

## **Draft Screening Assessment**

### **Thiocarbamates Group**

**Chemical Abstracts Service Registry Numbers**

**137-26-8**

**120-54-7**

**Environment and Climate Change Canada  
Health Canada**

**February 2018**

## Synopsis

Pursuant to sections 68 or 74 of the Canadian Environmental Protection Act, 1999 (CEPA), the Minister of Environment and the Minister of Health have conducted a screening assessment of two substances referred to collectively as the Thiocarbamates Group. Substances in this group were identified as priorities for assessment as they either met the categorization criteria under subsection 73(1) of CEPA or were considered a priority based on other human health concerns. The Chemical Abstracts Service Registry Numbers (CAS RN), their Domestic Substances List (DSL) names and their acronyms are listed in the table below.

### Substances in the Thiocarbamates Group

CAS RN	DSL name (acronyms)
137-26-8 <sup>a</sup>	Thioperoxydicarbonic diamide ( $[(H_2N)C(S)]_2S_2$ ), tetramethyl- (TMTD, Thiram, Thiuram)
120-54-7 <sup>b</sup>	Piperidine, 1,1'-(tetrathiodicarbonothioyl)bis- (DPTT)

<sup>a</sup> This substance has multiple uses associated with different acronyms.

<sup>b</sup> This substance was not identified under subsection 73(1) of CEPA but was included in this assessment as it was considered as a priority based on other human health concerns.

TMTD and DPTT do not occur naturally in the environment. Information obtained from DSL Inventory Update Phases 1 and 2 indicate that there was no company having manufactured either of them in Canada above the 100 kg reporting threshold. However, between 170 300 and 403 100 kg of TMTD was imported into Canada in 2008 and 150 000 kg of DPTT was imported in 2011.

TMTD is primarily used as a process regulator for manufacturing rubber products in Canada. It is used as a component in automotive parts and in sealants and adhesives. This substance is also registered as an active ingredient in pest control products in Canada (known as Thiram) and in the manufacture of a limited number of food packaging materials.

DPTT is only used as a process regulator for manufacturing rubber products in Canada.

Releases of TMTD and DPTT to surface water are expected to mainly occur as a result of discharges from wastewater treatment systems associated with rubber products manufacturing facilities.

TMTD and DPTT are expected to degrade rapidly in the environment and their potential for long-range transport is low. Bioconcentration factors based on empirical data are low for both substances; in addition, mammalian data suggest that they could undergo rapid metabolism and elimination. Current uses of these substances may only result in exposures to aquatic organisms near points of release.

Empirical data suggest that TMTD is highly toxic to aquatic organisms. DPTT does not demonstrate any effect on aquatic organisms at water solubility limits.

The ecological risk characterization for TMTD indicates that releases from current uses of this substance in manufacturing rubber products may pose a risk to aquatic organisms. The risk to aquatic organisms associated with current uses of DPTT in manufacturing rubber products is considered to be low.

Considering all lines of evidence presented in this draft screening assessment, it is proposed to conclude that TMTD meets the criterion under paragraph 64(a) of CEPA as it is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. However, it is proposed to conclude that TMTD does not meet the criterion 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.

Considering all lines of evidence presented in this draft screening assessment, it is proposed to conclude that DPTT does not meet the criteria under paragraphs 64(a) or (b) of CEPA as it is not 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 or that constitute or may constitute a danger to the environment on which life depends.

From a human health perspective, TMTD was reviewed internationally through the Cooperative Chemicals Assessment Programme of the Organization for Economic Cooperation and Development (OECD), the European Chemicals Agency in Europe (ECHA), the European Food Safety Authority (EFSA), the United States Environmental Protection Agency (US EPA), as well as by Health Canada's Pest Management Regulatory Agency (PMRA). The latter identified health effects of concern for TMTD associated with its pesticidal uses including developmental neurotoxicity and carcinogenicity. Pesticidal uses and sources of exposure to TMTD are being addressed, under the Pest Control Products Act, as part of Health Canada's re-evaluation of Thiram and will, consequently, not be addressed in this draft screening assessment.

For the general population of Canada, exposures to TMTD through environmental media from non-pesticidal uses are not expected to be a significant source of exposure, due to rapid photodegradation and hydrolysis in water, low persistence in soil, and low volatility. In Canada, TMTD is not a permitted food additive, nor is it used in any prescription or non-prescription drug, natural health product, or cosmetics. Regarding its use in the manufacture of a limited number of food packaging materials, dietary exposure from this use, if any, is expected to be negligible. Exposure to TMTD is not expected from its uses in automobiles or from rubber products since residues are not expected in the final products. In products available to the general population, exposure to TMTD from use of adhesive tape products is expected to be minimal.

DPTT was evaluated by the Threshold of Toxicological Concern (TTC)-based Approach for Certain Substances, which is based on the potential hazard of similar chemical structures as well as available chemical-specific genotoxicity data. The estimate of

exposure derived for DPTT was lower than the TTC value, indicating a low probability of risk to human health. Therefore, DPTT is considered to be a low concern for human health at current levels of exposure.

Based on the information presented in this draft screening assessment, it is proposed to conclude that TMTD and DPTT do not meet the criteria under paragraph 64(c) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Therefore, it is proposed to conclude that TMTD meets one or more of the criteria set out in section 64 of CEPA. It is proposed to conclude that DPTT does not meet any of the criteria set out in section 64 of CEPA.

TMTD is proposed to not meet the persistence or bioaccumulation criteria as set out in the Persistence and Bioaccumulation Regulations of CEPA.

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# 1. Introduction

Pursuant to sections 68 and 74 of the Canadian Environmental Protection Act, 1999 (CEPA), the Ministers of Environment and Health have conducted a screening assessment of two substances referred to collectively as Thiocarbamates to determine whether these substances present or may present a risk to the environment or to human health. These two substances were identified as priorities for assessment as they either met categorization criteria under subsection 73(1) of CEPA or were considered a priority based on other human health concerns (Canada 2006).

One of these two substances, Thioperoxydicarbonic diamide ( $[(\text{H}_2\text{N})\text{C}(\text{S})]_2\text{S}_2$ ), tetramethyl- (TMTD), was reviewed internationally through the Organisation for Economic Cooperation and Development (OECD) Cooperative Chemicals Assessment Programme (OECD 2010), the European Chemicals Agency (ECHA c2007-2015), the United States Environmental Protection Agency (US EPA 2004a and 2004b) and the European Food Safety Authority (EFSA 2016). In Canada, Health Canada's Pest Management Regulatory Agency (PMRA) reviewed this substance as an active ingredient in pesticides (Health Canada 2016a). These assessments undergo rigorous review and endorsement. Environment and Climate Change Canada and Health Canada consider these assessments as reliable and were used to inform this screening assessment.

Piperidine, 1,1'-(tetrathiodicarbonothioyl)bis- (DPTT), was included in the Health Canada Science Approach Document on the Threshold of Toxicological Concern (TTC)-based Approach for Certain Substances (Health Canada 2016b). In the approach, Health Canada used a structure-based decision tree and available chemical-specific data on genotoxicity (e.g., Ames test), to assign a human exposure threshold value for a chemical, below which there is a low probability of risk to human health (i.e., TTC value). For each substance in the TTC-based approach, potential exposure of the Canadian general population was characterized and compared to the TTC value assigned to the substance. This substance was associated with exposure lower than its assigned TTC value. Therefore, it is considered to be a low concern for human health at current levels of exposure.

This draft screening assessment includes consideration of information on physical-chemical properties, environmental fate, hazards, uses and exposure. Relevant data were identified up to October 2016. Empirical data from key studies as well as some results from predictive models were used to reach proposed conclusions.

This draft screening assessment was prepared by staff in the CEPA Risk Assessment Program at Environment and Climate Change Canada and Health Canada and incorporates input from other programs within these departments. The draft of this assessment has undergone external review and/or consultation. Comments on the technical portions relevant to the environment were received from peer reviewers invited by Environment and Climate Change Canada. While external comments were taken into

consideration, the final content and outcome of the screening assessment remain the responsibility of Environment and Climate Change Canada and Health Canada.

This draft screening assessment focuses on information critical to determining whether substances meet the criteria as set out in section 64 of CEPA, by examining scientific information and incorporating a weight of evidence approach and precaution<sup>1</sup>. The draft screening assessment presents the critical information and considerations upon which the proposed conclusions are made.

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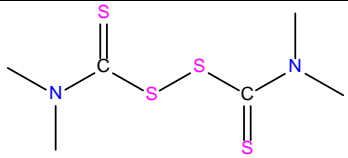
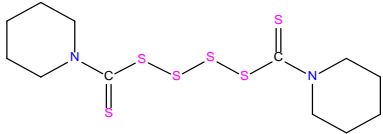
<sup>1</sup>A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products available to 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. Identity of substances

The Chemical Abstracts Service Registry Numbers (CAS RN<sup>2</sup>) and the names on the Domestic Substances List (DSL) of the two substances in the Thiocarbamates group are presented in Table 2-1. A list of additional chemical names (e.g., trade names) is available from the National Chemical Inventories (NCI 2014). For the purpose of this screening assessment report, CAS RNs 137-26-8 and 120-54-7 are referred to as TMTD and DPTT, respectively, although TMTD is also known as Thiram in toxicological literature.

