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Screening Assessment

Antimony-containing Substances

Environment and Climate Change Canada
Health Canada

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Synopsis

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA), the Minister of the Environment and the Minister of Health have conducted a screening assessment of 11 substances referred to collectively as the Antimony-containing Substances Group. Substances in this group were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA. The Chemical Abstracts Service Registry Numbers (CAS RN[1]), their *Domestic Substances List* (DSL) names and their common names are listed in the table below.

Substances in the Antimony-containing Substances Group

CAS RN	DSL name	Common name
1314-60-9	Antimony oxide (Sb_2O_5)	Antimony pentoxide
1327-33-9[a]	Antimony oxide	Antimony oxide
1345-04-6	Antimony sulfide (Sb_2S_3)	Antimony sulfide
10025-91-9	Stibine, trichloro-	Antimony trichloride
15432-85-6	Antimonate (SbO_3^{1-}), sodium	Sodium antimonate
15874-48-3	Phosphorodithioic acid, O,O-dipropyl ester, antimony(3+) salt	NA
15890-25-2	Antimony, tris(dipentylcarbamodithioato-S,S')-, (*OC*-6-11)-	Antimony diamyldithiocarbamate
15991-76-1	Antimony, tris[bis(2-ethylhexyl)carbamodithioato-S,S']-, (*OC*-6-11)-	NA
28300-74-5	Antimonate(2-), bis[μ-[2,3-di(hydroxy-κ*O*)butanedioato(4-)-κ*O*^{1}:κ*O*^{4}]]di-, dipotassium, trihydrate, stereoisomer	Antimony potassium tartrate (APT)
29638-69-5	Antimonate ($Sb_2O_7^{4-}$), tetrapotassium	Potassium antimonate
33908-66-6	Antimonate ($Sb(OH)_6^{1-}$), sodium, (*OC*-6-11)-	Sodium hexahydroxoantimonate

Abbreviations: NA, Not Available

[1] 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.

[a] This CAS RN is a UVCB (unknown or variable composition, complex reaction products, or biological materials).

Antimony (Sb) is a naturally occurring semi-metal. Results from surveys under section 71 of CEPA indicate that the 11 antimony-containing substances in this group were manufactured or imported above reporting thresholds in either 2008 or 2011. Uses and functions of these 11 substances include automobile manufacturing, corrosion inhibitor and anti-scaling agents, electronics and electrical manufactured items, flame retardants, intermediates, lubricants and greases, mordant in textile industry, non-ferrous smelting industry, paint and coatings, plating and surface treating agents, process regulators, rubber additive, solid separation agent and as an intermediate to produce other antimony compounds.

The ecological risks of the 11 substances in the Antimony-containing Substances Group were characterized using the Ecological Risk Classification of Inorganic Substances (ERC-I). The ERC-I is a risk-based approach that employs multiple metrics considering both hazard and exposure in a weight of evidence. Hazard characterization in ERC-I included a survey of existing predicted no-effect concentrations (PNEC) and water quality guidelines, and the derivation of new PNEC values when required. Exposure profiling considered two approaches: predictive modeling using a generic near-field exposure model for each substance, and an analysis of measured concentrations collected by federal and provincial water quality monitoring programs using antimony concentrations as a conservative indicator of exposure for the 11 substances. Modelled and measured predicted environment concentrations (PECs) were compared to PNECs, and multiple statistical metrics were computed and compared to decision criteria to classify the potential for causing harm to the environment. The ERC-I identified these 11 antimony-containing substances as having low ecological concern.

Considering all available lines of evidence presented in this screening assessment, there is a low risk of harm to the environment from the 11 antimony-containing substances. It is concluded that the 11 antimony-containing substances do not meet the criteria under paragraphs 64*(a)* or *(b)* of CEPA as they are 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.

Canadians may be exposed to the 11 antimony-containing substances, which include both trivalent and pentavalent forms of antimony, as they contribute to levels of antimony in environmental media, food, drinking water and/or products available to consumers. To characterize exposure, intake estimates from environmental media, food, drinking water and uses of certain product types were derived. Food (including breast milk and beverages), and to a lesser extent, drinking water are the primary sources of daily intake for the general population. Breast-fed infants had the highest daily intakes. In addition, exposures of the general population to antimony were derived from contact with textiles, and use of toys, lubricants and greases. Dermal exposure to infants from contact with textiles resulted in the highest exposure estimates from products available to consumers.

The human health risk characterization for the 11 antimony-containing substances, which include both trivalent and pentavalent forms of antimony, was based upon the no observed adverse effect level (NOAEL) reported in an oral developmental toxicity study in laboratory animals. In addition, for the inhalation route, a route specific risk characterization was conducted on the basis of lung inflammation in female rats. The resulting margins of exposure are considered adequate to address uncertainties in the health effects and exposure databases.

On the basis of the information presented in this screening assessment, it is concluded that the 11 antimony-containing substances 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 concluded that the 11 substances in the Antimony-containing Substances Group do not meet any of the criteria set out in section 64 of CEPA.

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1. Introduction

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999), the Minister of the Environment and the Minister of Health have conducted a screening assessment of 11 substances referred to collectively as the Antimony-containing Substances Group to determine whether these substances present or may present a risk to the environment or to human health. The substances in this group were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA (ECCC, HC [modified 2017]). This group does not include all antimony-containing substances on the *Domestic Substances List* (DSL) and does not include antimony trioxide (CAS RN 1309-64-4) which was previously assessed under the Challenge Initiative of Canada's Chemicals Management Plan (Environment Canada, Health Canada 2010).

The ecological risks of the 11 substances in the Antimony-containing Substances Group were characterized using the Ecological Risk Classification of Inorganic Substances (ERC-I) (ECCC 2018). The ERC-I is a risk-based approach that employs multiple metrics considering both hazard and exposure in a weight of evidence. Hazard characterization in ERC-I included a survey of past predicted no effect concentrations (PNEC) and water quality guidelines, or the derivation of a new PNEC value when required. Exposure profiling considered two approaches: predictive modeling using a generic near-field exposure model for each substance and an analysis of measured concentrations collected by federal and provincial water quality monitoring programs using antimony concentrations as a conservative indicator of exposure for the 11 substances. Modelled and measured predicted environmental concentrations (PECs) were compared to PNECs, and multiple statistical metrics were computed and compared to decision criteria to classify the potential for causing harm to the environment.

This screening assessment focuses on 11 remaining priority substances which contain and have the potential to release antimony through various transformation pathways. Different oxidation states of antimony (i.e., trivalent and pentavalent antimony) have been taken into consideration in this assessment. Engineered nanomaterials composed of, or containing, antimony are not explicitly considered in exposure scenarios of this assessment, but measured total antimony concentrations in the environment or human biomonitoring could include engineered nanomaterials containing antimony. However, health effects associated with nano-scale antimony are not being considered in this screening assessment. Total antimony refers to the total concentration of elemental antimony irrespective of its oxidation state or molecular form and is what is typically measured in environmental media, food, drinking water and biological matrices such as blood and urine.

