Government of Canada / Gouvernement du Canada

Risk Management Scope

for

Crude tall oil (CTO)

Chemical Abstracts Service Registry Number (CAS RN):

8002-26-4

Environment and Climate Change Canada

Health Canada

June 2019

Canada

Summary of proposed risk management

This document outlines the risk management options under consideration for crude tall oil from the Resins and Rosins Group, which has been proposed to be harmful to the environment.

The draft Screening Assessment Report (dSAR) for the Resins and Rosins Group proposes to conclude that there is risk of harm to the environment from tall oil as it meets criteria under paragraph 64(a) of the Canadian Environmental Protection Act, 1999 (CEPA). More information on the draft Screening Assessment Report is available at here.

Under the Domestic Substances List, tall oil (CAS RN 8002-26-4) covers two substances usually referred to in Canada as crude tall oil (CTO) and distilled tall oil (DTO).Exposure scenarios for the manufacturing of crude tall oil (CTO) indicate that there is a risk to aquatic organisms. As such, proposed risk management measures would focus on potential releases of CTO.

In particular, the Government of Canada is considering implementing regulatory and non-regulatory controls to prevent or minimize releases of CTO to the aquatic environment.

Moreover, because certain data gaps remain, the following information should be provided (ideally on or before August 21, 2019) to the contact details identified in section 8 of this document, to inform risk management decision-making:

1. Best management practices and technologies in place to reduce the risk of CTO releases to the aquatic environment from CTO manufacturing facilities;
2. Data on potential CTO releases to wastewater from CTO manufacturing facilities;
3. Efficiency of wastewater treatment methods in removing CTO from wastewater;
4. Presence of CTO in the Canadian environment, especially surface water, wastewater and sediment.

Risk management options may evolve based on the conclusions of the final screening assessment report, or as a result of risk management actions published for other Chemicals Management Plan substances. This is to ensure effective, coordinated, and consistent risk management decision-making.

Note: The above summary is an abridged list of options under consideration to manage CTO 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 option(s) might evolve through consideration of additional information obtained from the public comments period, literature and other sources.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Government of 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[1,2], and if so to manage the associated risks.

As part of the third phase of the Chemicals Management Plan, the Ministers are presently working to assess and manage, where appropriate, the potential health and ecological risks associated with approximately 1550 substances (Government of Canada, 2016).

The substance tall oil, Chemical Abstracts Service Registry Number (CAS RN[3]) 8002-26-4, is included in the Resins and Rosins Group of the third phase of the Chemicals Management Plan (Government of Canada, 2016). As previously mentioned, tall oil covers two substances usually referred to in Canada as crude tall oil (CTO) and distilled tall oil (DTO).

2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint screening assessment of the Resins and Rosins Group, including information relevant to the evaluation of CTO in Canada. A notice summarizing the scientific considerations of the draft Screening Assessment Report for the Resins and Rosins Group, including CTO, was published in the *Canada Gazette*, Part I, on June 22, 2019 (ECCC, HC, 2018). For further information on the draft Screening Assessment Report for Resins and Rosins Group, including CTO, refer to the draft screening assessment.

[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 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.

[3] 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 Draft screening assessment report conclusion

On the basis of the information available, the draft Screening Assessment Report proposes that tall oil is toxic under section 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 (ECCC, HC, 2018).

Under the Domestic Substances List, tall oil (CAS RN 8002-26-4) covers two substances usually referred to in Canada as crude tall oil (CTO) and distilled tall oil (DTO). Exposure scenarios for the manufacturing of crude tall oil (CTO) indicate that there is a risk to aquatic organisms. However, the draft Screening Assessment Report indicates there is low risk of harm to the environment from distilled tall oil (DTO). As such, proposed risk management described in this document focuses on CTO. Nonetheless, considering there may be a concern to the environment if exposure of DTO were to increase, follow-up activities to track changes in exposure or commercial use patterns are under consideration.