**Table 2-1. Substance identities for TMTD and DPTT**

CAS RN	DSL name (acronyms)	Chemical structure, molecular formula and SMILES <sup>a</sup> string	Molecular weight (g/mol)
137-26-8	Thioperoxydicarbonic diamide [(H <sub>2</sub> N)C(S)] <sub>2</sub> S <sub>2</sub> , tetramethyl- (TMTD, Thiram, Thiuram)	 $C_6H_{12}N_2S_4$ <chem>N(C(=S)SSC(N(C)C)=S)(C)C</chem>	240.4
120-54-7	Piperidine, 1,1'- (tetrathiodicarbonothioyl)bis- (DPTT)	 $C_{12}H_{20}N_2S_6$ <chem>N(C(=S)SSSSC(N(CCCC1)C1)=S)(CCCC2)C2</chem>	384.7

<sup>a</sup> SMILES, Simplified Molecular Input Line Entry System. The SMILES strings were cited from EPI Suite v4.11.

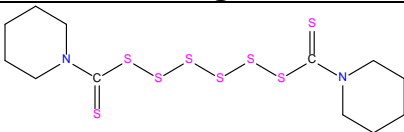
<sup>2</sup> The Chemical Abstracts Service Registry Number (CAS RN) is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

## 2.1 Selection of analogues and use of (Q)SAR models

A read-across approach using data from an analogue and the results of (Quantitative) Structure-Activity Relationship ((Q)SAR) models, where appropriate, have been used to inform the ecological assessments. The analogue was selected that was structurally similar and/or functionally similar to a substance within this group (e.g., based on physical-chemical properties, toxicokinetics), and that had relevant empirical data that could be used to read-across to the substance that was data poor. Details of the read-across data and (Q)SAR models chosen to inform the ecological assessment of DPTT are further discussed in the relevant sections of this report.

Information on the identity and the chemical structure of the analogue (CAS RN 971-15-3) used to inform this assessment is presented in Table 2-2.

**Table 2-2. Substance identity for the analogue CAS RN 971-15-3 for DPTT**

CAS RN	DSL name	Chemical structure, molecular formula, and SMILES <sup>a</sup> string	Molecular weight (g/mol)
971-15-3	Piperidine, 1,1'-(hexathiodicarbonothioyl) bis-	 $C_{12}H_{20}N_2S_8$ <chem>N(C(=S)SSSSSSC(N(CCCC1)C1)=S)(CCCC2)C2</chem>	448.8

<sup>a</sup> SMILES, Simplified Molecular Input Line Entry System. The SMILES string was cited from EPI Suite v4.11.

## 3. Physical and chemical properties

Both TMTD and DPTT are both solid at room temperature and will not volatilize. TMTD is soluble in water; while DPTT is less soluble in water. Both of them do not dissociate and remain as neutral compounds under environmental conditions (pH=6-9).

A summary of key physical and chemical properties of TMTD, DPTT and the analogue of DPTT (CAS RN 971-15-3) is presented in Tables 3-1, 3-2, and 3-3. When experimental information was limited or not available for a property for DPTT, data from the analogue were used for read-across or (Q)SAR models were used to generate predicted values for such properties.

**Table 3-1. Physical and chemical property values for TMTD**

Property	Value or range <sup>a</sup>	Reference
Melting point (°C)	144-156	ECHA c2007-2015; KEMI 2015; UH PPDB 2015; Kidd and James 1991
Boiling point (°C)	129 at 20 mmHg	Lide 2003
Vapour pressure (Pa)	$2 \times 10^{-5}$ – $2.4 \times 10^{-3}$ at 25 °C	CHRIP c2008; ECHA c2007-2015
Henry's law constant (Pa·m <sup>3</sup> /mol)	0.035 (calculated <sup>b</sup> )	Not applicable
Water solubility (mg/L)	16.5-30 at 25 °C	CHRIP c2008; HSDB 1983-
Log K <sub>ow</sub> (dimensionless)	1.73-2.1	Tomlin 2003; ECHA c2007-2015; KEMI 2015; OECD 2010
Log K <sub>oc</sub> (dimensionless)	2.83	Schuurmann et al. 2006; OECD 2010
Log K <sub>oa</sub> (dimensionless)	6.90 (modelled)	EPI Suite v4.11
pK <sub>a</sub> (dimensionless)	0.1-0.9	ACD/Percepta 2015

Abbreviations: K<sub>ow</sub>, octanol–water partition coefficient; K<sub>oc</sub>, organic carbon–water partition coefficient; K<sub>oa</sub>, octanol-air partition coefficient; pK<sub>a</sub>, acid dissociation constant.

<sup>a</sup> Reported values are empirical data, unless otherwise specified.

<sup>b</sup> Henry's Law Constant was calculated based on the empirical water solubility (16.5 mg/L at 25 °C) and vapour pressure (0.0024 Pa at 25 °C).

**Table 3-2. Physical and chemical property values for DPTT**

Property	Value or range <sup>a</sup>	Reference
Melting point (°C)	96-98	CHRIP c2008
Boiling point (°C)	510 at 760 mmHg	Chemnet 2015
Vapour pressure (Pa)	$2.13 \times 10^{-8}$ at 25 °C	Chemnet 2015
Henry's law constant (Pa·m <sup>3</sup> /mol)	$8.19 \times 10^{-4}$ (calculated <sup>b</sup> )	Not applicable
Water solubility (mg/L)	Not available <sup>c</sup>	Not applicable
Log K <sub>ow</sub> (dimensionless)	2.8	CITI 1991
Log K <sub>ow</sub> (dimensionless)	4.33 (modelled)	EPI Suite v4.11
Log K <sub>oc</sub> (dimensionless)	3.66 (modelled <sup>d</sup> )	EPI Suite v4.11
Log K <sub>oa</sub> (dimensionless)	5.36 (modelled <sup>d</sup> )	EPI Suite v4.11
pK <sub>a</sub> (dimensionless)	0.2-0.8 (modelled)	ACD/Percepta 2015

Abbreviations: K<sub>ow</sub>, octanol–water partition coefficient; K<sub>oc</sub>, organic carbon–water partition coefficient; K<sub>oa</sub>, octanol-air partition coefficient; pK<sub>a</sub>, acid dissociation constant.

<sup>a</sup> Reported values are empirical data, unless otherwise specified.

<sup>b</sup> Henry's Law Constant was calculated based on the read-across water solubility (0.01 mg/L at 20 °C) and the empirical vapour pressure ( $2.13 \times 10^{-8}$  Pa at 25 °C).

<sup>c</sup> The read-across data for CAS RN 971-15-3 (0.01 mg/L) was used to characterize this physical-chemical property for DPTT.

<sup>d</sup> Calculated based on the empirical log K<sub>ow</sub>=2.8.

**Table 3-3. Physical and chemical property values for CAS RN 971-15-3**

Property	Value or range <sup>a</sup>	Reference
Melting point (°C)	121	ECHA c2007-2015
Boiling point (°C)	>250	ECHA c2007-2015
Vapour pressure (Pa)	< 1×10 <sup>-7</sup> at 25 °C	ECHA c2007-2015
Henry's law constant (Pa·m <sup>3</sup> /mol)	< 4.48×10 <sup>-3</sup> (calculated <sup>b</sup> )	Not applicable
Water solubility (mg/L)	0.01 at 20 °C	ECHA c2007-2015
Log K <sub>ow</sub> (dimensionless)	4.33 (modelled)	EPI Suite v4.11
Log K <sub>oc</sub> (dimensionless)	5.56 (modelled)	EPI Suite v4.11
Log K <sub>oa</sub> (dimensionless)	6.61 (modelled)	EPI Suite v4.11
pK <sub>a</sub> (dimensionless)	0.2-0.8 (modelled)	ACD/Percepta 2015

Abbreviations: K<sub>ow</sub>, octanol–water partition coefficient; K<sub>oc</sub>, organic carbon–water partition coefficient; K<sub>oa</sub>, octanol-air partition coefficient; pK<sub>a</sub>, acid dissociation constant.

<sup>a</sup> Reported values are empirical data, unless specified.

<sup>b</sup> Henry's Law Constant was calculated based on the water solubility (0.01 mg/L at 20 °C) and the vapour pressure (1×10<sup>-7</sup> Pa at 25 °C).

## 4. Sources and uses

TMTD and DPTT do not occur naturally in the environment.

Both substances have been included in surveys issued pursuant to section 71 of CEPA such as DSL Inventory Updates (DSL IUs) (Environment Canada 2009 and 2013). Follow-ups with stakeholders were conducted in 2016 aiming to confirm the current uses and the recent import volumes of these substances in Canada. There was no report of manufacturing of DPTT above the 100 kg reporting threshold; there were two reports of manufacturing TMTD but neither were above the 100 kg reporting threshold. However, both substances were imported into Canada and quantities are summarized in Table 4-1.

**Table 4-1. Summary of information on Canadian manufacturing and imports of DPTT and TMTD submitted pursuant to a section 71 survey of CEPA**

Acronym	Total imports (kg) <sup>a</sup>	Reporting year	Survey reference
DPTT	150 000	2011	Environment Canada 2013
TMTD	170 300 - 403 100	2008	Environment Canada 2009

<sup>a</sup> Values reflect quantities reported in response to the surveys conducted under section 71 of CEPA (Environment Canada 2009, 2013). See surveys for specific inclusions and exclusions (schedules 2 and 3).

TMTD is primarily used as a process regulator (accelerator and curing agent) for the manufacture of rubber products in Canada (Environment Canada 2009). This substance is applied as a component in automotive sealants and adhesives; it is also used in other various automotive parts (Environment Canada 2009). TMTD is also used in adhesive tape products available to consumers (Environment Canada 2009). These uses are consistent with global uses (OECD 2010), including industrial use in Europe as a matrix in general rubber goods and the tire industries, as well as as a biocide (KEMI 2015).