This screening assessment includes consideration of information on chemical properties, environmental fate, hazards, uses and exposures, including additional information submitted by stakeholders. Relevant data were identified up to October 2017. Empirical data from key studies as well as results from models were used to

reach conclusions. When available and relevant, the information presented in assessments from other jurisdictions was considered.

This screening assessment was prepared by staff in the CEPA Risk Assessment Program at Health Canada and Environment and Climate Change Canada and incorporates input from other programs within these departments. The ecological portion of the assessment is based on the ERC-I document (published May 12, 2018), which was subject to an external peer-review and a 60-day public comment period. The human health portion of this assessment has undergone external review and consultation. Comments on the technical portions relevant to human health were received from Dr. Tiina Titma (Tallinn University of Technology, Estonia), Dr. Richard A. Manderville (University of Guelph, Guelph, Canada) and Dr. Jonathan W. Martin (Stockholm University, Sweden). Additionally, the draft of this screening assessment (published September 15, 2018) was subject to a 60-day public comment period. While external comments were taken into consideration, the final content and outcome of the screening assessment remain the responsibility of Health Canada and Environment and Climate Change Canada.

This 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.[2] This screening assessment presents the critical information and considerations on which the conclusion is based.

2. Identity of substances

The Chemical Abstracts Service Registry Numbers (CAS RN[3]), DSL names, common names, and acronyms for the individual substances in the Antimony-containing Substances Group are presented in Table 2-1.

[2]A determination of whether one or more of the criteria of section 64 of CEPA are met is based on 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.

[3] 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.

Table 2-1. Substance identities

CAS RN	DSL name (common name, acronym)	Oxidation state	Molecular formula	Molecular weight (g/mol)
1314-60-9	Antimony oxide (Sb_2O_5) (Antimony pentoxide)	+5	Sb_2O_5	323.52
1327-33-9[a]	Antimony oxide (NA)	+3	Sb_2O_3	291.52
1345-04-6	Antimony sulfide (Sb_2S_3) (Antimony trisulfide)	+3	Sb_2S_3	339.72
10025-91-9	Stibine, trichloro- (Antimony trichloride)	+3	$SbCl_3$	228.12
15874-48-3	Phosphorodithioic acid, O,O-dipropyl ester, antimony(3+) salt (NA)	+3	$C_{18}H_{42}O_6P_3S_6Sb$	761.59
15890-25-2	Antimony, tris(dipentylcarbamodithioato-S,S')-, (*OC*-6-11)- (Antimony diamyldithiocarbamate)	+3	$C_{33}H_{66}N_3S_6Sb$	819.06
15991-76-1	Antimony, tris[bis(2-ethylhexyl)carbamodithioato-S,S']-, (*OC*-6-11)- (NA)	+3	$C_{51}H_{102}N_3S_6Sb$	1071.54
15432-85-6	Antimonate (SbO_3^{1-}), sodium (Sodium antimonate)	+5	$NaSbO_3$	192.75
28300-74-5	Antimonate(2-), bis[μ-[2,3-di(hydroxy-κ*O*)butanedioato(4-)-κO^1:κO^4]]di-, dipotassium, trihydrate, stereoisomer (Antimony potassium tartrate, APT)	+3	$C_8H_{10}K_2O_{15}Sb_2$	667.87
29638-69-5	Antimonate ($Sb_2O_7^{4-}$), tetrapotassium (Potassium antimonate)	+5	$K_4Sb_2O_7$	511.91
33908-66-6	Antimonate ($Sb(OH)_6^{1-}$), sodium, (*OC*-6-11)- (Sodium hexahydroxoantimonate)	+5	$NaSb(OH)_6$	246.79

Abbreviations: NA, Not Available

[a] This CAS RN is a UVCB (unknown or variable composition, complex reaction products, or biological materials).

3. Physical and chemical properties

Antimony occurs in the environment in various oxidation states (+5, +3, 0 or -3). In biological and environmental media, it is more commonly found in trivalent Sb(+3) and pentavalent Sb(+5) states. These oxidation states differ in biological activity and physicochemical properties. The substances in this group include both the Sb(+3) and Sb(+5) oxidation states (Table 2-1). The water solubility of antimony-containing substances in this group varies from low (e.g., antimony oxide) to high (e.g., APT and antimony trichloride) (Appendix A). Most of the dissolved antimony (pentavalent) that might be discharged to natural water would rapidly precipitate as antimony trioxide or antimony pentoxide and be removed by sedimentation (Health Canada 1997). These 11 antimony-containing substances have low volatility (HSDB 2016) (Appendix A). Once in the environment, these 11 antimony-containing substances, whether released by commercial use or as the by-product of an industrial process, may further transform depending on the properties of the receiving environment (Skeaff et al. 2013).

4. Sources, uses and releases

Antimony (Sb) is a naturally occurring semi-metal. There are natural and anthropogenic sources of antimony in the environment. Some of the antimony substances in this group are naturally occurring (e.g., antimony sulfide, antimony oxide) and some are anthropogenic (e.g., antimony diamyldithiocarbamate, antimony potassium tartrate). Natural sources of antimony include releases via natural discharges, such as windblown dust, volcanic eruption, sea spray, forest fires and other natural processes (CPHG 1997; HSDB 2016).

In 2016, annual global antimony production amounted to approximately 142 000 metric tonnes (USGS 2017). Prior to 2013, Canada produced 0.1% of the global production (CAREX 2017). With the closure of the Beaver Brook Antimony Mine in Newfoundland and Labrador in 2013, the production of antimony decreased significantly in Canada (MAC 2016). The United States Geological Survey (USGS) reported antimony production in Canada from antimony ore concentrate, lead concentrates and lead-zinc concentrates (USGS 2014). National antimony production in Canada decreased from 148 tonnes in 2013, to 1 tonne by 2015, with preliminary estimates of “0” tonnes for 2016 (NRCan 2017).

All of the substances in the Antimony-containing Substances Group have been included in a survey issued pursuant to section 71 of CEPA (Canada 2009, 2012) and in a voluntary follow-up data collection initiative (ECCC 2016). Table 4-1. Summary presents a summary of the total manufacture and total import quantities for the Antimony-Containing Substances Group in Canada for the reporting year 2008 or 2011 and the results of the voluntary follow-up for the reporting year 2015. The section 71 survey was conducted prior to the reduction of antimony production in Canada. The voluntary data collection initiative in 2017 provided information for one of the 11 substances.

