoseb is used in very low quantities. Facilities using high volumes of dinoseb could also potentially

pose a risk to the environment, depending on the handling practices used at the facility (Canada 2021a).

#### **5.1 Environmental presence**

Dinoseb does not naturally occur in the environment. It was used in Canada as an herbicide until 2001. The results for dinoseb from the monitoring of surface water in Quebec from 2003 to 2005 were all non-detects, at a method detection limit (MDL) of 0.04  $\mu$ g/L (Environment Canada 2011). Analysis of water samples collected from three locations in the St. Clair River in 2018 showed no detection of dinoseb at a detection limit of 0.0004  $\mu$ g/L (personal communication, presentation from the Water Quality Monitoring and Surveillance Division, Environment and Climate Change Canada (ECCC), October 24, 2018; unreferenced).

Industry data on dinoseb concentrations measured in several samples of untreated wastewater, from a facility that uses dinoseb, were provided to Environment and Climate Change Canada. In eight out of nine samples, dinoseb was not present at levels above the method detection limit of 0.05  $\mu$ g/L. In one sample, a concentration of 0.117  $\mu$ g/L was measured (personal communication, confidential data provided by email to Environment and Climate Change Canada, dated October 24, 2018; unreferenced).

## 5.2 Releases and exposure of concern in Canada

A generic analysis was conducted to determine the predicted environmental concentrations (PECs) in surface water resulting from releases from industrial facilities. Multiple PECs were calculated by varying the inputs for certain parameters to capture a range of potential situations. Once released to water, dinoseb is expected to primarily remain in that medium due to its moderate 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, 2021a).

Additional information about releases and exposures of concern in Canada can be found in the screening assessment report for dinoseb (Canada, 2021a).

## 6. Risk Management Considerations

#### 6.1 Alternatives and Alternate Technologies

Other chemical substances may be used as potential alternatives to dinoseb in its application as a polymerization retarder in the production of styrene monomer. Such potential alternatives include Green PRISM retarder technology (Xu et al, 2012), phenol, 2-methyl-4,6-dinitro- (DNOC, CAS RN 534-52-1), phenol, 4-methyl-2,6-dinitro- (DNPC, CAS 609-93-8), phenol, 2,4-dinitro- (CAS RN 51-28-5), phenol, 2-(1-methylpropyl)dinitro- (CAS RN 1344-30-5), and 1-piperidinyloxy, 4-hydroxy-2,2,6,6-tetramethyl- (CAS RN 2226-96-2). A screening assessment for DNOC (CAS RN 534-52-1) was published in 2009 (Canada 2009). Other sources of information available describe possible alternatives and alternate technologies for dinoseb (Nufarm, 2019; Dorf Ketal, 2016; Ecolab, 2019; AICHE Academy, 2012; Hua and Metzler, 2017.) These alternatives have not been evaluated to determine whether they are safe for human health and the environment.

The Identification of Risk Assessment Priorities (IRAP) approach describes the ongoing prioritization activity for chemicals and polymers. Certain substances that may be used as alternatives to dinoseb, specifically phenol, 2-methyl-4,6-dinitro- (CAS RN 534-52-1), phenol, 4-methyl-2,6-dinitro- (609-93-8), and phenol, 2,4-dinitro- (CAS RN 51-28-5) were evaluated as part of the 2017 IRAP review. The recommended outcome for these three substances as a result of this review process is further data gathering (IRAP, 2019). Other potential alternatives or substances that are structurally similar to dinoseb, such as Phenol, 2-(1-methylpropyl)dinitro- (CAS RN 1344-30-5), 1,2-Benzenediol, 4-(1,1-dimethylethyl)- (CAS RN 98-29-3), and 1-Piperidinyloxy, 4-hydroxy-2,2,6,6-tetramethyl- (CAS RN 2226-96-2) may be considered in future IRAP reviews.

As indicated in this Risk Management Scope for dinoseb, other activities to track commercial use patterns associated with styrene monomer production or more broadly, with additives in the chemical sector, are being considered.

#### 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, 2021a) 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, where possible).

#### 6.3 Socio-economic context

Socio-economic factors have been considered in the selection process for the instrument respecting preventive or control actions, and in the development of the risk management objective. Socio-economic factors as identified in the *Cabinet Directive on Regulation* (Canada, 2018d), Red Tape Reduction Action Plan (Canada, 2012b) and the *Red Tape Reduction Act* (Canada, 2015) will be considered in the development of the instrument.