In Canada, TMTD may be used in the manufacture of a limited number of food packaging materials (email from Health Product Food Branch, Health Canada to Existing Substances Risk Assessment Bureau, Health Canada, August 2016; unreferenced).

TMTD is listed in the Natural Health Products Ingredients Database with a non-natural health product role as it is not a naturally occurring substance falling under Schedule 1 to the Natural Health Products Regulations. As such, it is not listed in the Licensed Natural Health Products Database as being present in currently licensed natural health products in Canada. TMTD is not listed as a product in Health Canada's Drug Product Database or Internal Non-medicinal Ingredient Database as medicinal or non-medicinal ingredients present in final pharmaceutical products or veterinary drugs in Canada (email from Health Product Food Branch, Health Canada to Existing Substances Risk Assessment Bureau, Health Canada, August 2016; unreferenced). Health Canada's Cosmetic Ingredient Hotlist is an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances may contravene the general prohibition found in section 16 of the Food and Drugs Act (FDA) or may contravene one or more provisions of the Cosmetic Regulations. TMTD (Thiuram, CAS RN 137-26-8) is identified as being prohibited on the Cosmetic Ingredient Hotlist (Cosmetic Ingredient Hotlist, 2015).

It is noted that TMTD (known as Thiram) is registered as an active ingredient in pest control products in Canada (email from Pest Management Regulatory Agency, Health Canada to Risk Management Bureau, Health Canada, July 2016, unreferenced). On the basis of a re-evaluation, its uses in all pest control products are proposed for cancellation (Health Canada 2016a).

Presently, the only Canadian use of DPTT is as a process regulator (accelerator and curing agent) in the rubber products manufacturing for automotive industry (Environment Canada 2013). It is not used in any pest control products, drug or natural health products, cosmetic, or food/food-related products (food processing, manufacturing, or packaging), or other products available to consumers in Canada.

## **5. Releases to the environment**

Based on information obtained from a follow-up conducted in 2016 regarding submissions made for DSL IUs (Environment Canada 2009 and 2013), a study report for the rubber products manufacturing sector (Cheminfo 2013), and Environment and Climate Change Canada's visit to representative rubber compounding/processing facilities, releases of these two substances may vary from site to site depending on specific practices but are expected to mainly occur as a result of discharges from

wastewater treatment systems<sup>3</sup> associated with rubber products manufacturing facilities. During rubber compounding/processing, wastewater is generated from industrial operations such as cleaning, milling, cooling and vulcanizing.

For cleaning, releases to wastewater can come from washing tanks/mixers, equipment, filters, floors, storage and transportation containers. Available information suggests that the use of these substances to manufacture rubber products at an industrial site takes place between one and several times per week, over multiple weeks per year. Cleaning may be conducted after each or a few batches of production. Therefore, releases from cleaning in rubber compounding/processing facilities to surface water after treatment are not expected to be continuous. Quantification of the environmental exposure is discussed in detail in the exposure assessment.

For milling and cooling as Cheminfo (2013) indicates, the wastewater releases can come from use of contact water with unvulcanised rubber when rubber sheets and strips pass through a soap and water bath to provide a lubrication/anti-tack layer. Additionally, an anti-tack solution can be applied through surface spraying to rubber sheets. For vulcanizing, releases may occur from autoclave steam and condensate during the vulcanizing process that ultimately enters the wastewater. However, no information is available to quantify releases from mixing, cooling or vulcanizing.

TMTD is also used as a component in automotive sealants and adhesives and in other various automotive parts. The substance is expected to transform during these applications and therefore, releases of the unreacted substance are not expected. Based on information provided by stakeholders, there is a potential for the uncured sealants and adhesives to have a contact with water during automotive manufacturing that can result in minor releases of TMTD to wastewater at their sites. However insufficient information is available to characterize such releases.

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<sup>3</sup> In this assessment, the term “wastewater treatment system” refers to a system that collects domestic, commercial and/or institutional household sewage and possibly industrial wastewater (following discharge to the sewer), typically for treatment and eventual discharge to the environment. Unless otherwise stated, the term wastewater treatment system makes no distinction of ownership or operator type (municipal, provincial, federal, indigenous, private, partnerships). Systems located at industrial operations and specifically designed to treat industrial effluents will be identified by the terms “on-site wastewater treatment systems” and/or “industrial wastewater treatment systems”.

## 6. Environmental fate and behaviour

### 6.1 Environmental distribution

A Level III fugacity model (EQC 2011) has been used to characterize partitioning of TMTD and DPTT into the various environmental media. Results are presented in Tables 6-1 and 6-2 below.

**Table 6-1. Summary of the Level III fugacity modelling (EQC 2011) for TMTD, showing percent partitioning into each environmental medium for three release scenarios**

Substance released to:	Air (%)	Water (%)	Soil (%)	Sediment (%)
Air (100%)	3.6	5.1	91.2	0.2
Water (100%)	Negligible	96.3	Negligible	3.7
Soil (100%)	Negligible	1.3	98.7	Negligible

**Table 6-2. Summary of the Level III fugacity modelling (EQC 2011) for DPTT, showing percent partitioning into each environmental medium for three release scenarios**

Substance released to	Partitioning in air (%)	Partitioning in water (%)	Partitioning in soil (%)	Partitioning in sediment (%)
Air (100%)	Negligible	1.7	97.8	0.5
Water (100%)	Negligible	88.6	Negligible	11.4
Soil (100%)	Negligible	0.2	99.7	0.1

If released to air, both substances are expected to mainly partition into soil.

If released to water, both substances are expected to remain mainly in the aquatic compartment, with only a small fraction partitioning into sediment. Volatilization of the substances from surface water to air is unlikely. Due to its lower water solubility and higher potential for adsorbing to particles, the partitioning of DPTT into sediment is higher than that of TMTD.

If released to soil, the majority of both substances are expected to remain in this compartment.

### 6.2 Environmental persistence

#### 6.2.1 TMTD

##### 6.2.1.1 Degradation

TMTD possesses a low vapour pressure and is not expected to volatilize. This substance undergoes rapid photodegradation and hydrolysis in water. A few studies

reported a photodegradation half-life in water ranging from 4.1 to 8.8 hours (ECHA c2007-2015 and OECD 2010). Using spiked river water, the photodegradation half-life was reported as 28 minutes, suggesting that organic matter and other natural river components may increase the photodegradation rate of this substance (Filipe et al. 2013).

Hydrolysis is another important route of transformation for TMTD in the environment; alkaline and neutral conditions favour the degradation with half-lives ranging from a few days to a couple weeks (Health Canada 2016a); acidic environments may slow down transformation, resulting in a half-life up to a few months (Norris et al. 1996; Gutpa et al. 2012; ECHA c2007-2015). There has been only one biodegradation study identified for this substance, reporting a slow biodegradation in activated sludge over a 14-day test period (CHRIP c2008). This suggests that biodegradation is not a major degradation pathway for TMTD.

TMTD, therefore, transforms rapidly in both aerobic and anaerobic aquatic environments, with half-lives being 1.2–2.2 days and 4.2 days, respectively (Health Canada 2016a). This substance degrades in the water-sediment environment with a reported half-life of 1.6 days (UH PPDB 2015).

TMTD also transforms rapidly in soil. Under aerobic conditions, the transformation half-life ranges from 1.5 to 15 days (Health Canada 2016a; UH PPDB 2015). This substance also degrades rapidly in plants with half-lives ranging from 5.8 to 11.3 days (Gutpa et al. 20120).

To understand the long range transport potential for this substance in the aquatic medium, TaPL3 (2000) was used to estimate the characteristic travel distance (CTD), which is defined as the maximum distance travelled by 63% of the substance after being released into the environment. Zarfl et al. (2011) have proposed a threshold CTD of 5200 km for classifying organic substances as having long-range transport potential. Using TaPL3 (2000), the CTD was calculated for TMTD, assuming a river with a current of 3.6 km/h and depth of 20 metres. The predicted CTD in water is approximately 202 km for this substance.

In summary, TMTD is expected to undergo rapid degradation and the potential for long-range transport in either the atmospheric or aquatic medium are low. Releases of this substance associated with its uses considered in the assessment may cause short-term exposures to aquatic organisms near points of release, but exposures over a long period of time or far from sources are not expected.

#### **6.2.1.2 Degradation products from environmental pathways**

Degradation products of TMTD have been studied in different environmental media. Gupta et al. (2012) examined the degradation of this substance in water, soil, and plants. Regardless of the test medium, the immediate degradants are primary products resulting from hydrolysis of the disulphide bond (-S-S-) of TMTD. TMTD and its primary



degradants undergo further degradation via oxidation or cleavage at the -C-S- bond and form other intermediate compounds (Gupta et al. 2012).

In soil, degradation products include dimethyldithiocarbamate, dithiocarbamate, dimethylamine and carbon disulfide (HSDB 1983-). The ultimate transformation products of TMTD in the environment are CO<sub>2</sub> and CS<sub>2</sub>, which are both volatile and, therefore, not expected to remain in soil or water (Health Canada 2016a).

### **6.2.2 DPTT**

Only one biodegradation study has been identified for DPTT, reporting a slow biodegradation in activated sludge over a 14-day test period (CHRIP c2008). This suggests that biodegradation is not a major degradation pathway for DPTT.