Most components of CTO are moderately persistent in water, and are expected to be moderately to highly persistent in sediments. CTO representative components show low to moderate bioconcentration overall, while certain CTO components are predicted to have a high bioaccumulation potential. However, components of CTO also occur naturally from plants, and thus, near continuous background exposure is likely present in many aquatic environments (ECCC, HC, 2018). For more information on persistence and bioaccumulation potential for CTO components, please refer to the draft Screening Assessment Report.

The exposure sources of concern, identified in the draft Screening Assessment Report, are based on the potential release of CTO from its manufacturing. As such, this document will focus on this activity as the exposure source of concern (refer to section 5).

2.2 Proposed recommendation under CEPA

On the basis of the findings of the draft screening assessment conducted as per CEPA, the ministers propose to recommend that crude tall oil be added to the List of Toxic Substances in Schedule 1 of the Act][4].

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.

If the ministers finalize the recommendation to add crude tall oil to Schedule 1, a risk management instrument must be proposed within 24 months from the date

[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.

on which the final Screening Assessment Report is published, and finalized within 18 months from the date on which the risk management is proposed, 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 this substance, the proposed environmental objective is to minimize the presence of crude tall oil in the aquatic environment to levels that would prevent or minimize the effects on the aquatic environment. The aquatic predicted no-effect concentrations (PNECs) for CTO in surface water may be used as a goal to achieve this objective.

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 is to prevent or minimize releases of crude tall oil in the final effluent of pulp and paper facilities to a level that is protective of the aquatic environment, taking into account technical and economic feasibility and consideration of socio-economic factors.

The risk management actions outlined in this document may evolve based on the conclusions of the final screening assessment report, or as a result of risk management actions published for other Chemicals Management Plan substances. This is to ensure effective, coordinated, and consistent risk management decision-making.[5]

[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) and Red Tape Reduction Action Plan (TBS, 2012b). Of note, the Government of Canada has introduced the "One-for-One" Rule and the Small Business Lens (TBS, 2012b). The "One-for-One" Rule and the Small Business Lens apply only to regulations. Depending on the risk management

Such objectives will be refined on the basis of consultation with stakeholders, the proposed risk management, consideration of further information received, the outcome of the final Screening Assessment Report, and socio-economic and technical considerations (such as may be 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 final Screening Assessment Report for CTO, or in subsequent risk management documents (*e.g*., consultation document on proposed instrument), as the case may be.

3.3 Proposed risk management options under consideration

To achieve the proposed risk management objective and to work towards achieving the proposed environmental objective, the proposed risk management options under consideration for crude tall oil include the implementation of regulatory and non-regulatory controls to prevent or minimize releases of CTO to the aquatic environment.

3.4 Risk management information gaps

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

1. Best management practices and technologies in place to reduce the risk of CTO releases to the aquatic environment from CTO manufacturing facilities;
2. Data on potential CTO releases to wastewater from CTO manufacturing facilities;
3. Efficiency of wastewater treatment methods in removing CTO from wastewater;
4. Presence of CTO in the Canadian environment, especially surface water, wastewater and sediment.

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instrument(s) selected for these substances, the “One-for-One” Rule and/or the Small Business Lens may apply.

The “One-for-One” Rule is designed to control the overall administrative burden on Canadian business. The Rule will reduce administrative burden in two ways: first, by removing an existing regulation if a new regulation introduces administrative burden and second, when a new regulation or amendment increases administrative burden, that an equal amount of administrative burden is reduced from an existing regulation.

The purpose of introducing a Small Business Lens is to ensure that the specific needs of small businesses are considered and that the least burdensome but most effective approach to addressing these needs is identified.

Should stakeholders have further information to help address these gaps, they should provide it ideally on or before August 21, 2019 to inform the risk management decision-making process, within the timelines (and to the contact) identified in section 8 of this document.