Table 4-1. Summary of information on Canadian manufacturing and imports of 11 antimony-containing substances submitted pursuant to a section 71 survey of CEPA and voluntary follow-up data collection

CAS RN	DSL name	Total manufac-ture[a] (t)	Total imports[a] (t)	Repor-ting year	Survey data reference[b]
1314-60-9	Antimony oxide (Sb_2O_5)	NR; 1 to 10	10 to 100; 10 to 100	2011; 2015	EC 2013; ECCC 2016
1327-33-9	Antimony oxide	>100	100 to 225	2008	EC 2009
1345-04-6	Antimony sulfide	0.1 to 1	>100	2008	EC 2009
10025-91-9	Stibine, trichloro-	NR	1 to 10.1	2008	EC 2009
15432-85-6	Antimonate (SbO_3^{1-}), sodium	NR	1 to 100	2008	EC 2009
15874-48-3	Phosphorodithioic acid, O,O-dipropyl ester, antimony(3+) salt	NR	3.2 to 32	2008	EC 2009
15890-25-2	Antimony, tris(dipentylcarbamodithioato-S,S')-, (*OC*-6-11)-	NR	10 to 100	2008	EC 2009
15991-76-1	Antimony, tris[bis(2-ethylhexyl)carbamodithioato-S,S']-, (*OC*-6-11)-	NR	0.1 to 10	2008	EC 2009
28300-74-5	Antimonate(2-), bis[μ-[2,3-di(hydroxy-κ*O*)butanedioato(4-)-κO^1:κO^4]]di-, dipotassium, trihydrate, stereoisomer	NR	10 to 100	2008	EC 2009
29638-69-5	Antimonate ($Sb_2O_7^{4-}$), tetrapotassium	NR	10 to 100	2008	EC 2009
33908-66-6	Antimonate ($Sb(OH)_6^{1-}$), sodium, (*OC*-6-11)-	>100	NR	2008	EC 2009

Abbreviations: NR – Not reported in concentrations higher than the reporting limit of 100 kg per reporting year

[a] 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).

[b] Survey data reference EC 2009 = Environment Canada 2009; EC 2013 = Environment Canada 2013; ECCC 2016 = Environment and Climate Change Canada 2016.

In 2016, approximately 2,560 tonnes of antimony and articles thereof, including waste and scrap (Harmonized System (HS) code 8110), antimony oxides (HS code 282580) and antimony ores and concentrates (HS code 261710) were imported into Canada

(CIMT 2017). Canadian exports totaled approximately 11 tonnes (CIMT 2017). However, quantities reported from the Canadian International Merchandise Trade (CIMT) are not likely representative of the quantities of the 11 substances in the Antimony-containing Substances Group as they would include antimony trioxide (CAS RN 1309-64-4), the most economically relevant antimony compound, and accounting for approximately 80% of global antimony consumption (US EPA 2014). Antimony trioxide (CAS RN 1309-64-4) is not a part of this assessment as it was assessed under Batch 9 of the Challenge under the Chemicals Management Plan (Environment Canada, Health Canada 2010).

Table 4-2. Summary below presents a summary of major uses and functions of the 11 substances in the Antimony-containing Substances Group according to information reported pursuant to CEPA section 71 surveys (Environment Canada 2009, 2013).

Table 4-2. Summary of the major uses/functions of 11 antimony-containing substances in Canada (based upon information reported pursuant to a section 71 survey of CEPA)

CAS RN	Common name (Oxidation State)	Use[a]/Function
1314-60-9	Antimony pentoxide (+5)	Flame retardants, Metal passivator, Paint and coatings
1327-33-9	Antimony oxide (+3)	Intermediates, Flame retardants, Rubber additive
1345-04-6	Antimony trisulfide (+3)	Intermediates, Automobile manufacturing, Non-ferrous smelting industry
10025-91-9	Antimony trichloride (+3)	Corrosion inhibitor and anti-scaling agents, Electronics and electrical products
15432-85-6	Sodium antimonite (+5)	Plating and surface treating agents, Flame retardants, Automobile manufacturing
15874-48-3	Phosphorodithioic acid, O,O-dipropyl ester, antimony(3+) salt (+3)	Lubricants and Greases, Automobile manufacturing
15890-25-2	Antimony diamyldithiocarbamate (+3)	Lubricants and Greases, Automobile manufacturing
15991-76-1	Antimony, tris[bis(2-ethylhexyl)carbamodithioato-S,S']-, (*OC*-6-11)-(+3)	Lubricants and Greases
28300-74-5	Antimony potassium tartrate (APT) (+3)	Mordant in textile industry, Solid separation agent
29638-69-5	Potassium antimonite (+5)	Process Regulators
33908-66-6	Sodium hexahydroxoantimonate (+5)	Intermediate to produce other antimony compounds

Abbreviations: NA, Not Available

[a] Uses 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).

The uses listed in Table 4-2 for the 11 substances in the Antimony-containing Substances Group are consistent with uses of antimony reported elsewhere. Globally, antimony is used as a heat stabilizer for plastics, in flame retardants, and in lead-acid batteries (USGS 2017). Flame retardants were estimated to account for about one-half of global primary antimony consumption, followed by lead-acid batteries and plastics (USGS 2016).

In Canada, antimony oxide may be present in food packaging materials and antimony diamyldithiocarbamate may be present as a component in an incidental additive[4] used in food processing establishments (personal communication, emails from the Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated July 11, 2016; unreferenced). Several antimony-containing substances are listed in the Natural Health Products Ingredients Database (NHPID) for use as a medicinal ingredient with a homeopathic role in natural health products (NHPs); as well as being listed in the Licensed Natural Health Products Database (LNHPD) as being present as such in currently licensed NHPs in Canada. Homeopathic uses are regulated under the *Natural Health Products Regulations* (Canada 2003). APT is also listed in the NHPID with a non-NHP role as not a naturally occurring substance included in Schedule 1 to the *Natural Health Products Regulations* ; therefore, it is not present in currently licensed NHPs in Canada (NHPID [modified 2019]; LNHPD [modified 2018]).

Antimony and its compounds are included as prohibited ingredients on the List of Prohibited and Restricted Cosmetic Ingredients (more commonly referred to as the Cosmetic Ingredient Hotlist or simply The Hotlist), 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*. Section 16 of the FDA states that "No person shall sell any cosmetic that has in or on it any substance that may cause injury to the health of the user". In addition, the Hotlist includes certain substances that may make it unlikely for a product to be classified as a cosmetic under the FDA (Health Canada 2015).

