



**Risk Management Scope**  
**for**  
**TPAE-1**  
**of the Thiophosphate Alkyl Ester Group**

**Chemical Abstract Service Registry Number**  
**(CAS RN): 91745-46-9**

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Environment and Climate Change Canada

Health Canada

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## Summary of proposed risk management

This document outlines the risk management options under consideration for reaction products of 4-methyl-2-pentanol and diphosphorus pentasulfide, propoxylated, esterified with diphosphorus pentoxide, and salted by amines, C12-14- tert—alkyl (CAS RN 91745-46-9, CAN 11145-3), hereinafter referred to as TPAE-1, which has been proposed to be harmful to the environment.

The Government of Canada is considering regulatory and non-regulatory options for the metalworking fluid sector such as environmental release guidelines (section 54 of CEPA), codes of practice (section 54 of CEPA), pollution prevention planning notices (section 56 of CEPA), and regulations (section 93 of CEPA) to minimize the release of the TPAE-1 into the aquatic and terrestrial environments.

Metalworking fluids are oils and other liquids that are used to cool and /or lubricate metal when it is being machined, ground, milled, or manipulated in another way. The metalworking fluid sector is composed of users of metalworking fluids. This includes facilities that manufacture metal products or machinery, and those that are involved in the rebuilding and/or maintenance of these products.

To inform risk management decision-making, information on the following topics should be provided (ideally on or before May 12, 2021), to the contact details identified in section 8 of this document:

- Existing best practices to prevent the release of metalworking fluids to wastewater;
- Potential non-toxic alternatives for TPAE-1 as an anti-wear and extreme pressure additive in metalworking fluids; and
- Analytical methods to measure the concentrations of the alkyl (di)thiophosphate components in surface water, or the aliphatic amine components in surface water or soil.

The risk management options outlined in this Risk Management Scope 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 options under consideration 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 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 the Minister of Health (the ministers) to conduct assessments to determine if substances are harmful to the environment or human health as set out in section 64 of CEPA<sup>1,2</sup>, and if so to manage the associated risks.

The substance reaction products of 4-methyl-2-pentanol and diphosphorus pentasulfide, propoxylated, esterified with diphosphorus pentoxide, and salted by amines, C12-14- tert—alkyl (CAS RN 91745-46-9, CAN 11145-3) is hereinafter referred to as TPAE-1. TPAE-1 is also called amines, C12-14-alkyl, reaction products with hexanol, phosphorus oxide (P<sub>2</sub>O<sub>5</sub>), phosphorus sulfide (P<sub>2</sub>S<sub>5</sub>) and propylene oxide and is included in Thiophosphate Alkyl Esters Group of the Chemicals Management Plan (Canada 2021).

TPAE-1 is a UVCB (unknown or variable composition, complex reaction products, or biological materials). More specifically, TPAE-1 is an alkylamine salt of complex phosphate esters and contains about 10 major structures. For the purpose of this document, there are two notable groups of component of this substance: the alkyl (di)thiophosphate components, which include various alkyl thiophosphates and alkyl dithiophosphates, most of which have a negatively charged phosphate ion, and the aliphatic amine components, which are primary C12-C14 tert-alkyl amines, and have a positively charged amine ion (Canada 2021).

## 2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment of TPAE-1 in Canada. A notice summarizing the scientific considerations of the draft screening assessment for this substance was published in the *Canada Gazette*, Part I, on March 13, 2021 (Canada 2021). For further information, refer to the [draft screening assessment for the Thiophosphate Alkyl Esters Group](#).

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<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*

- (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.*

<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 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 TPAE-1 is toxic under section 64 (a) of CEPA because it may be entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity (Canada 2021).

The draft screening assessment also proposes that TPAE-1 meets 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).

The exposure source of concern identified in the draft screening assessment is the potential release of TPAE-1 to surface water and soil from its use in metalworking fluids. As such, this document will focus on this exposure source (refer to section 5).