The model EPI Suite (c2000-2012) considers thiocarbamates as hydrolysable compounds as they contain a -((S-C)=S)-N- structural substitute. Findings in Gupta et al. (2012) reported that metabolite formation in both aquatic and soil media is initiated by breakdown of the S-S bond via hydrolysis, suggesting that DPTT may undergo this degradation pathway. Catalogic v5.11.13 (2015) predicted hydrolysis products for DPTT via breakdown of the -S-S- bond; the model also predicted metabolites via other reactions, such as oxidative thio desulfuration, oxidative deamination and N-dealkylation, and oxidation of piperidine. Given the above, DPTT is anticipated to undergo rapid degradation in the environment and not persist in the environment. Occasional releases of this substance are therefore not expected to cause long-term exposure to organisms.

Regarding the long range transport potential for DPTT in the aquatic medium, the predicted CTD in water is approximately 403 km for this substance (TaPL3 2000), far below the 5200 km cut-off for having a low LRTP in water as proposed by Zarfl et al. (2011).

In summary, DPTT is expected to undergo rapid degradation; its potentials for long-range transport in either the atmospheric or aquatic medium are low. Releases of this substance associated with its uses considered in the assessment may cause short-term exposure to aquatic organisms near points of release, but exposures over a long period of time or far from sources are not expected.

## **6.3 Potential for bioaccumulation**

Empirical bioaccumulation data are available for both substances. Measured bioconcentration factors (BCF) are up to 4.4 and 32 L/kg for TMTD and DPTT, respectively (Table 6-3).

**Table 6-3. Bioconcentration factors for TMTD and DPTT**

<b>Substance</b>	<b>Test organism</b>	<b>Experimental duration</b>	<b>BCF (L/kg)</b>	<b>Reference</b>
TMTD	Fish Carp	6 weeks	1.1-4.4	OECD 2010
TMTD	Not specified	Not specified	3.39	EPI Suite v4.11 (training set)
DPTT	Not specified	Not specified	3.89	Catalogic v5.11.13 (training set)
DPTT	Fish Cyprinus carpio	6 weeks	1.9-32	CHRIP c2008
DPTT	Not specified	Not specified	17.1	EPI Suite v4.11 (training set)

Metabolism and distribution of TMTD have been studied in birds and mammals (Health Canada 2016a; Gay et al. 1992; Gay 1987; Norris 1993a and 1993b). Findings in these studies suggest that the majority of this substance undergoes rapid elimination and metabolism.

The empirical BCFs for both substances and the rapid metabolism/elimination of TMTD in birds and mammal studies suggest little accumulation of these two substances in organisms.

Given the above, it is considered that TMTD and DPTT do not bioaccumulate in organisms to significant levels.

## **7. Potential to cause ecological harm**

### **7.1 TMTD**

#### **7.1.1 Ecological effects assessment**

##### **7.1.1.1 Mode/mechanism of action**

TMTD is a dithiocarbamate fungicide considered to have a multi-site mode of action (Health Canada 2016a; Yang et al. 2011). Broad biological activity, involving a variety of endpoints related to growth and development, neurological, and immunological effects across taxa, has been reported for TMTD. Although the mechanisms through which TMTD acts are not fully known, the structural profile of TMTD suggests the thiol groups in this molecule can undergo covalent reactions (binding) with biological macromolecules such as RNA (and DNA) and other proteins via S<sub>N</sub>2 (nucleophilic substitution) resulting in the formation of disulfide bridges (Chipinda et al 2007; Hermens 1990). These interactions can also interfere with protein transcription and synthesis resulting in structural deformations within organisms. The molecule was also profiled to have a high reactivity (above 21% peptide depletion) via the Direct Peptide Reactivity Assay (DPRA) which evaluates the ability of chemicals to react with proteins to reduce glutathione production (a detoxification mechanism) and may disrupt protein synthesis and metabolism (Nollet 2000). TMDT also demonstrated effects on mitochondrial functions, by inducing irreversible oxidation of NAD(P)H and glutathione

(GSH) pools, collapse of transmembrane potential, and uncoupling of oxidative phosphorylation (Balakirev and Zimmer 2001) leading to cell death.

The above mechanisms are consistent with both observed fish embryo and mammalian evidence for lethal and developmental effects and suggestive of the potential for reproductive effects in vertebrates.

TMTD has also been reported to affect the endocrine systems of mammals. For example, it interferes with corticosteroid hormones which are involved in the regulation of energy, immune reactions, and stress responses (Atanasov et al. 2003; Garbrecht et al. 2006; DCED 2012). In the rat, this substance was observed to delay or block ovulation and inhibit spermatogenesis affecting fecundity (HCN 2003; Stoker et al. 1993 and 2003; Mishra et al. 1998). TMTD may also inhibit thyroid hormone synthesis similarly to thyroid peroxidase inhibitors (DCED 2012). It may also act as a neuroendocrine disruptor, by inhibiting conversion of dopamine to norepinephrine (Lopez-Antia et al. 2015).

In summary, TMTD is a suspected uncoupler of oxidative phosphorylation and a known reactive thiol that covalently interacts with biological tissues resulting in adverse morphological changes and uncoupling of oxidative phosphorylation. There are in vivo data indicating that the substance is capable of causing lethal and developmental effects within 24hrs of exposure. Effects data on aquatic, sediment, and soil organisms, and birds are discussed in the following sections.

#### 7.1.1.2 Effects on aquatic organisms

The toxicity of TMTD to aquatic organisms has been well characterized. The available empirical toxicity data identified for this substance cover more than ten species in three major groups of aquatic organisms (fish, invertebrates, and algae) for ECHA (c2007-2015) and reviews by other jurisdiction (US EPA 2004; European Commission 2003; Health Canada 2016a). Due to the limited number of species of invertebrates, a Species Sensitivity Distribution analysis was not performed. These data indicate that this substance is highly toxic to aquatic organisms (Table 7-1).

**Table 7-1. Summary of ecotoxicity data for TMTD for aquatic organisms**

Test duration	Organism	Endpoint <sup>a</sup>	Range of values (mg/L)
Short-term	Fish	EC <sub>50</sub> /LC <sub>50</sub>	0.0017 – 0.79
Short-term	Invertebrates	EC <sub>50</sub> /LC <sub>50</sub>	0.0033 – 0.38
Short-term	Algae	EC <sub>50</sub> /LC <sub>50</sub>	0.06 – 0.19
Long-term	Fish	NOEC	0.0011 – 0.02
Long-term	Invertebrates	NOEC	0.002 – 0.04

Acronyms: EC<sub>50</sub>, concentration of a substance that is estimated to cause some toxic sublethal effect on 50% of the test organisms; LC<sub>50</sub>, concentration of a substance that is estimated to be lethal to 50% of the test organisms; NOEC, the highest concentration in a toxicity test not causing a statistically significant effect in comparison with the controls.

<sup>a</sup> Endpoints for the short-term toxicity studies include survival, growth and mobility. Endpoints for the long-term toxicity studies include survival, growth and reproduction.

Available information suggests that the use of TMTD to manufacture rubber at an industrial site takes place between one and several times per week. Releases from floor cleaning in rubber compounding/processing facilities to surface water after treatment are not expected to be continuous and would result in short term environmental exposures. Given that, acute toxicity data were considered for estimating the predicted no-effect concentration (PNEC) for aquatic organisms.

The lowest acute endpoint comes from a study on zebrafish (Teraoka et al. 2006), in which fish embryos within 3-hour post fertilization (hpf) of spawning were exposed to TMTD for 24 hours. A 24-hpf EC<sub>50</sub> of 0.0017 mg/L and a NOEC 0.0012 mg/L were reported based on observations of distorted notochords disorganized somites, and shortened yolk sac extensions. The Teraoka et al. 2006 study was reviewed and found to be reliable; therefore, the 24-hpf EC<sub>50</sub> of 0.0017 mg/L was selected as the critical toxicity value (CTV). Considering the number of species in the available dataset, an assessment factor of 9 was applied to the CTV to extrapolate from short-term median effects to short-term no effects and to account for interspecies variation for specifically acting substances. The resulting PNEC is calculated as 0.00019 mg/L for aquatic organisms.

#### **7.1.1.3 Effects on sediment organisms**

There are limited sediment and soil toxicity data identified for TMTD. In a sediment toxicity study using *Chironomus* larvae, a chronic NOEC of 1 mg/L was reported without specifying the test period (European Commission 2003). This substance inhibited the growth of denitrifying bacteria and an EC<sub>50</sub> was reported above 3 mg/L (Milenkovski et al. 2010).

A sediment study has been conducted using mayflies (*Hexagenia* spp.) and fresh water amphipods (*Hyalella Azteca*) (ECCC 2016b). In the range-finding experiment (ECCC 2016b), both organisms were exposed to TMTD in sediment for up to 3 weeks at 5 concentrations (nominal) ranging from 0.1 and 1000 mg/kg-dry weight (dw) sediment (ECCC 2016b). The LC<sub>50</sub> and EC<sub>50</sub> (growth) were determined as 230 and 61 mg/kg-dw sediment, respectively, for mayflies and 190 and 140 mg/kg-dw sediment, respectively, for amphipods. With a longer exposure period up to 6 weeks as part of the same study (ECCC 2016b), LC<sub>50</sub>s of 110 and 86 mg/kg-dw sediment for mayflies and amphipods were determined, respectively. The 6-week EC<sub>50</sub> (growth) on mayflies was determined to be 69 mg/kg-dw sediment, similar to the 3-week exposure EC<sub>50</sub> (growth) of 61 mg/kg-dw sediment. With amphipods, there was no effect on growth after 6-week exposure to TMTD at any test concentrations.