Antimony is found in children’s toys and jewellery. The quantity of antimony in surface coatings of toys in Canada is regulated under Section 23 of the *Toys Regulations* under the *Canada Consumer Product Safety Act* (Canada 2010, 2011). Toys that have a surface coating material applied to them “must not contain antimony if more than 0.1% of antimony dissolves in 5% hydrochloric acid after being stirred for 10 minutes at 20ºC”. The quantity of antimony in surface coatings of baby gates, cribs, cradles, and bassinets is subject to the same restrictions as specified under the *Expansion Gates and Expandable Enclosures Regulations* and the *Cribs, Cradles and Bassinets Regulations* under the *Canada Consumer Product Safety Act* (Canada 2010, 2011, 2016a,b).

None of the substances in this group are listed as approved food additives (Health Canada [modified 2017]), personal communication, emails from the Food Directorate,

[4] While not defined under the Food and Drugs Act (FDA), incidental additives may be regarded, for administrative purposes, as those substances which are used in food processing plants and which may potentially become adventitious residues in foods (e.g. cleaners, sanitizers).

Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated July 11, 2016; unreferenced), included in the internal Drug Product Database as medicinal or non-medicinal ingredients in disinfectant, human or veterinary drug products in Canada (DPD [modified 2017]),or were formulants or active ingredients in pest control products registered in Canada (PMRA 2010; personal communication, emails from the Pesticide Management Regulatory Agency, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated July 05, 2016; unreferenced).

Antimony-containing substances may also be released as a result of activities such as fossil fuel combustion, metal refining, or when used as an intermediate (Environment Canada, Health Canada, 2010). In 2015, The National Pollutant Release Inventory (NPRI) reported releases of antimony and its compounds of 2.7 tonnes to air, 1.8 tonnes to water, and 0.007 tonnes to land (NPRI 2011-2015). Data specific to the 11 antimony-containing substances in this group are not available.

5. Potential to cause ecological harm

5.1 Characterization of ecological risk

The ecological risks of the 11 antimony-containing substances were characterized using the Ecological Risk Classification of Inorganic Substances (ERC-I). The ERC-I is a risk-based approach that employs multiple metrics that consider both hazard and exposure in a weight of evidence. Hazard characterization in ERC-I included a survey of past domestic and international assessment PNEC and water quality guidelines. When no suitable existing PNEC or water quality guideline was found, hazard endpoint data were collected and dependent on data availability, either a species sensitivity distribution (SSD) or an assessment factor (AF) approach was taken to derive a new PNEC value. In the case of the 11 antimony-containing substances, a suitable previous ecological hazard evaluation was identified for read across: the 2010 screening assessment of antimony trioxide, which derived a PNEC for the aquatic compartment applicable to soluble forms of antimony (Environment Canada, Health Canada 2010; EU 2008).

Exposure profiling considered two approaches: predictive modelling using a generic near-field exposure model and an analysis of measured concentrations collected by federal and provincial water quality monitoring programs. The generic near-field exposure model used input data from the NPRI, surveys issued pursuant to CEPA section 71 notices, international trade data from the Canada Border Services Agency (CBSA), and third-party market research reports to generate PECs. In the case of the 11 antimony-containing substances, input data from surveys issued pursuant to CEPA section 71 notices and CBSA were available. Input data were available from the NPRI for “antimony and its compounds” (defined as the total of the pure element and the equivalent weight of the element contained in any compound, alloy or mixture) (NPRI 2011-2015).

Consideration of PECs derived from NPRI data for “antimony and its compounds”, as well as from water quality monitoring data for total, dissolved, and extractable antimony was a conservative assumption for this screening assessment, as “antimony” itself (CAS RN 7440-36-0) and the most commercially relevant antimony-containing substance (CAS RN 1309-64-4) are not among the 11 antimony-containing substances in this assessment.

Measured antimony concentrations were available for total and dissolved antimony from the National Long-term Water Quality Monitoring (NLTWQM) network, the Environmental Monitoring System of the British Columbia Ministry of the Environment and Climate Change Strategy, the Surface Water Quality Program of Alberta Environment and Parks, the Regional Aquatics Monitoring Program, the Canada-Alberta Joint Oil Sands Environmental Monitoring program, the *Banque de données sur la qualité du milieu aquatique* of the Government of Québec, and the Baseline Monitoring of Lower Order Streams in Saskatchewan. Total antimony concentrations were also available from the Long term Water Quality Monitoring Network of the Government of Manitoba and the Chemicals Management Plan Environmental Monitoring and Surveillance of wastewater treatment systems. Extractable antimony concentrations were available from the NLTWQM network for the Atlantic region and the Surface Water Quality Program of Alberta Environment and Parks. Data were compiled for a period of approximately 10 years, between 2005 and 2015.

Modelled and measured PECs were compared to PNECs, and statistical metrics considering both the frequency and magnitude of exceedances were computed and compared to decision criteria to classify the potential for ecological risk as presented in ECCC (2018). The results are summarized in Table 5-1.

Table 5-1. Ecological risk classification of inorganics results for the 11 antimony-containing substances

Monitoring (Total/Extractable)	Monitoring (Dissolved)	Modelling (DSL-IU)	Modelling (NPRI)	Modelling (CBSA)	Overall ERC-I Score
Low	Low	Moderate	Low	Low	Low

The ERC-I identified the 11 substances in the Antimony-containing Substances Group as being of low ecological concern.

6. Potential to cause harm to human health

6.1 Health effects assessment

6.1.1 Toxicokinetics

The absorption, distribution, and excretion of antimony depend on both the route of administration and its oxidation state (OEHHA 2016; ATSDR 1992; ATSDR 2017 (draft)). Antimony absorption after oral intake is relatively low (WHO 2003; Health

Canada 1997). Gastrointestinal (GI) absorption is mainly determined by the solubility and chemical form (oxidation state) of the substance (OEHHA 2016; ATSDR 2017 (draft)). GI absorption of the relatively insoluble antimony trioxide (+3) in humans was approximately 1% (EU 2008). On the basis of acute intoxication data from four individuals, 5% absorption was reported for APT, which is a highly water soluble form of antimony (Iffland and Bösche 1987; Lauwers et al. 1990). ICRP (1981) has recommended reference values for GI absorption of different forms of antimony in humans, which include 10% absorption for APT and 1% for all the other forms of antimony (ATSDR 2017 (draft)).

California EPA does not consider systemic exposure from the dermal route to be significant based on the low solubility of most antimony-containing substances (OEHHA 2016). Due to the low oral absorption and dermal absorption of antimony, a dermal to oral relative absorption factor of 0.1 (10%) has previously been established for antimony when conducting dermal to oral extrapolation in risk characterization (Health Canada 2004).

Orally absorbed antimony is distributed via blood to spleen, liver, kidney, bone, lung and thyroid (OEHHA 2016). There is insufficient evidence to determine if there are differences in the distribution of orally administered antimony of different oxidation states (e.g., +3, +5). Both trivalent and pentavalent antimony are capable of entering the red blood cells (Barrera et al. 2016; Lopez et al. 2015; Quiroz et al. 2013). Several investigators have suggested various transport mechanisms that may support trivalent antimony transportation to cells. These include, transport via aquaglyceroporins (which are membrane proteins) or via hexose transporters (Maciaszczyk-Dubinska et al. 2012). Others have suggested that trivalent antimony is transported to cells by forming a stable complex with glutathione (Sun et al. 2000).