Two substances were assessed under the Thiophosphate Alkyl Esters Group. The draft screening assessment proposes that phosphorothioic acid, O,O-dibutyl ester, mixed (C8,C16,C18) alkylamine salt, hereinafter referred to as TPAE-2, does not meet any of the criteria set out in section 64 of CEPA. Based on current levels of exposure, there is low risk of harm to the environment from TPAE-2. However, this substance has a similar hazard profile to TPAE-1.

## 2.2 Proposed recommendation under CEPA

On the basis of the findings of the draft screening assessment, the ministers propose to recommend that TPAE-1 be added to the List of Toxic Substances in Schedule 1 of the Act<sup>3</sup>.

The ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment for the Thiophosphate Alkyl Esters Group and this Risk Management Scope document.

If the ministers finalize the recommendation to add TPAE-1 to Schedule 1, risk management instruments must be proposed within 24 months from the date on which the ministers recommended that TPAE-1 be added to Schedule 1 of CEPA, and finalized within 18 months from the date on which the risk management instruments are proposed, as outlined in sections 91 and 92 of CEPA (refer to section 8 for publication timelines applicable to this group of substances).

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<sup>3</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 substance, add the substance to the Priority Substances List for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act.

## 3. Proposed risk management

### 3.1 Proposed environmental objectives

Proposed environmental objectives are quantitative or qualitative goals to address environmental concerns.

For this substance, the proposed objectives address the exposure sources of concern outlined in section 5 of this document. The proposed environmental objectives for TPAE-1 are to:

- reduce the concentration of TPAE-1 in surface water to levels protective of aquatic organisms such that the concentration of all of the alkyl (di)thiophosphate components together are below the aquatic predicted no-effect concentration (PNEC) of 5.5 µg/L and that the concentration of all of the aliphatic amine components together are below the aquatic PNEC of 0.22 µg/L; and
- reduce the concentration of TPAE-1 in soil to levels protective of soil organisms such that the concentration of all of the aliphatic amine components together are below the soil PNEC of 1 mg/kg dry wt.

The environmental objective for soil does not include a quantitative objective for the alkyl (di)thiophosphate components because no empirical or modelled soil toxicity data were available for these components, and therefore it was not possible to derive a soil PNEC for the alkyl (di)thiophosphate components (Canada 2021).

### 3.2 Proposed risk management objective

Proposed risk management objectives set quantitative or qualitative targets for risk management regulations, instruments and/or tools. The proposed risk management objective for TPAE-1 is to minimize the release of TPAE-1 from the use of metalworking fluids, such that concentrations in final effluents released to surface water are protective of aquatic organisms. This risk management objective would work towards achieving both environmental objectives described in Section 3.1. Reducing the release of TPAE-1 would reduce the concentration that enters wastewater treatment plants, and therefore would lead to reductions of concentration in both effluent and biosolids that may be applied to agricultural fields as a soil amendment.

This objective will be refined on the basis of stakeholder consultation and new information, the proposed risk management, the outcome of the screening assessment, and socio-economic and technical considerations (refer to section 6). If the final screening assessment confirms that TPAE-1 is harmful to the environment, environmental and risk management objectives will be revised where needed and presented in the Risk Management Approach document that will be published concurrently with the screening assessment.

### 3.3 Proposed risk management options under consideration

To achieve the proposed risk management objective and to work towards achieving the proposed environmental objectives, the following regulatory and non-regulatory risk management options are being considered for TPAE-1 for the metalworking sector: environmental release guidelines (section 54 of CEPA), codes of practice (section 54 of CEPA), pollution prevention plans (section 56 of CEPA), and regulations (section 93 of CEPA). ECCC will consult with stakeholders during the development of the selected instrument(s).

Metalworking fluids are oils and other liquids that are used to cool and /or lubricate metal when it is being machined, ground, milled, or manipulated in another way. The metalworking fluid sector is composed of users of metalworking fluids. This includes facilities that manufacture metal products or machinery, and those that are involved in the rebuilding and/or maintenance of these products.