Based on the above results, TMTD is expected to possess low toxicity to sediment organisms.

#### **7.1.1.4 Effects on soil organisms**

A 14-day LC<sub>50</sub> of 540 mg/kg was reported for earthworms (OECD 2010; UH PPDB 2015; European Commission 2003). Using *Lactuca sativa*, a 7-day EC<sub>50</sub> of 32-100 mg/kg and a 14-day EC<sub>50</sub> of 54 mg/kg were reported (OECD 2010); however the effect endpoint was not specified. When testing the effect of this substance via a water solution to which the plant was exposed, an EC<sub>50</sub> of 1.6 mg/L for biomass was reported after a 7-day period (UH PPDB 2015).

These limited results indicate that TMTD has low toxicity to soil organisms.

#### **7.1.1.5 Effects on birds**

Effects of TMTD on birds have been reported in dietary studies. In mallard ducks, effects were noted in avian reproduction studies on this substance and included abnormal egg production, reductions in eggs laid, abnormal embryos, and hatchlings (US EPA 2004a). The no-observable-adverse-effect concentration (NOEC) was reported as 9.6 mg/kg-diet (US EPA 2004a). In two studies using Japanese quail (*Coturnix coturnix japonica*) and mallard duck (*Anas platyrhynchos*), the 14-day LC<sub>50</sub> was reported to be greater than 805.2 mg/kg bodyweight (bw) for test animals in these studies (ECHA c2007-2015). After a 23-week exposure to this substance, a NOEC (for mortality, body weight, feed consumption and reproductive parameter) was determined to be 500 mg/kg diet for *Colinus virginianus* (ECHA c2007-2015).

These results indicate that TMTD has low-to-moderate dietary toxicity to birds; it can cause reproductive and development effects, likely associated with underlying specific mode(s) of action.

### **7.1.2 Exposure assessment**

#### **7.1.2.1 Environmental monitoring data**

No environmental monitoring data were identified for TMTD in surface water or any other environmental medium in Canada. There are very limited monitoring data reported by other countries. A few databases in the US contain either no record or no detection of this substance in ground water or surface water (US EPA 2004). In Japan, this substance was included in a few environmental monitoring projects (CHRIP c2008). The limit of detection was 0.9-1 µg/L for the water sample and 0.02 µg/g dw for the sediment sample. TMDT was not found in any sample collected in sediment or surface water; however, no information on the sampling locations was available (CHRIP c2008).

### 7.1.2.2 Exposure scenario

#### 7.1.2.2.1 Industrial local exposure scenario: rubber compounding/processing

As discussed in the section on Releases to the Environment, wastewater generated from rubber compounding/processing facilities is considered to be the main source of potential releases of rubber accelerators, including TMTD, to the environment. It is noted that different processes (e.g., latex rubber processors vs. solid rubber processors) use different quantities of water and may result in different releases.

Based on the information obtained from DSL IU2 (Environment Canada 2013) and the follow-up conducted in 2016, TMTD has been used at up to ten rubber compounding sites for manufacturing rubber products. Information from Canadian Border Services Agency's database suggests that there may be more potential users of this substance in Canada. Given this, a generic approach was selected to simulate releases of this substance from floor cleaning in raw material weighing/handling and compounding areas. Such releases will go through wastewater treatment systems and will ultimately enter surface water. The exposure of this substance in the aquatic environment is estimated in the form of a Predicted Environmental Concentration (PEC), as follows:

$$\text{PEC (mg/L)} = \frac{Q \times L \times (1 - R)}{D} \times 1\,000\,000$$

The values selected for each of the parameters included in this equation are described in Table 7-2. Additional explanations are also provided later in this section.

**Table 7-2. Values of parameters used in calculating PECs for TMTD**

Symbol <sup>a</sup>	Input	Value	Justification and reference
Q	Quantity used per site per day (kg/day)	509	Quantity was estimated based on daily rubber product production capacities for users identified and the known concentrations of the substance in rubber compounds. Overall quantities used among these sites range from 100 to 1,000 kg/day; the average (509 kg) was used as the representative daily use quantity.
L	Losses to wastewater	0.0021  0.0003	According to the OECD Emission Scenario Document for Plastic Additives (OECD 2009), releases from raw material handling and compounding for powders of particles size more than 40 µm is 0.21%.  In the Tyre and General Rubber Goods Generic Exposure Scenario guidance document (ChemRisk 2010), the upper bound emission factor for small or moderate scale use (based on the total annual quantity) with no pre-treatment is 0.03%.
R	Wastewater treatment system removal efficiency	0.16	The available information suggests that wastewater from the majority of rubber compounding and processing facilities is discharged to wastewater treatment systems that use a secondary treatment. The removal efficiency associated with secondary wastewater treatment was estimated using the SimpleTreat (4.0) model as 16%.
D	Dilution volume <sup>b</sup> (L/day)	40 846 000	This representative dilution volume approximately corresponds to the median of the dilution volumes associated with confirmed users of the substance. This value corresponds to the 25 <sup>th</sup> percentile of the distribution of the dilution volumes associated with 46 compounding and processing sites in the rubber sector in Canada.

<sup>a</sup> 1 000 000 is applied to convert kg to mg.

<sup>b</sup> The term “dilution volume” is used to express the potential dilution capacity of the receiving water body in relation to the effluent flow of the wastewater treatment system. It is calculated as the effluent flow (L/day) times the dilution factor of the receiving waterbody. Dilution factor is capped at 10. The 2.5th percentile of water flow of receiving water body is used to account for the short term occasional releases.

For the purpose of estimating environmental exposure of Thiocarbamates, two emission estimation documents, namely an OECD Emission Scenario Document for Plastic Additives (OECD 2009) and a Tyre and General Rubber Goods Generic Exposure

Scenario guidance document (ChemRisk 2010), have been considered for determining the losses of a substance to wastewater.

OECD Emission Scenario Document (ESD) for Plastic Additives (OECD 2009) is one in a series of documents developed under the auspices of the Organisation for Economic Co-operation and Development (OECD). These ESDs are developed by regulatory agencies in collaboration with industry, are peer-reviewed by other Exposure Assessment Task Force members (now Working Party on Exposure Assessment) and are approved for declassification by OECD member countries prior to publication. These documents typically estimate 'high end' or 'realistic worst case' releases.

The ChemRisk guidance document (2010) emission factor, which incorporates risk management measures, was developed by ChemRisk for the European Tyre & Rubber Manufacturers' Association (ETRMA). Facilities employing a number of different types of practices and wastewater treatment were included in the analysis but the specific data for each facility was not provided in the report, making it difficult to evaluate the variability of releases between practices and to extrapolate the results to the Canadian context. These concerns associated with lack of available data in Specific Environmental Release Categories (SpERC) documents developed for use under European REACH Legislation are in line with reservations expressed by other jurisdictions in relying on these values (Ahrens et al., 2011). For these reasons, a lower weight is given to this source of information when estimating losses of a substance into wastewater.

Based on estimated values for the parameter of Losses to wastewater from the above two emission estimation documents (OECD 2009; ChemRisk 2010), PECs in the receiving water nearby discharge sites (i.e., close to wastewater treatment systems discharge point) are estimated to be 0.022 and 0.0031 mg/L.

Considering the environmental fate anticipated for this substance, TMTD is expected to mainly partition to the aquatic compartment in surface water after being discharged from wastewater treatment systems. Partitioning into sediment is not expected to be significant. Due to low removal efficiency (16%) via the wastewater treatment process, a very small quantity of this substance is expected to sorb to biosolids. Any further application of biosolids to agricultural land or disposal in landfill is not expected to cause significant release to terrestrial environments. Given the above, exposure of TMTD to organisms in sediment or soil is expected to be minor and is not quantified in this exposure assessment.

#### **7.1.2.2.2 Automotive and adhesive & sealants manufacturing sectors**

Data obtained in 2016 in a follow-up for DSL IU1 including information from the Canadian Vehicle Manufacturing Association (CVMA), were analyzed, suggesting that TMTD has also been imported to Canada as an ingredient in ready-to-use sealant products and as a part of finished vehicles, as well as different rubber products. In these rubber products or finished vehicles imported in Canada, the TMTD would be



vulcanized or cured, so only traces of TMTD are expected to remain as the parent compound in these products.

However, there are some possibilities for TMTD to enter a wastewater stream at the facility associated with the use of sealants. When applying sealants on automobiles at vehicle assembly plants, the vehicle frame is subject to a cleaning process, prior to curing under high temperature and painting; there may then be releases of TMTD during this cleaning process. The TMTD-containing cleaning water is transferred to the on-site wastewater treatment system and the effluent from this treatment facility is subsequently sent to a publicly-owned wastewater treatment plant. Releases from this industrial use would eventually enter surface water via the publicly-owned wastewater treatment plant. Data for the automotive industry also suggest that if some sealants come off from the automobile body during the cleaning process, these sealants will be collected in a sludge tank and treated as hazardous waste. Given that the quantity of TMTD applied as sealants in vehicle assembly plants is expected to be small this source of release is expected to result in low exposure to TMTD in the aquatic environment.

A few companies reported via DSL IU1 (Environment Canada 2009) using TMTD to manufacture adhesive and sealant products (i.e., adhesive and sealant tapes). Although limited quantities were reported, there may be some releases of this substance via raw material handling and cleaning of formulation vessels. Given the limited volumes, this source of release was not quantified in the assessment.