4. Background

4.1 General information on tall oil and crude tall oil

Tall oil is a generic term which refers to a resinous liquid obtained as a byproduct in the manufacture of chemical wood pulp. Under the Domestic Substances List, tall oil (CAS RN 8002-26-4) covers two substances usually referred to in Canada as crude tall oil (CTO) and distilled tall oil (DTO).

CTO and DTO are considered to be substances of Unknown or Variable Composition, Complex Reaction Products or Biological Materials (UVCB) (ECCC, HC, 2018).

Most of the Resins and Rosins Group substances are derivatives from CTO, which is a co-product of Kraft pulping of coniferous wood (including pine) formed by acidifying black liquor soap skimmings with sulfuric acid. This is usually done in the pulp mill facilities (NCASI 2017).

CTO is a dark oily liquid with 26–42% resin acids (represented by abietic acid, isopimaric acid (IPA), and dehydroabietic acid (DHA)), 36–48% fatty acids (e.g., linoleic acid), and 10–38% neutral compounds (represented by β-sitosterol, abietinol and abietinal) (Huibers 2000). Variability in composition may be due to both the pulpwood variability (e.g. tree species used) and the process/operational conditions. Canadian CTO typically contains a higher amount of neutral compounds compared to that from the US (ECCC, HC, 2018).

Distilled tall oil (DTO) is produced as a product of CTO distillation. (Zinkel and Russell 1989). DTO consists of 25–30% resin acids (represented by abietic acid, IPA, and DHAA), 60-70% fatty acids (represented by linoleic acid), and 2-6% neutrals (represented by β-sitosterol and abietinol, however, the neutrals fraction of DTO has not been characterized) (Holmbom et al. 2010).

In the United States, the substance identified under CAS RN 8002-26-4, named tall oil, is defined as “A complex combination of tall oil rosin and fatty acids derived from acidulation of crude tall oil soap and including that which is further refined. Contains at least 10% rosin” (US EPA, 2018a).

In Europe, under ECHA registry, two substance identifiers refer to CAS RN 8002-26-4. EC 232-304-6, defined as “A complex combination of tall oil rosin and fatty acids derived from acidulation of crude tall oil soap and including that which is further refined. Contains at least 10% rosin” (ECHA, 2018a), refers to distilled tall oil (DTO). The substance identified under EC 931-433-1, and defined as “Crude

Tall Oil (CTO), is obtained from the wood pulping industry. It is a dark brown viscous liquid extracted and processed from softwoods and hardwoods. CTO has a complex composition of fatty acids, resin acids, and neutrals". EC 931-433-1 has no associated CAS RN number under ECHA (ECHA, 2018b).

While CTO (CAS RN 8002-26-4) is named differently in various jurisdictions, these names are generally understood to refer to the same UVCB substance.

4.2 Current use(s) and identified sector(s)

As mentioned in Section 4.1, Crude tall oil is a co-product of Kraft pulping of coniferous wood (including pine). CTO may serve as a source material for several downstream products manufactured through fractional distillation of CTO. CTO refining is not known to occur currently in Canada; however, the downstream products of CTO are imported into Canada. Based on information received during stakeholder engagement, some facilities sell the resulting CTO while others burn it onsite for fuel (ECCC, HC, 2018).

In addition, CTO that is imported into Canada may have various commercial and industrial applications, and may be used as raw material for oil and gas drilling applications (ECCC, HC, 2018).

5. Exposure source and identified risk

The major sources of releases for CTO to the environment are related to manufacturing and industrial uses in Canada. Potential releases of concern occur primarily to surface water.

Exposure scenarios were developed for the manufacturing and industrial use of CTO. Risk quotient analyses were conducted to compare estimated aquatic concentrations to adverse effect concentrations assuming a concentration addition of the components of the UVCBs in aquatic organisms for different exposure scenarios.