Environmental Release Guidelines under section 54 of CEPA are voluntary instruments that set out recommended limits (expressed as concentrations or quantities) to releases of substances into the environment from works, undertakings or activities. They set out official national guidelines that should be followed by those subject to them. They can be used to control any aspect of a substance's life-cycle, from its manufacture to its use, storage, transport, release and ultimate disposal. Release guidelines are flexible instruments in the sense that they provide:

- A choice in the approach to achieve the limit;
- Flexibility in terms of jurisdictional cooperation, considerations and convergence; and
- Adaptability at any level of government, by industry and internationally.

Codes of practice, under section 54 of CEPA, are voluntary instruments that identify recommended procedures and practices or environmental controls relating to works, undertakings, and activities, including any subsequent monitoring activities. These set out official national standards that companies and organizations should follow.

Pollution prevention planning is a process to examine current operations and develop a mandatory plan to eliminate or reduce pollution at the source. By developing a pollution prevention plan, under section 56 of CEPA, entities are able to identify options according to the environmental protection hierarchy (prevention, reuse/recycle, treatment, control, waste disposal), evaluate these options and implement them within a specified period. Pollution prevention planning places emphasis on identifying the most cost effective options, including those where facilities can see a return on investment.

Regulations under section 93 of CEPA impose restrictions on an activity related to a substance specified in Schedule 1. Under this section, limits on the

concentrations of a substance for use, release to the environment, or presence in a product could be set.

Note that these 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 other sources will be considered in the instrument selection and development process<sup>4</sup>. The risk management options may also evolve through consideration of assessments and risk management options or actions published for other CMP substances (such as long-chain aliphatic amines, which includes one of the components of TPAE-1, and 2-mercaptobenzothiazole and its precursors, which is also used in the metalworking sector) 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>5</sup>. The aim is to determine whether human health and/or environmental objectives have been met and whether there is a need to revisit the risk management approach for that substance. In evaluating progress and revisiting risk management, as warranted, these activities together will aim to manage risks effectively over time. To achieve this, the Government of Canada plans to review the effectiveness of the risk management actions for TPAE-1.

The Government of Canada plans to measure the effectiveness and progress of the risk management actions towards meeting the risk management and environmental objectives. The Government of Canada plans to collect and analyze data, such as data on the presence of TPAE-1 in surface water and soil in order to establish a baseline environmental presence, and again over time to measure progress.

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.

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<sup>4</sup> 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 Regulation (TBS, 2018), the Red Tape Reduction Action Plan (TBS, 2012), and in the case of a regulation the *Red Tape Reduction Act* (Canada, 2015).

<sup>5</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
- 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).

### **3.5 Risk management information gaps**

Interested stakeholders can provide further information to inform risk management decision-making regarding TPAE-1, including:

- Existing best practices to prevent the release of metalworking fluids to wastewater;
- Potential non-toxic alternatives for TPAE-1 as an anti-wear and extreme pressure additive in metalworking fluids; and
- Analytical methods to measure the concentrations of the alkyl (di)thiophosphate components in surface water, or the aliphatic amine components in surface water or soil.

Stakeholders that have information to help address these data gaps should provide it on or before May 12, 2021 to the address identified in section 8.

## **4. Background**

### **4.1 Current uses and identified sectors**

TPAE-1 is used in lubricant products including metalworking fluids, automatic transmission fluids, industrial hydraulic and gear oils, and greases (ECCC 2015, 2018). According to information submitted in response to a CEPA section 71 survey, TPAE-1 was reported to be imported into Canada in quantities between 100 000 to 1 000 000 kg in 2011 but was not reported to be manufactured in Canada at a reporting threshold of 100 kg (ECCC 2015).

#### **4.1.1 Metalworking fluids**

Metalworking fluids are used in operations designed to alter a metalwork piece through formation and removal of chips. Metal removal operations include all forms of cutting and grinding. Metal forming operations include all forms of stamping, forming, and extruding (Independent Lubricant Manufacturers Association 1990).

TPAE-1 is used as an additive in metalworking fluids to provide anti-wear or extreme pressure protection (ECCC 2015). These metalworking fluids can be used in various industries including aviation, shipbuilding, automotive, electronic equipment manufacturing, transportation, etc.