Styrene is one of the highest-volume commodity chemicals traded, with about 30% of global annual production traded internationally. It is also a global undifferentiated commodity product, which makes the styrene market very price-competitive.

North American styrene supply comes mainly from the United States. There are six producers in North America with a total capacity of around 5.9 million metric tons. There are two producers of styrene in Canada – Shell Canada in Scotford, Alberta and INEOS Styrolution in Sarnia, Ontario – with a combined annual capacity of 881,000 metric tons and annual production of 693,000 metric tons. The two Canadian styrene plants satisfy domestic demand and then export the remaining volume to the United States. Most of the styrene produced in Canada is exported (597 000 metric tons or 86% of total domestic production) to the United States; there is a small demand of styrene in Canada directed to expandable polystyrene (EPS) and unsaturated polyester resin (UPR) production.

INEOS Styrolution is the largest styrene producer in the world, operating three plants in North America and three plants in Western Europe (Belgium), for over 2.2 million metric tons of worldwide capacity.

## 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 discontinued 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  $\mu$ g/L for irrigation water (46  $\mu$ g/L for cereals, tame hays and pastures, 93  $\mu$ g/L for legumes, and 16  $\mu$ g/L for other crops), and 150  $\mu$ g/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  $\mu$ g/L<sup>7</sup> 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).

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

<sup>&</sup>lt;sup>7</sup> This value and the PNEC were derived from the same study, but different assessment factors were applied.

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 United States 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 listed in Annex III of the Rotterdam Convention subject to the prior informed consent procedure (PIC) (UNEP, 2010). In the European Union (EU), the 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 EU, the Rotterdam Convention on prior informed consent procedure for certain hazardous chemicals and pesticides in international trade.

As a whole, Canada aligns with the United States on dinoseb. In the United States, all pesticide uses of dinoseb were cancelled in 1986 as a result of reproductive effects on humans (US EPA, 1986). It is not a registered pesticide under The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (US EPA, 2020). The Safe Drinking Water Act (SDWA) in the United States specifies the maximum contaminant level (MCL) for dinoseb at 7  $\mu$ g/L (US EPA, 2017a). 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 United States, 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).

Canada aligns to a certain extent with the EU on dinoseb. In the 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 (European Union, 2009). In the EU, dinoseb is prohibited in cosmetic products. In Canada, dinoseb is not listed under the Cosmetic Ingredient Hot List, however, it was not notified as an ingredient in cosmetic products in Canada according to the Cosmetic Notification System

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).

## 8. Next Steps

#### 8.1 Public Comment Period

Industry and other interested parties are invited to submit comments on the content of this Risk Management Approach or other information that would help to inform decision-making (such as outlined in section 3.5. Please submit additional information and comments prior to April 7, 2021.

Comments and information submissions on the Risk Management Approach should be submitted to the address provided below:

Environment and Climate Change Canada Gatineau, Quebec K1A 0H3

Telephone: 1-800-567-1999 (in Canada) or 819-938-3232

Fax: 819-938-3231

Email: eccc.substances.eccc@canada.ca

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

Following the public comment period on the Risk Management Approach document, the Government of Canada will initiate the development of the specific risk management instrument(s), where necessary. Comments received on the Risk Management Approach document will be taken into consideration in the selection or development of these instrument(s). Consultation will also take place as instrument(s) are developed.

## 8.2 Timing of Actions

Electronic consultation on the Risk Management Approach: February 6, 2021 to April 7, 2021.

Publication of responses to public comments on the Risk Management Approach document: Concurrent to the publication of the proposed instrument(s).

Publication of the proposed instrument(s): At the latest, 24-month from the date on which the Ministers recommended that dinoseb be added to Schedule 1 of CEPA.

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

Publication of the final instrument(s): At the latest, 18-month from the publication of each proposed instruments.

These are planned timelines, and are subject to change. Please consult the <u>schedule of risk management activities and consultations</u> for updated information on timelines.

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## **ANNEX A. Synonyms and Trade Names**

CAS RN	DSL Name (English)	Common Name/Simplified Name	Chemical Formula	Substance Category
88-85-7	Phenol, 2-(1- methylpropyl)- 4,6-dinitro	Dinoseb/DNBP	C <sub>10</sub> H <sub>12</sub> N <sub>2</sub> O <sub>5</sub>	dinitrophenols