There are differences in the distribution of trivalent and pentavalent antimony substances from inhalation exposure; trivalent antimony accumulates more rapidly in the liver than the pentavalent form, while pentavalent antimony predominantly accumulates in the skeleton (ATSDR 1992).

The major metabolic pathway of antimony is the oxidation of the trivalent to the pentavalent form (Ogra 2009; OEHHA 2016). Conversely, pentavalent antimony can also be reduced to the trivalent form in the presence of glutathione (GSH) (Lopez et al. 2015; Hansen et al. 2011; Prezard et al. 2001).

Antimony is excreted rapidly via feces and urine and exhibits differences in oxidation states in the excretion pattern. Trivalent antimony is excreted primarily in the feces whereas pentavalent antimony is excreted primarily in urine (Tylenda et al. 2015; Elinder and Friberg 1986; Health Canada 1997). In human studies where volunteers were intravenously (i.v.) or intramuscularly (i.m.) administered trivalent or pentavalent antimony, 25% of the trivalent form was found in urine versus 80% for the pentavalent form, respectively (Tylenda et al. 2015; Abdallah and Saif 1962). When patients were

intramuscularly given a pentavalent antimony in the form of sodium stibogluconate , about 95% was recovered in urine within 6 hours of administration (Rees et al. 1980).

6.1.2 Health effects

The current assessment is focused on the health effects of exposure to antimony released from both trivalent and pentavalent antimony-containing substances listed in Table 2-1. Thus, the health effects database consists of studies where humans or animals were exposed to antimony from various antimony substances, such as organic forms of antimony, inorganic trivalent antimony, inorganic pentavalent antimony, antimony-containing drugs and metallic antimony.

The health effects of trivalent and pentavalent antimony-containing substances have previously been assessed by other international organizations (ATSDR 2017 (draft); OEHHA 2016; ICH 2014; US EPA 2014; ANSES 2011; WHO 2011; Environment Canada, Health Canada 2010; AFSSA 2007; Health Canada 1997; EU 2008; ATSDR 1992; IARC 1989).

On the basis of available human and animal data, antimony exposure has been associated with hepatocellular damage and impaired liver metabolism (ATSDR 2017 (draft); OEHHA 2016). In general, it is considered that the severity of toxic effects of antimony via oral route varies depending on the type of antimony. Highly water soluble trivalent antimony substances, such as APT and antimony trichloride, are likely to have greater potential for toxicity via oral route than other antimony substances. There is also a difference in hazard potential by oxidation state, as the trivalent forms appear to be more toxic than the pentavalent antimony substances (ATSDR 2017 (draft); OEHHA 2016).

In a sub-chronic toxicity study by Poon et al. (1998), male and female Sprague Dawley rats (15/sex/dose) were treated with a trivalent antimony substance, APT (+3), in drinking water at concentrations of 0, 0.5, 5, 50 or 500 ppm for 90 days. These doses were equivalent to 0, 0.06, 0.56, 5.58 and 42.17 mg Sb/kg-bw/day in males and 0.06, 0.64, 6.13 and 45.69 mg Sb/kg-bw/day in female rats. Histopathological changes were reported in the thyroid, spleen, liver, thymus and pituitary gland. Cholesterol levels for the highest-dose females were significantly lower than controls. Alkaline phosphatase and creatinine were decreased in both male and female rats in the highest dose group. Hematological parameters (red blood cell counts, mean corpuscular volume, platelets) were significantly different from controls for highest-dose males, while for highest-dose females the only significant hematological difference was a depression of monocyte counts. The study authors selected 0.5 ppm (0.06 mg Sb/kg-bw/day) as the no observed adverse effect level (NOAEL) for the study based upon the histopathological changes and marked accumulation of antimony in red blood cells at the 5 ppm (approximately 0.6 mg/kg-bw/day), and persistence of antimony in the spleen, along with a decrease in the glucose level in females at the same level.

Different authors or regulatory agencies have used different criteria to interpret the point of departure (POD) from the Poon et al. (1998) study when deriving exposure guidance values. Lynch et al. (1999) reviewed the results of Poon et al. and concluded that the effects noted in the study were not necessarily indicative of overt toxicity. They proposed a NOAEL of 50 ppm (6 mg Sb/kg-bw/day). PODs have ranged from a high of 6 mg Sb/kg-bw/day to a low of 0.06 mg Sb/kg-bw/day (WHO 2003; OEHHA 2016; ATSDR 2017 (draft)). However, owing to the high water solubility of APT, it is unlikely that the results of this study are relevant to other, less soluble antimony substances.

Rossi et al. (1987) exposed pregnant rats to a trivalent antimony substance, antimony trichloride (+3), in drinking water at 0, 0.1 or 1 mg/dL from gestation day 1 to weaning (22nd day after delivery). While dose conversions presented in ATSDR (2017 (draft)) were 0, 0.07 or 0.7 mg Sb/kg-bw/day, dose levels were not reported in Rossi et al. Using dose conversions, based upon assumed water intakes of 40-75 mL/day for a pregnant rat, the achieved dose levels in Rossi et al. (1987) were calculated to be 0, 0.16 and 1.6 mg Sb/kg-bw/day. After weaning, the pups were exposed to the same drinking water concentrations from 22nd to 60th day of age. Health effects were limited to significantly decreased maternal and pups' body weight at the highest dose tested. While food consumption was not reported, other authors have suggested that antimony trichloride causes loss of appetite following exposure (Clayton and Clayton 1994). Due to the high water solubility and corrosive nature of antimony trichloride, it is unlikely that this study is applicable to other antimony compounds.

The trivalent antimony substance, antimony trioxide (+3), exhibits lower toxicity compared to APT and antimony trichloride, likely owing to lower solubility (Sunagawa 1981; Hext et al. 1999). The Environment Canada and Health Canada (2010) screening assessment report on antimony trioxide identified an endpoint from Sunagawa (1981) as the critical endpoint for risk characterization. In this oral repeated-dose toxicity study, male Wistar rats were fed 0, 1, or 2% antimony trioxide (corresponding to 0, 418, or 836 mg Sb/kg-bw/day, respectively) in diet for 24 weeks. The lowest observed effect level (LOEL) identified was 418 mg Sb/kg-bw/day based upon liver histopathological changes and increased aspartate transaminase (AST) activity (Sunagawa 1981). It is noteworthy that health effects noted for APT and antimony trichloride differ from the results noted for antimony trioxide.