### 7.1.3 Characterization of ecological risk

The approach taken in this ecological screening assessment was to examine assessment information and develop proposed conclusions based on a weight-of-evidence approach and using precaution as required under CEPA. Evidence was gathered to determine the potential for TMTD to cause harm in the Canadian environment. Lines of evidence considered include those that directly support the characterization of ecological risk (e.g., measured endpoints or properties), as well as indirect lines of evidence (e.g., classification of hazard or fate characteristics by other regulatory agencies).

#### 7.1.3.1 Risk quotient analysis

**Table 7-3. Summary of risk quotients obtained for the aquatic compartment and exposure scenarios for TMTD**

Compartment	Scenario	PEC (mg/L)	PNEC (mg/L)	RQ
Water	Industrial local exposure scenario: rubber compounding/processing	0.022 <sup>a</sup>	0.00019	116
Water	Industrial local exposure scenario: rubber compounding/processing	0.0031 <sup>b</sup>	0.00019	16

- <sup>a</sup> The PEC estimated based on OECD 2009.  
<sup>b</sup> The PEC estimated based on ChemRisk 2010.

### **7.1.3.2 Consideration of all lines of evidence and their weights for determining potential to cause harm to the Canadian environment**

Technical information for various lines of evidence for ecological risk of TMTD was examined in this assessment to develop a conclusion as required under CEPA. A weight-of-evidence approach, where several lines of evidence are used in the decision-making in all portions of the risk assessment, as well as precaution (as appropriate), were applied. Consideration of the lines of evidence in an integrated manner led to the risk assessment conclusion under CEPA. An overall description of each line of evidence is discussed in the following paragraphs. The weighting of key lines of evidence is presented Table 7-4.

TMTD possesses moderate water solubility and is not volatile. If released to the environment, the substance is expected to mainly partition in the aquatic compartment and undergo rapid degradation. It is not expected to persist in the environment and the potential for long range transport is low; based on the occasional releases resulting from the current industrial uses of this substance, there is only short-term exposure of this substance to organisms in areas near points of release. TMTD is not expected to accumulate in organisms.

This substance is expected to be widely used by rubber compounders. Releases to wastewater are expected to occur one to several times per week as a result of this use. A generic approach using representative information from sector facilities was used in the exposure assessment to quantify releases of this substance. The resulting aquatic PECs were estimated to be 0.022 mg/L and 0.0031 mg/L, based on two emission estimation documents (OECD 2009; ChemRisk 2010).

Structural evidence and in vivo and in vitro data confirm the high potency mode of action for TMTD and its high toxicity to aquatic organisms. This substance can have sub-lethal effects during a short-term exposure at low concentrations. Based on findings from a short-term developmental study with fish embryos, a PNEC of 0.00019 mg/L was derived.

It should be noted that this substance is not expected to significantly partition into sediment or be released to soil and, therefore, it is not expected to result in exposure to organisms in these two compartments. Furthermore, TMTD does not accumulate in organisms, hence birds and wildlife organisms will not be exposed to it via the food chain. Given the above, no PNEC was calculated for organisms in sediment or soil or wildlife organisms.

Comparing the aquatic PECs to the PNEC for aquatic organisms, the risk quotient (RQ) for harm to aquatic organisms (PEC/PNEC) is 116 and 16, based on two emission estimation documents (OECD 2009; ChemRisk 2010). The results suggest that

releases of TMTD from its use in manufacturing rubber products are expected to pose a risk to aquatic organisms in the environment.

The scope of this screening assessment is limited to TMTD. It can be noted that there are other thiuram rubber accelerators belonging to the chemical class of thiocarbamates. Some of these other thiuram rubber accelerators have similar physical-chemical properties as TMTD and, hence, could be present in similar environmental compartments. Available empirical data suggest that these substances may also be highly toxic to organisms. As such, replacement of TMTD by these substances for the manufacturing of rubber products may not reduce the risk to the environment.

As discussed above, the weighting of key lines of evidence are presented Table 7-4 below. The level of confidence refers to the combined influence of data quality and variability, data gaps, causality, plausibility and any extrapolation required within the line of evidence. The relevance refers to the impact the line of evidence has when determining the potential to cause harm in the Canadian environment. Qualifiers used in the analysis ranged from low to high.

**Table 7-4. Weighted lines of key evidence considered to determine the potential for TMTD to cause harm in the Canadian environment**

<b>Line of evidence</b>	<b>Level of confidence<sup>a</sup></b>	<b>Relevance in assessment<sup>b</sup></b>	<b>Weight assigned<sup>c</sup></b>
Persistence in the environment	high	high	high
Long-range transport potential	high	high	high
Bioaccumulation in aquatic organisms	high	high	high
Mode of action and/or other non-apical data	moderate	moderate	moderate
PNEC for aquatic organisms	high	high	high
Critical Body Residue for organisms	N/A	N/A	N/A
Monitoring data for concentrations in the Canadian environment	NA	NA	NA
Model estimates for concentrations in wastewater effluents and surface water	moderate	high	moderate to high
Risk quotient for water	moderate	high	moderate to high

Abbreviations: NA, Not Available; N/A, Not Applicable.

<sup>a</sup> Level of confidence is determined according to data quality, data variability, data gaps and if the data are fit for purpose.

<sup>b</sup> Relevance refers to the impact of the evidence in the assessment.

<sup>c</sup> Weight is assigned to each line of evidence according to the combined level of confidence and relevance in the assessment.

## **7.2 DPTT**

### **7.2.1 Ecological effects assessment**

#### **7.2.1.1 Mode of action**

Using the OECD Toolbox and profiling in the ERC approach (ECCC 2016a), there are a few structural alerts profiled, suggesting that DPTT is a bioactive chemical and may be associated with the potentials for protein and DNA binding; it is noted that other profilers have not generated such alerts. This substance is considered as a narcotic and possibly bioactive compound. However, there is a lack of empirical toxicity data to confirm these potentials or clarify the mode of action. This substance is not included in ToxCast (2016) for profiling. No evidence has been identified suggesting potential genotoxicity associated with this substance.

Regarding the potential for endocrine disruptive effects, there are no empirical data for DPTT.

#### **7.2.1.2 Effects data**

There is a lack of empirical ecotoxicity data for DPTT; available QSAR models are considered not applicable to estimate toxicity for this substance. A Materials Safety Data Sheet reported a 48-hour LC<sub>50</sub> as 500 mg/L in a fish study (Americas International 2016). This value is much higher than the water solubility of this substance; no further details were available.

In an algal study conducted with the analogue CAS RN 971-15-3, no effects were observed on test organisms at an average measured concentration of 0.0079 mg/L after a 72-hour exposure (ECHA c2007-2015). This measured concentration is very close to its water solubility (0.01 mg/L), suggesting that the analogous substance hasn't demonstrated any effect on the test organism at its saturation level in water.

A reproduction toxicity study on the analogue (CAS RN 971-15-3) has been identified (ECHA c2007-2015). The test animals (both F0 and F1 generations) were administered the test substance at a dosage of 1000 mg/kg-bw/day during the test period. The No Observed Effect Level (NOEL) for parental toxicity, reproductive performance (mating and fertility), or toxic effects on progeny was considered to be 1000 mg/kg/day. These findings for the analogue have not suggested that DPTT is associated with a strong endocrine disruption potential.

For sediment, a study was conducted on mayflies (*Hexagenia* spp.) and fresh water amphipods (*Hyalella Azteca*) (ECCC 2016b). After a 3-week exposure to DPTT, there were no lethal effects observed on any test species at test concentrations up to 1000 mg/kg-dw (nominal) sediment. For growth effects, an EC<sub>25</sub> of 980 mg/kg-dw sediment was reported for mayflies; while on fresh water amphipods, there were no effects on

growth at any test concentration up to 1000 mg/kg-dw sediment. These data suggest that DPTT possesses a low toxicity to sediment organisms.

For soil organisms as well as for wildlife, no empirical data were identified for either DPTT or its analogue. No estrogen receptor binding or protein binding alerts were triggered in the OECD Toolbox (v3.3.5), mainly due to a lack of phenol or aromatic amine in the molecular structure of this substance.

### 7.2.1.3 Lethal Body Burden and the external effect concentration

Due to a lack of empirical ecotoxicity data, the Lethal Body Burden (LBB) approach is considered to provide an additional line of evidence for characterizing the effects of DPTT on aquatic organisms. In the LBB approach, the body burden associated with a lethal narcotic effect is assumed fairly constant; such an internal effect concentration is the result of the bioconcentration factor (BCF) and the external effect concentration (median lethal concentration, or LC<sub>50</sub>). To account for any specifically acting Mode of Action, an additional assessment factor may be applied to account for the uncertainty associated with the extrapolation.

$$\text{LBB} = \text{LC}_{50} \times \text{BCF}$$

Based on the internal toxicity thresholds (to cause an acute or chronic effect on organisms) and the BCF, the external effect concentration (i.e., in surface water) can be calculated as:

$$\text{LC}_{50} \text{ (mmol/L)} = \frac{\text{LBB (mmol/kg)}}{\text{BCF (L/kg)}}$$

The tissue residues associated with acute lethality for narcotic substances range from 2-8 mmol/kg (median of 3 mmol/kg); applying an acute-to-chronic ratio of 10, the median chronic lethality is 0.3 mmol/kg. However, considering structural alerts predicted by the OECD Toolbox (2006), the OASIS component (v1.3) suggests that this substance may be bioactive. To account for the potential bioactivity, an assessment factor of 30 was applied to estimate the tissue residues (ECCC 2016a), the tissue residues for effect thresholds from acute exposures are calculated to be 0.1 mmol/kg and 0.01 mmol/kg, respectively, for DPTT.