#### **4.1.2 Lubricant oils**

TPAE-1 is used as an additive in lubricant oils (e.g., in automotive or industrial gear oils, hydraulic oils, compressor oils and engine oils) to provide anti-wear or extreme pressure protection (ECCC 2015). The spent lubricant oils are expected to be collected and disposed of in accordance with provincial and territorial requirements, such as those that require recycling of the used oils (ECCC 2019).

### **4.1.3 Greases**

Thiophosphate alkyl esters such TPAE-1 are used as additives for anti-wear or extreme pressure protection in greases. Greases are semi-solid lubricants that have higher viscosity than liquid lubricants. They are used on equipment that can be lubricated infrequently and where a lubricating oil would not stay in position.

## **5. Exposure sources**

The exposure source of concern identified in the draft screening assessment is from metalworking fluids that may be rinsed off from metalworking processes. These metalworking fluids may enter into wastewater streams and be discharged to wastewater treatment systems. This could lead to TPAE-1 in surface water and/or soil, as biosolids produced from wastewater treatment systems may be applied to agricultural fields as a soil amendment. Some spent oil-based metalworking fluids may be collected and disposed of when they are no longer suitable for service.

TPAE-1 used in lubricant oils (e.g., in automotive or industrial gear oils, hydraulic oils, compressor oils and engine oils for light duty trucks) and greases are not expected to be an exposure source of concern. Lubricant oils and greases will either be recycled or incinerated and are therefore not expected to be released to the environment. There are provincial regulations that require recycling of used lubricating oils (ECCC 2019). Environment and Climate Change Canada's report entitled "Follow Up on the Final Decision on the Assessment of Releases of Used Crankcase Oils (UCOs) to the Environment" summarizes provincial and territorial risk management measures in place regarding used crankcase oils. (Environment Canada 2011).

## **6. Risk management considerations**

### **6.1 Alternatives and alternate technologies**

The potential alternatives presented in this section have not been evaluated to determine whether they are safe or environmentally sustainable, and it is understood that not all alternatives may be appropriate or provide the equivalent result in quality or stability to a product. It should also be noted that TPAE-1 can only be measured in the environment as the aliphatic amine or alkyl (di)thiophosphate components. Some of the alternatives listed below have not been assessed under CEPA but may contain one of these components, and therefore may contribute to the presence of these components in the environment if released. Table 6-1 provides a non-exhaustive list of substances that can be used as anti-wear and extreme pressure additives.

**Table 6-1. Potential alternatives for TPAE-1 as a metalworking fluid additive**

<b>Alternative</b>	<b>Type of Additive</b>	<b>Comments</b>
zinc dithiophosphates <sup>a</sup>	Anti-wear	Contains alkyl dithiophosphate components
acid phosphates <sup>a</sup>	Anti-wear	
chlorine compounds <sup>a</sup>	Anti-wear	
sulfides and disulfides <sup>a</sup>	Anti-wear	
molybdenum complexes of 1-aryl-2,5-dithiohydrazodicarbonamid <sup>b</sup>	Extreme pressure	
chlorinated or sulfurized hydrocarbons <sup>c</sup>	Extreme pressure	
organo-phosphorus compounds (e.g. metal dialkyl dithiophosphates, phosphates, etc.) <sup>d</sup>	Anti-wear and extreme pressure	Metal dialkyl dithiophosphates contain alkyl dithiophosphate components
organo-sulphur compounds (e.g. disulphides, dialkyl mono, di, or polysulphides, sulphurised olefins, sulphurised fats, and dithiocarbamates) <sup>d</sup>	Anti-wear and extreme pressure	
organo-chloro compounds (e.g. chlorinated alkanes) <sup>d</sup>	Anti-wear and extreme pressure	
carbon nanotori dispersed in distilled water <sup>e</sup>	Anti-wear and extreme pressure	

<sup>a</sup> Reference is (Noria Corporation 2019)

<sup>b</sup> Reference is (Rastogi, Yadav & Bhattacharya 2002)