The toxicity database for pentavalent antimony substances is primarily based upon the therapeutic use of sodium stibogluconate (which is not a substance in the group currently under assessment) for treatment of parasitic infections in humans (ATSDR 1992; OEHHA 2016). These studies are not suitable for human health characterization in the general population primarily due to the route of exposure, such as i.v. or i.m. Hence, animal toxicity studies were identified for the oral risk assessment of pentavalent antimony substances. In an available developmental toxicity study, pregnant rats were given oral gavage doses of 0, 100, 300 or 1000 mg/kg-bw/day of sodium hexahydroxoantimonate (corresponding to 0, 49, 148, or 493 mg Sb/kg-bw/day, respectively) during gestation days 6-19 (ECHA 2014a). Based upon a slight delay in fetal skeletal development observed in the intermediate and high dose groups, a

developmental toxicity NOAEL of 49 mg Sb/kg-bw/day was derived. Maternal toxicity was not observed at any of the dose levels tested and the highest dose level of 493 mg Sb/kg-bw/day was identified as the maternal NOAEL (ECHA 2014a). This developmental study for sodium hexahydroxoantimonate (+5) is presented for read across for other pentavalent antimony compounds including sodium antimonite and antimony pentoxide (also in this group) in the ECHA registration dossier (ECHA 2014a,b,c).

There are many studies available to assess the genotoxic potential of antimony substances (ATSDR 2017 (draft)). Overall, in *vivo* studies for antimony trioxide were negative for clastogenicity and bone marrow aberrations. In *vivo* assays for chromosomal aberrations and micronuclei formation were negative. Worker studies were likewise negative for micro nuclei formation and sister chromatid exchange. In *vitro* assays were generally negative for gene mutations. However, some positive responses were noted for antimony trichloride and pentachloride (highly soluble antimony substances) in chromosomal aberration and micronuclei formation assays. Overall, there is low concern for genotoxicity for the antimony substances in the group.

Antimony trioxide has been classified as a group 2B carcinogen (IARC 1989, 2014) via the inhalation route (CAS RN 1309-64-4). Under European Commission regulation on classification, labeling and packaging (CLP-Regulation (CE) No 1272/2008), antimony trioxide was classified as a Category 2 carcinogen (suspected human carcinogen). According to a European Union risk assessment report, antimony trioxide is classified in Annex 1, Directive 67/548/EEC as “Carc. Cat. 3: R40” (Limited evidence of a carcinogenic effect) (EU 2008). The European Union (EU 2008) further indicated that there was no evidence of tumours for orally administered antimony. In chronic studies in which APT was orally administered to mice and rats, cancer incidence has not increased (ATSDR 1992).

While antimony trioxide is not included in this assessment, the results of the NTP (2016) and Newton et al. (1994) studies conducted with antimony trioxide form the basis of the chronic inhalation health effects review, in the absence of studies conducted with an antimony substance from the grouping. NTP also published a draft Report on Carcinogens (RoC) for antimony trioxide in 2017 (NTP 2017).

In the NTP (2016) bioassay, groups of 60 male and female Han Wistar rats and B6C3F1/N mice were exposed to whole body inhalation to antimony trioxide(+3) at concentrations of 0, 3, 10 or 30 mg/m^3. Exposures were 6 hours per day, 5 days per week for 105 weeks. Both species showed a time- and dose-dependent increase in inflammatory changes as a response to antimony trioxide exposure. Both male and female rats showed an incidence of alveolar/bronchiolar adenomas whereas only male rats showed incidence of alveolar/bronchiolar carcinomas as a response to antimony trioxide exposure. In mice, significantly increased incidence of alveolar/bronchiolar adenomas and carcinomas were evident at an incidence greater than the chamber controls. The studies also reported increases in adrenal gland tumours in rats, and increases in lymphoma and skin tumours in mice.

On the basis of the continuous increase in lung burden in rats and mice, NTP (2017) concluded that exposed doses reached pulmonary overload. Thus, these lung tumours were not considered to be relevant to the general population as tumours only occurred at doses that caused lung overload.

An inhalation study conducted by Newton et al. (1994) was identified as the key study to examine the health effects of antimony exposure in the general population. In this study, groups of 50 male and female Fisher 344 rats were exposed to a trivalent antimony substance, antimony trioxide, for 6 hours per day, 5 days per week for 13 weeks at concentrations of 0, 0.21, 0.902, 4.11 or 19.60 mg Sb/m^3. At doses of 4.11 mg/m^3 and higher, increased lung weights, with macrophage infiltration, fibrosis and inflammation were noted in both males and females. A draft review by ATSDR (2017 (draft)) determined a human equivalent point of departure, $BMCL_{HEC}$ of 0.008 mg/m^3, (from a $BMCL_{10}$ of 0.01 mg Sb/m^3) on the basis of chronic lung inflammation in female rats. This reference dose is considered adequate to protect against the range of lesions noted in long-term animal bioassays and represents a more conservative approach to the German MAK Commission value of 0.3 mg/m^3 (MAK 2014).

6.2 Exposure assessment

There are numerous studies which have measured antimony in various media including urine, air, drinking water, food, soil, dust and products available to consumers. These studies provide concentrations of total antimony in these media, but not substance-specific data. It is not possible to determine from these studies the form of antimony that is present (i.e., oxidation state or molecular structure). In this assessment, total antimony data will be used as a surrogate for substance-specific exposure data. Data on total antimony are considered to be an acceptable, although protective, surrogate for CAS RN specific data.

In addition, the substances in this group account for a minor proportion of the total antimony in commerce, as the most commercially important antimony compound is antimony trioxide (CAS RN 1309-64-4). Antimony trioxide accounts for over 80% of global antimony use (US EPA 2014). The use of total antimony measurements from environmental media, food, drinking water and products is considered to be a conservative estimate for the 11 substances considered in this assessment, as total antimony data would include naturally occurring antimony (e.g., natural discharges such as windblown dust, volcanic eruption, sea spray, forest fires and other natural processes) and contribution from the use of antimony trioxide (CAS RN 1309-64-4).

6.2.1 Biomonitoring

Total antimony concentrations have been measured in urine in the Canadian Health Measures Survey (CHMS) of participants aged 6 to 79 years (N= 5492) in cycle 1(2007–2009), and 3 to 79 years (N= 6311) in cycle 2 (2009–2011) (Health Canada 2013). In 2009-2011, median and 95th percentile concentrations of Canadians aged 3 to 79 years were 0.044 and 0.16 μg/g creatinine (Health Canada 2013). However, urine

antimony concentrations were not considered suitable for use as quantitative biomarkers of exposure to the pentavalent or trivalent forms of antimony. Trivalent forms of antimony are predominately excreted in feces. Pentavalent antimony is predominately excreted in urine; however, available metabolism studies indicate that once absorbed, pentavalent antimony can be converted to the trivalent form and vice versa. Hence, urine antimony concentrations do not accurately reflect the original form or quantity of antimony to which a person was exposed. More details on the toxicokinetics of the trivalent and pentavalent antimony are presented in section 6.1.1.