Among the few empirical BCFs reported for DPTT (Table 6-3), the highest value of 32 L/kg (CHRIP C2008) was selected to calculate the LC<sub>50</sub>. This BCF value was normalized to a standard 5% lipid content for mid-trophic level fish to yield a value of 32.65 L/kg. Considering the acute and chronic internal toxicity thresholds as determined above, the external concentrations required to cause an acute or a chronic lethal effect on aquatic organisms are calculated as follows.

$$\text{Acute LC}_{50} = \frac{\text{LBB (mmol/kg)}}{\text{BCF (L/kg)}} = \frac{0.1 \text{ (mmol/kg)}}{32.65 \text{ (L/kg)}} \times 384.7 \text{ mg/mmol} = 1.18 \text{ mg/L}$$

$$\text{Chronic LC}_{50} = \frac{\text{LBB (mmol/kg)}}{\text{BCF (L/kg)}} = \frac{0.01 \text{ (mmol/kg)}}{32.65 \text{ (L/kg)}} \times 384.7 \text{ mg/mmol} = 0.12 \text{ mg/L}$$

The resulting acute and chronic LC<sub>50</sub> values are 1.18 and 0.12 mg/L, respectively. Both values are well above the water solubility of DPTT (0.01 mg/L based on analogue data).

## 7.2.2 Ecological exposure assessment

### 7.2.2.1 Environmental monitoring data

There have been no environmental monitoring data identified for DPTT in surface water or any other environmental medium in Canada. There are very limited monitoring data reported in other countries. In Japan, this substance was included in a few environmental monitoring projects in 1980 (CHRIP c2008). The limit of detection was 0.002-0.07 µg/L for the water sample and 0.2 µg/g dw for the sediment sample. DPTT was not found in any sample collected in sediment or surface water; however, no information on the sampling locations was available (CHRIP c2008).

### 7.2.2.2 Exposure scenarios

DPTT is used in manufacturing rubber products in Canada. Similarly to TMTD, loss of this substance to wastewater generated from rubber manufacturing facilities is considered to be the main source of potential releases to the environment.

Based on information from DSL IU2 (Environment Canada 2013) and follow ups conducted in 2016, there are fewer than four industrial sites using this substance to manufacture rubber products. This substance is not expected to have as broad a use as TMTD. One site has been selected as being representative of the activities involving this substance for developing an exposure scenario; it is the compounding site of the industrial company that reported the highest import quantity of DPTT. The environmental exposure is estimated and presented in the form of a Predicted Environmental Concentration (PEC), as follows.

$$\text{PEC (mg/L)} = \frac{Q \times L \times (1 - R)}{D} \times 1\,000\,000$$

The values selected for each of the parameters included in this equation are described in Table 7-5.

**Table 7-5. Values of parameters used in calculating PECs for DPTT**

Symbol <sup>a</sup>	Input	Value	Justification and reference
Q	Quantity used per site per day (kg/day)	581	Quantity was estimated based on daily rubber product production capacity for the selected industrial site and the known concentration of DPTT in rubber compounds.
L	Losses to wastewater	0.0021  0.0003	According to the OECD Emission Scenario Document for Plastic Additives (OECD 2009), releases from raw material handling and compounding for powders of particle size greater than 40 µm is 0.21%.  In the Tyre and General Rubber Goods Generic Exposure Scenario guidance document (ChemRisk 2010), the upper bound emission factor for small or moderate scale use (based on the total annual quantity) with no pre-treatment is 0.03%.
R	Wastewater treatment system removal efficiency	0.41	The available information suggests that wastewater from this facility is discharged to a wastewater treatment plant that uses a secondary treatment. The removal efficiency associated with secondary wastewater treatment was estimated using the SimpleTreat (v4.0) model as 41%.
D	Dilution volume <sup>b</sup> (L/day)	25 776 000	This value corresponds to the effluent rate of the local wastewater treatment plus the 2.5 percentile of the flow rate of the receiving water (to account for the occasional releases resulting in short-term exposure).

<sup>a</sup> 1 000 000 is applied to convert kg to mg.

<sup>b</sup> The term “dilution volume” is used to express the potential dilution capacity of the receiving water body in relation to the effluent flow of the wastewater treatment system. It is calculated as the effluent flow (L/day) times the dilution factor of the receiving waterbody. Dilution factor is capped at 10. The 2.5th percentile of water flow of receiving water body is used.

Considering all the above, the PECs in the receiving water nearby discharge sites are estimated to be 0.028 mg/L and 0.004 mg/L, based on two emission estimation documents (OECD 2009; ChemRisk 2010).

After being discharged from wastewater treatment systems, DPTT is expected to mainly partition to the aquatic compartment in surface water and to undergo degradation; partitioning into sediment is not expected to be significant. During the wastewater treatment process, there is some sorption to biosolids. However, any further application of biosolids to agricultural land or disposal in landfill is not expected to cause significant release to terrestrial environments. Given the above, exposure of DPTT to organisms in

sediment or soil is expected to be minor and is not quantified in the exposure assessment.

### **7.2.3 Characterization of ecological risk**

The approach taken in this ecological screening assessment was to examine assessment information and develop proposed conclusions based on a weight-of-evidence approach and using precaution as required under CEPA. Evidence was gathered to determine the potential for DPTT to cause harm in the Canadian environment. Lines of evidence considered include those that directly support the characterization of ecological risk (e.g., measured endpoints or properties), as well as indirect lines of evidence (e.g., classification of hazard or fate characteristics by other regulatory agencies).

#### **7.2.3.1 Risk quotient analysis**

Based on the available toxicity data identified for DPTT and the analogue, this substance is not expected to demonstrate any effect on aquatic organisms at its water saturation level. It also possesses low toxicity to sediment organisms. Given that, a quantitative risk quotient analysis is not conducted for aquatic or sediment compartment for this substance.

#### **7.2.3.2 Considerations of all lines of evidence their weights for determining potential to cause harm to the Canadian environment**

Technical information for various lines of evidence for ecological risk of DPTT was examined in this assessment to develop a conclusion as required under CEPA. A weight-of-evidence approach, where several lines of evidence are used in the decision-making in all portions of the risk assessment, as well as precaution (as appropriate), were applied. Consideration of the lines of evidence in an integrated manner led to the risk assessment conclusion under CEPA. An overall description of each line of evidence is discussed in the following paragraphs. The weighting of key lines of evidence is presented Table 7-6.

There is a general lack of empirical data for DPTT; available data for the analogous substance, CAS RN 971-15-3, have been considered when assessing this substance. DPTT possesses low vapour pressure and low solubility in water (0.01 mg/L). It is expected to undergo rapid degradation and not persist in the environment. It does not accumulate in organisms.

Available information suggests that this substance is not widely used in Canada as only a few companies have been reported using DPTT in manufacturing rubber products. Releases from industrial uses are expected to be occasional and would enter surface water via a wastewater treatment system. In the aquatic environment, the substance is expected to undergo rapid degradation and the potential for long-range transport in water is low. Therefore, the current uses of this substance are expected to result in



short-term exposures to organisms in surface water in the vicinity of the discharge site. The PECs in the receiving water nearby discharge sites are estimated to be 0.004 and 0.028 mg/L, which is slightly higher than the water solubility of DPTT (0.01 mg/L based on analogue) but of the same order of magnitude.

Although structural evidence suggests that DPTT is bioactive, there is a lack of in vivo and in vitro studies to further characterize its mode of action. It is noted that structural alerts from QSAR models suggest the potential for DNA binding by this substance; there is also mutagenic effect reported in an in vitro assay for the analogue, which has the same structural profiling results as DPTT. However, in vivo, no generic effect was observed in test animals with exposure to the analogous substance at fairly high dosage. Different findings from the available in vitro assays and mammalian studies on the analogue suggest that metabolism of these substances may play an important role in demonstrating effects in organisms. These substances are expected to undergo rapid metabolism and elimination; hence the internal concentration in organisms may not reach a level to trigger a molecular initiating event which could lead to further adverse outcomes.

Based on the acute toxicity data for the analogue, DPTT is not expected to cause any effect at its water saturation following short-term exposure.

Using the LBB approach, the external effect concentration causing an acute lethal effect in fish is estimated as 1.18 mg/L, which is approximately 2 order of magnitude higher than the water solubility of DPTT and the PECs in surface water. If considering the water solubility (0.01 mg/L) and the bioaccumulation potential ( $BCF=32.65$  L/kg) of this substance, the internal residue in fish will be approximately 0.00085 mmol/kg. This value is much lower than the acute internal lethal effect threshold (0.1 mmol/kg) that has been established for DPTT as a specifically active substance. There is a wide margin between the maximum exposure to aquatic organisms and the minimal external concentration to cause an acute effect.

As discussed above, the weighting of key lines of evidence are presented Table 7-6 below. The level of confidence refers to the combined influence of data quality and variability, data gaps, causality, plausibility and any extrapolation required within the line of evidence. The relevance refers to the impact the line of evidence has when determining the potential to cause harm in the Canadian environment. Qualifiers used in the analysis ranged from low to high.