<sup>c</sup> Reference is (Lara, Kotvis & Tysoe 1997)

<sup>d</sup> Reference is (Forbes 1970)

<sup>e</sup> Reference is (Peña-Parás et al. 2019)

It should be noted that another substance in the thiophosphate alkyl ester group, TPAE-2, may also be used as an anti-wear additive in lubricants. While this substance contains the aliphatic amine and alkyl thiophosphate components, it was not proposed toxic under section 64 of CEPA due to a low risk for exposure, as it is not known to be currently used in metalworking fluids in Canada. Changes in use patterns for TPAE-2, such as using it as an alternative for chemicals with similar uses or functions, could lead to a higher risk of exposure. For this reason, follow-up activities to track changes in exposure or use patterns for TPAE-2 are being considered.

## **6.2 Socio-economic and technical considerations**

Socio-economic factors will be considered in the selection process for a regulation or instrument respecting preventive or control actions, and in the development of the risk management objective(s) as per the guidance provided in the Treasury Board document Assessing, Selecting, and Implementing Instruments for Government Action (Treasury Board of Canada Secretariat 2007).

In addition, socio-economic factors will be considered in the development of regulations, instrument(s) or tool(s), to address risk management objective(s), as identified in the Cabinet Directive on Regulation (Canada 2018) and Red Tape Reduction Action Plan (Canada 2012) and the Red Tape Reduction Act (Canada 2015).

## **7. Overview of existing risk management**

There does not appear to be specific risk management actions for TPAE-1 domestically or internationally. However, there are risk management actions for lubricant oils in place that apply to this substance as discussed in section 5.

### **7.1 Related Canadian risk management context**

Currently there is no specific risk management for this substance in Canada.

### **7.2 Pertinent international risk management context**

#### **7.2.1 The United States**

Currently there is no specific risk management for this substance in the United States. However, there are regulations applying generally to metalworking fluids. Metalworking fluids containing certain amines must not contain, or require the addition of, nitrosating agents as per 40 CFR 747.115, 40 CFR 747.195 and 40 CFR 747.200. ASTM International has a “Standard Practice for Safe Use of Water-Miscible Metal Removal Fluids” covering product selection, storage, dispensing, and maintenance (ASTM International 2017). Additionally, there are local sewer discharge standards that apply to used water-based metalworking fluids. These discharge standards vary depending on the region and focus on chemical oxygen demand, total suspended solids, pH, oil and grease, metals, and other inorganics (Milacron 2019).

## 7.2.2 The European Union

The European Chemicals Agency (ECHA) has assessed TPAE-1 under the REACH Regulation (EC) No 1907/2006 in 2014 (Republic of Slovenia Ministry of Health 2014). Based on this assessment, the European Union concluded that no further risk management actions were necessary for this substance.

Furthermore, metalworking fluids in general are controlled by various regulations. Regulation (EU) No 528/2012 controls the biocide component of metalworking fluids. In the United Kingdom, there is a good practice guide for Safe Handling and Disposal of Metalworking fluids that was created in collaboration with the Health and Safety Executive and industry (United Kingdom Lubricants Association 2018). Directive 2010/75/EU on industrial emissions requires facilities using metalworking fluids to control the concentration of harmful compounds released to the environment (The European Parliament and The Council of The European Union 2010). This may affect the releases of TPAE-1 to the environment.

## 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 3.5). Please submit additional information and comments prior to May 12, 2021.

The Risk Management Approach document, which will outline and seek input on the proposed risk management instruments, will be published at the same time as the screening assessment. At that time, there will be further opportunity for consultation.

Comments and information submissions on this 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  
Email: [eccc.substances.eccc@canada.ca](mailto:eccc.substances.eccc@canada.ca)

Companies who have a business interest in TPAE-1 are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding TPAE-1 and may be contacted for further information.

## **8.2 Timing of actions**

Electronic consultation on the draft screening assessment report and Risk Management Scope: March 13, 2021 to May 12, 2021. This should include the submission of public comments, additional studies, and/or information on long-TPAE-1.

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 TP AE-1 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).

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