6.2.2 Environmental media, food, and drinking water

Antimony is a naturally occurring element that is present in environmental media in Canada. Total antimony has been measured in outdoor, indoor and personal air samples, drinking water distribution systems, household dust, soil and in foods as part of several research and monitoring initiatives undertaken by Health Canada and Environment and Climate Change Canada and assessments conducted by the provinces. Concentrations of antimony measured as part of these studies are presented in Table 6-1 below. Antimony-containing substances included in this screening assessment may contribute to total antimony measurements in environmental media and food. However, the extent of their contribution to the total antimony measurements is unknown.

Table 6-1. Concentrations of total antimony in environmental media in Canada

Media	Range	Median	95th percentile	n	Reference
Outdoor air $PM_{2.5}$ (ng/m^3)	NA	0.65	1.87	447	Rasmussen 2016
Indoor air $PM_{2.5}$ (ng/m^3)	NA	0.21	0.70	437	Rasmussen 2016
Personal air samples $PM_{2.5}$ (ng/m^3)	NA	0.29	1.49	445	Rasmussen 2016
Outdoor air $PM_{2.5}$ (ng/m^3)	0.01 - 5.09	0.17	0.72	910	NAPS 2011
Drinking water, distribution systems (µg/L)	0.25 - 0.80	0.25	0.25	97	Tugulea 2016
House dust (mg/kg)	NA	8.5	32	1025	Rasmussen 2016
Soil (Ottawa, ON, Sudbury, ON, Ontario Typical range, ON, Alberta, Greater Vancouver Area, BC (mg/kg)[a]	0 – 8.1	0.12 - 0.48	0.48 - 15	50 - 8148	Rasmussen et al. 2001; SARA 2008; ON MOECC 2015; Millennium 2016; BC MOE 2010

Media	Range	Median	95th percentile	n	Reference
Soil, Flin Flon, Manitoba (mg/kg)	<0.1 - 9 (Max)	1.0	3.6	93	Intrinsik 2010
Soil Creighton, Saskatchewan (mg/kg)	<0.1 – 2.7	0.7	2.1	13	Intrinsik 2010
Soil, Port Colborne, Ontario (mg/kg)	0.1 - 23.6	1.1	5.2	2000	ON MOE 2002
Soil, Catamaran, NB(mg/kg)	13.6 - 62.8	NA	NA	122	Great Atlantic Resource Corp. 2016

Abbreviations: NA, Not Available
[a] National level soil data not available

In a study conducted in Windsor, Ontario, 24-hour $PM_{2.5}$ air filter samples from corresponding indoor residential, outdoor residential and personal environments, showed that the median and 95th percentile of total antimony concentration was higher outdoor versus indoor (Rasmussen 2016). These outdoor concentrations in Windsor were higher than concentrations obtained in the National Air Pollution Surveillance database (NAPS 2011). Little is known about the chemical forms of antimony present in air and particulate matter (ATSDR 2017 (draft)).

Pentavalent antimony is expected to be the predominant form in drinking water due to strongly oxidizing treatments, such as chlorination used in the treatment of drinking water (Belzile et al. 2011). When water samples from Canadian drinking water distribution systems were tested for antimony, only 3.3% of the samples from the distribution lines contained detectable concentrations of antimony at a limit of detection 0.5 µg/L. There was no difference in concentration at the source and the treated water (Tugulea 2016). None of the samples collected from various points in the distribution lines exceeded the drinking water guideline; maximum acceptable concentration (MAC) of 6 µg/L (Health Canada 1997). Antimony was detected in all house dust samples collected in the Canadian house dust study (n=1025). The median antimony concentration was higher in house dust than in outdoor soil. The median bioaccessibility of antimony in the house dust is 14% (Rasmussen 2016).

Both pentavalent and trivalent forms of antimony are found in soils and sediments (Environment Canada, Health Canada 2010; US EPA 2014; ATSDR 2017 (draft)). National level data on antimony soil concentrations in Canada are not available. Soil antimony data from Ontario, Alberta and British Colombia are available; median concentrations ranged from 0.1-0.5 mg/kg (Rasmussen et al. 2001; SARA 2008; ON MOECC 2015; Millennium 2016; BC MOE 2010). In a study conducted in Flin Flon, Manitoba, near a base metals and smelting facility, antimony concentrations ranged from 0.1– 9 mg/kg and were only slightly higher than neighboring Creighton, Saskatchewan (Intrinsik 2010). In another study conducted in Port Colborne, which was undertaken as part of a soil investigation for a human health risk assessment in a

community close to a nickel smelter, median antimony concentration at 0-5 cm depth was 1.1 mg/kg. In a geochemical survey conducted in Catamaran, New Brunswick, which focused on the discovery and development of mineral assets (Antimony/Gold project), soil antimony concentrations were considerably higher, ranging from 14 to 63 mg/kg (Great Atlantic Resource Corp. 2016). There is no soil quality guideline for antimony in Canada.

Food and water are considered to be the primary sources of general population exposure to antimony (US EPA 2014). There are both natural and anthropogenic sources of antimony in food. Antimony is absorbed by the roots of vegetables and other crops grown on antimony-containing soils (WHO 2003). In one study conducted by Ren et al. (2014), pentavalent antimony was found in higher concentrations than trivalent antimony in rice regardless of the form that the rice was exposed to (i.e., trivalent or pentavalent). Concentrations have been reported in a wide array of foods including fruits and vegetables, cereal grains, dairy products, meat and seafood, and beverages.

Estimates of dietary exposure to total antimony for the general Canadian population were generated by Health Canada's Food Directorate (Table B-1 in Appendix B). Food consumption data from the Canadian Community Health Survey (CCHS) - Cycle 2.2 (Statistics Canada 2004) were used. Canadian occurrence data were available from several surveys conducted by the Canadian Food Inspection Agency (CFIA), and Environment and Climate Change Canada's Water Quality Monitoring and Surveillance Program. No Canadian antimony breast milk data were available from the Maternal Infant Research on Environmental Chemicals (MIREC) project or other sources; therefore, occurrence data on antimony in human milk were instead obtained from scientific literature. The CFIA surveys included five National Chemical Residues Monitoring Program **(**NCRMP) surveys (2011 – 2016), five Children's Food Project surveys (2010 – 2016), and nine other surveys (2008 – 2016). Over 43,000 analytical results covering a wide variety of foods were assembled, as well as additional data for human milk and fish; however, only 13% of these results contained detectable concentrations of antimony at limits of detection (LODs) ranging from 0.0001 to 0.01 µg/g. For all persons, all age-sex groups, mean and 95th percentile total dietary antimony exposure estimates ranged from 0.013–0.130 µg/kg-bw/day and from 0.023–0.270 µg/kg-bw/day, respectively (Table B-1 in Appendix B). For adults aged 19 or above, orange juice, milk, and breakfast cereal were the main contributors to total dietary exposure, accounting for approximately 16%, 12%, and 9%, respectively. For the children 1 to 3 years of age, consumption of milk, apple juice, and orange juice account for approximately 26%, 19%, and 14%, respectively, of total dietary antimony exposure.