Based on the analysis of sources and use information along with relevant monitoring data, CTO is anticipated to be released to water from the CTO manufacturing process at Kraft pulping or stand-alone facilities in Canada. Releases of concern occur primarily to surface water where certain components may transfer to sediments via partition from overlying water (ECCC, HC, 2018). Exposure scenarios for the commercial and industrial uses of CTO did not indicate that there is a risk to aquatic organisms.

Components of CTO could have non-specific (i.e. narcotic) or compound-specific effects on sediment and aquatic organisms at low concentrations of exposure.

6. Risk management considerations

6.1 Alternatives and alternate technologies

No alternative technologies were identified for CTO production from tall oil soap (acidulation process), at Kraft pulping facilities.

As CTO is a co-product that is formed during the Kraft pulping process, consideration of alternatives is not relevant as there is no possibility of substituting it with another substance in that industrial process.

6.2 Socio-economic and technical considerations

Socio-economic factors will be considered in the selection and development of any regulation, 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

Effluents from pulp and paper mills are regulated by the *Pulp and Paper Effluent Regulations* (PPER) under the *Fisheries Act*. These regulations establish effluent release limits for biochemical oxygen demand (BOD) and total suspended solids (TSS), and prohibit the discharge of acutely lethal effluent to fish. Although CTO is not within the prescribed list of deleterious substances of the PPER, the level of wastewater treatment required to meet the PPER requirements may also remove organic substances such as CTO.

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

7.2 Pertinent international risk management context

7.2.1 United States

In the United States, tall oil (CAS RN 8002-26-4) has active commercial status under the Toxic Substances Control Act (TSCA) Inventory. In addition, tall oil is also listed on the US High Production Volume Challenge Program List (HPVC List) and under the High Production Volume / Voluntary Children Chemical Evaluation Program Information (HPVIS) (US EPA, 2018a).

Tall oil is listed under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), under the List 3 - Inerts[6] of unknown toxicity (US EPA, 2018a, 2018b).

7.2.2 Europe

Tall oil (CAS RN 8002-26-4 / EC 232-304-6) is registered under the European Union's Registration, Evaluation, and Authorization of Chemicals (REACH) (ECHA, 2018a).

Under the ECHA Classification and Labelling, Tall oil has been classified with no hazards but may cause an allergic skin reaction according to the notifications provided by companies to ECHA in REACH registrations (ECHA, 2018a).

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 (such as outlined in section [3.2 (and/or) 3.3]). Please submit additional information and comments prior to August 21, 2019.

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 final Screening Assessment Report. 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
Gatineau, Quebec K1A 0H3
Telephone: 1-800-567-1999 (in Canada) or 819-938-3232
Fax: 819-938-5212

[6] *Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), all pesticides sold or distributed in the United States must be registered with EPA. Because of concern that some inert ingredients might also cause adverse effects to humans and the environment, EPA outlined its strategy for regulating inert ingredients in 1987. EPA categorized inert ingredients into four toxicological categories; List 1-Inerts of toxicological concern, List 2-Potentially toxic inerts/high priority for testing, List 3-Inerts of unknown toxicity, and List 4-Inerts of minimal concern. In 1989, EPA subdivided List 4 into two lists. List 4 became List 4A, representing minimal risk inert ingredients. List 4B was created to represent inert ingredients for which EPA had sufficient data to conclude that their current use patterns in pesticide products will not adversely affect the environment. Substances without Chemical Abstracts Service (CAS) Registry Numbers have not been added to the Chemical Registry.* (US EPA, 2018c).

Email: mailto:eccc.substances.eccc@canada.ca

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

8.2 Timing of actions

Electronic consultation on the draft screening assessment report and Risk Management Scope: June 22, 2019 to August 21, 2019.This should include the submission of public comments, additional studies or information on CTO.

Publication of responses to public comments on the draft screening assessment report and Risk Management Scope: concurrent to the publication of the screening assessment and, if required, the Risk Management Approach document.

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 date on which the Ministers recommended that CTO be added to Schedule 1 of CEPA.

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

9. References

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