**Table 7-6. Weighted lines of key evidence considered to determine the potential for DPTT to cause harm in the Canadian environment**

Line of evidence	Level of confidence <sup>a</sup>	Relevance in assessment <sup>b</sup>	Weight assigned <sup>c</sup>
Persistence in the environment	high	high	high
Long-range transport potential	high	high	high
Bioaccumulation in aquatic organisms	high	high	high
Mode of action and/or other non-apical data	low	moderate	low to moderate
PNEC for aquatic and sediment organisms	N/A	N/A	N/A
CBR for aquatic organisms	moderate	moderate	moderate
Monitoring data for concentrations in the Canadian environment	NA	NA	NA
Model estimates for concentrations in wastewater effluents and surface water	moderate	high	moderate to high
Risk quotient for water and sediment <sup>d</sup>	N/A	N/A	N/A

Abbreviations: NA, Not Available; N/A, Not Applicable.

<sup>a</sup> Level of confidence is determined according to data quality, data variability, data gaps and if the data are fit for purpose.

<sup>b</sup> Relevance refers to the impact of the evidence in the assessment.

<sup>c</sup> Weight is assigned to each line of evidence according to the combined level of confidence and relevance in the assessment.

<sup>d</sup> The quantitative risk analysis is not conducted for DPTT.

### 7.3 Sensitivity of conclusion to key uncertainties

It is noted that wastewater generated from the rubber manufacturing is expected to be the main source of releases of TMTD and DPTT; however such releases may vary from site to site depending on specific practices. There is uncertainty due to a lack of information on the frequency of usage for TMTD in manufacturing rubber products in Canada. Based on information obtained from some industrial users, this substance may be used between one and several times every week in manufacturing rubber products. TMTD enters wastewater mainly from wastewater generated from rubber manufacturing sites. Such cleaning activities may occur after each or several batches of production. Consequently, releases of this substance to surface water from each cleaning after going through the wastewater treatment is expected to be as frequent as its usage or less.

It is noted that there is a lack of empirical toxicity data for DPTT on organisms. However, multiple lines of evidence mutually support the understanding of the fate in the environment and releases of this substance to surface water, which is the primary medium of concern in this assessment. The substance is expected to degrade rapidly

and its potential for long-range transport in water is low. Given that, releases are not expected to pose long-term exposure in the far field. However, there may be short-term exposures near wastewater discharge points. Considering the environmental exposure expected for this substance, DPTT may not be able to reach the internal concentration necessarily to trigger a molecular initiating event leading to further adverse outcomes. Thus, DPTT is proposed to not cause ecological harm, , based on the read-across toxicity data and the predicted external effect concentration via the LBB approach.

## 8. Potential to cause harm to human health

### 8.1 DPTT

The human health risk of DPTT was characterized using the TTC-based Approach for Certain Substances (Health Canada 2016b). In the approach, a decision tree was used considering chemical structural features and chemical-specific data on genotoxicity (e.g., Ames test) when available, to assign a human exposure threshold value for a chemical, below which there is a low probability of risk to human health (i.e. TTC value). Structural representations of substances were retrieved and used to derive TTC values. Substances were examined against exclusion criteria. Then, for each substance in the TTC-based approach, conservative estimates of exposure were generated. Environmental exposures were as a result of potential releases into the environment from commercial activities. Exposure was estimated for substances which may be used in products available to consumers, such as fragrance ingredients in cosmetics, food (e.g., possible food flavouring agents and substances used in the manufacture of food packaging materials), and products available to consumers such as lubricants and adhesives. For each substance, exposure estimates were compared to their assigned TTC value, and substances that had exposure estimates below TTC values were considered to be of low concern to human health based on current levels of exposure. Results of the TTC-based approach specific to DPTT are presented in Table 8-1. Additional details with regards to data and considerations used to in the TTC-based approach are presented in the Approach paper (Health Canada 2016b).

**Table 8-1. Results of the TTC-based approach for DPTT**

<b>CAS RN</b>	<b>TTC value (µg/kg bw/day)</b>	<b>Environmental intake estimate (µg/kg bw/day)</b>	<b>Exposure estimate from use of products (µg/kg bw/day)</b>
120-54-7	1.5	3.42E-1	n/a

Based on this, DPTT was considered not to be a concern for human health at current levels of exposure.

## 8.2 TMTD

### 8.2.1 Exposure assessment

TMTD does not occur naturally in the environment. According to ECHA (2010), TMTD is of moderate water solubility but degrades quickly in water. It has low vapour pressure so is not expected to be in air. It is also not expected to bioaccumulate nor is it persistent. TMTD has also not been detected in freshwater, marine water, rain water, or groundwater in Europe (ECHA c2007-2015). There is no Canadian data for substances in the Thiocarbamates Group in biomonitoring studies, dust, indoor or outdoor air, or drinking water. Distribution to the environment was estimated by ChemCAN, based on the average concentrations over broad regions. This model predicted low TMTD concentrations (nanogram levels) primarily to surface water, with less than 0.001% partitioning to soil, air, or sediment (ChemCAN 2003). The estimated concentration in surface water was used as a surrogate for drinking water data, with a resultant drinking water intake from  $1.3 \times 10^{-6}$  mg/kg bw/day to  $5.5 \times 10^{-5}$  mg/kg bw/day for formula fed infants (zero to six months) and toddlers (6 months to 4 years), respectively. Hence, the environment is not expected to be a significant source of human exposure to TMTD.

According to data collected from the follow-up in 2016, no residues are expected from TMTD use in automobile manufacturing. Because TMTD is desulfurated within minutes in the rubber vulcanization process, no TMTD residues are expected from rubber products; it is also not detected in final products (Bergendorff et al. 2007).

Regarding exposure from products available to consumers, minimal exposure is expected from adhesive tape products based on the low concentration of TMTD in the adhesives (personal communication from some DSL IU submitters; Health Canada 2016) and the limited dermal contact area.

Exposure, if any, to TMTD from its possible use in the manufacture of food packaging materials is expected to be negligible (email from Health Product Food Branch, Health Canada to Existing Substances Risk Assessment Bureau, Health Canada, August 2016; unreferenced).

To summarize, exposure of the general population to non-pesticidal uses of TMTD is not expected or exposure is expected to be low or negligible.

### 8.2.2 Health effects assessment

Based on the PMRA review on Thiram (Health Canada 2016a), by the oral route, this substance is quickly absorbed, distributed, and metabolized. It is primarily eliminated through respiration, and to a minor extent in feces, with low distribution to tissues. It is of slight acute oral toxicity, low acute dermal and inhalation toxicity, moderately irritating to the eyes but not the skin, and is a skin sensitizer. The no adverse effect level of 1.86 mg/kg bw/day was used to characterize risks of all exposures and durations, based on developmental neurotoxicity at 4.36 mg/kg bw/day. Young rats demonstrated altered

motor activity, decreased motor activity habituation, and effects on learning in memory, in the absence of maternal toxicity. Young rats also exhibited decreased body weight in the absence of parental effects in a two-generation reproductive toxicity study in rats. Reproductive toxicity was observed in another reproductive toxicity study in rats, based on sperm abnormalities, testicular effects, and decreased fertility at higher doses. Thiram is also considered to be genotoxic and carcinogenic. A cancer unit risk value of  $3.5 \times 10^{-2} \text{ (mg/kg bw/day)}^{-1}$  was also established based on a two-year dietary carcinogenicity study with increased thyroid C-cell adenomas in female rats and hepatocellular adenomas in male rats.

### **8.2.3 Characterization of risk to human health**

TMTD is a chemical that is used primarily as an additive to manufacture other chemicals and products, and as a pesticide (known as Thiram). The cancer risk estimate from drinking water is  $1.9 \times 10^{-6}$ , and risk is expected to be less because of the conservative nature of the exposure estimate (e.g. rapid hydrolysis in water, low vapour pressure, and low potential for bioaccumulation or persistence). As such the health risk from environmental media is not of concern. No residues are expected from its use as an additive in the rubber products. Exposure, if any, from use of TMTD to manufacture food packaging materials is expected to be negligible. There may be potential for minimal exposure to residual TMTD from use of certain adhesive products.

While exposure of the general population from non-pesticidal uses of TMTD is not of concern at current levels, this substance is considered to have health effects of concern including developmental neurotoxicity and carcinogenicity. Therefore, there may be a concern for human health if exposures were to increase.

### **8.2.4 Uncertainties in evaluation of risk to human health**

Lack of environmental monitoring data is an uncertainty, but given the volumes being used and rapid degradation, exposure via industrial releases of TMTD are not expected to be of concern to humans.

## **9. Conclusion**

Considering available lines of evidence presented in this draft screening assessment, there is risk of harm to organisms from TMTD but not from DPTT. It is proposed to conclude that TMTD meets the criteria under paragraphs 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; however, it is also proposed to conclude that this substance does not meet the criteria under paragraph 64(b) of CEPA as it is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends.

Considering available lines of evidence presented in this draft screening assessment, there is low risk of harm to organisms and the broader integrity of the environment from DPTT. It is proposed to conclude that DPTT does not meet the criteria under paragraphs 64(a) or (b) of CEPA as it is not 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 or that constitute or may constitute a danger to the environment on which life depends.

Based on the information presented in this draft screening assessment, it is proposed to conclude that TMTD and DPTT do not meet the criteria under paragraph 64(c) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Therefore, it is proposed to conclude that TMTD meets one or more of the criteria set out in section 64 of CEPA; DPTT does not meet any of the criteria set out in section 64 of CEPA.

TMTD is proposed to not meet the persistence and bioaccumulation criteria as set out in the Persistence and Bioaccumulation Regulations of CEPA.

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