Studies have shown that antimony migrates into food and food simulants from packaging in very low part per billion levels (Dabeka et al. 2002; Shotyk et al. 2006; Sánchez-Martínez et al. 2013; Hansen and Pergantis 2006; Westerhoff et al. 2008). Of the antimony-containing substances in this screening assessment, antimony oxide may be used in food packaging and antimony diamyldithiocarbamate is reported as a component in an incidental additive used in food manufacturing/processing

establishments (personal communication, emails from the Foods Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated July 11, 2016; unreferenced). Antimony-containing catalysts are used during the production of polyethylene terephthalate (PET) which is used in various food packaging applications, such as trays and bottles. The contribution of food packaging materials to overall dietary antimony exposure was accounted for in the present dietary exposure assessment through the inclusion of antimony occurrence data in a wide variety of foods, including packaged foods that are sold in Canada.

Most of the CFIA survey data for antimony investigated domestic and imported packaged foods available on the Canadian retail market that were packaged in a variety of materials, including plastic, glass, metal, Tetra Pak and cardboard. The 2010-2011 survey included juice and bottled water while the 2011-2012 and 2012-14 surveys included nut and seed butters, condiments, and frozen or shelf-stable heat-and-serve meals; the 2012-14 survey also sampled processed fruit and vegetable products. In the 2012-14 survey (n=1208), none of the samples contained detectable concentrations of antimony while the 2010-11 (n=359) and 2011-12 (n=621) surveys reported that approximately 2% of the samples in each survey contained detectable levels of antimony (CFIA 2012, 2016a,b).

However, food packaging is considered to make a negligible contribution to overall dietary antimony exposure (Personal communication, email from the Foods Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated July 11, 2016).

The contribution from the 11 antimony-containing substances to the exposure estimates remains uncertain, since the dietary exposure estimates were conducted on the basis of total antimony. Some of the foods that contribute most notably to dietary antimony exposure have been found to contain more pentavalent (+5) antimony species or organic antimony species than trivalent antimony (+3). For instance, Cava-Montesinos et al. (2003) reported that although inorganic antimony species constitute 100% of the element present in milk samples (i.e., as opposed to organic), only 22.1% to 35.7% of the inorganic antimony in cow's milk samples is in the form of trivalent Sb, with the remainder being pentavalent Sb. Similarly, Ulrich (2000) reported that only pentavalent Sb was detected in orange juice and that they did not find any trivalent Sb or organic antimony. Furthermore, only 46% to 74% of the antimony in meat samples and 40% to 46% of the antimony in vegetable samples were identified as inorganic antimony (+3 or +5) by Ruiz-de-Cenzano et al. (2017).

Intake estimates were generated for total antimony based upon concentrations in environmental media and drinking water (Table 6-1) and dietary intake estimates generated by Health Canada’s Food Directorate (Table B-2 in Appendix B). On the basis of these estimates, average daily intake of antimony for the general public from environmental media, food and drinking water ranges from 0.02 to 0.26 µg/kg-bw/day (Table B-2 in Appendix B). Of these, food, including breast milk and beverages (range 70-90%), and to a lesser extent, drinking water (range 8 - 30%) are the primary sources

of daily intake. It should be noted that the vast majority of food samples were below the detection limit (87%), so the dietary intakes are strongly influenced by the detection limit. Air, house dust and soil were minor contributors to the daily intake from environmental media. Highest intake estimates were for the 0-6 month age group at 0.27 µg/kg-bw/day. This intake estimate will be used to characterize risk for the antimony-containing substances in this group.

6.2.3 Products

The Sources, uses and releases section presents the summary of major activities and functions in Canada of antimony-containing substances reported pursuant to a section 71 survey and from public databases of product information and a search of publicly available material safety datasheets. Both trivalent and pentavalent antimony-containing substances are used as additive flame retardants, pigments, catalysts, and corrosion inhibitors in a wide range of products in Canada available to consumers. These substances are used in products available to consumers, including building materials, textiles, plastics and rubber, lubricants and greases, paints and coatings, toys, electrical and electronic products, vehicle interiors, and ammunition (Environment Canada 2009, 2013; Health Canada 2009a, 2009b, 2012a, 2012b, 2017; CPCat 2017; Gunney et al 2014; CAREX 2017; Belzile et al. 2011; US HPD 2017; KEMI 2013; CPID 2017).The only other consumer use identified for antimony trichloride is as a resistor in electrical and electronic products (Environment Canada 2009). It should be noted that although a given antimony compound may be used in the manufacture of, or be present in, a given product available to consumers, this may not be the form of antimony that consumers may be exposed to as the substance may transform once incorporated into the product or during release, leaching and/or breakdown of the product.

When used in the manufacture of plastics and textiles, antimony acts as a flame retardant, pigment, or as a catalyst in the polymerization of polyethylene terephthalate (PET) or poly vinyl chloride (PVC) fibers during manufacture. According to information submitted under section 71 of CEPA, both trivalent (antimony oxide CAS RNs 1327-33-9) and pentavalent (antimony pentoxide CAS RNs 1314-60-9 and sodium antimonate CAS RN 15432-85-6) substances are used as additive flame retardants in plastics, rubber, paper products, building, and construction material and in textiles (see Table 4-2). The concentration of antimony compounds used in a given product depends on the polymer used and the intended use of the finished product. Antimony is usually in the range of 2–5% in polymers (Weil and Sergei 2009; Ranken 2009; Cusack 1997). A recent study conducted in the UK, using a field-portable XRF on plastic items obtained from domestic, school, vehicular and office settings, showed that antimony was detected in 18% of over 800 measurements performed, with concentrations ranging approximately from 60 to 60,000 µg/g (0.006 to 6%) (Turner and Filella 2017). Several migration studies have been conducted for antimony on different types of fabrics. A leaching study conducted using different biological fluids (e.g., urine, sweat) on PVC cot mattress covers showed leaching of antimony from the mattress cover, however, the extent of leaching did not correlate well with the antimony content of the PVC material (Jenkins et al. 1998).

In addition to the uses notified through the surveys under section 71 of CEPA, in publicly available databases and in material safety data sheets (MSDS), total antimony has been measured in many products available to consumers in studies carried out by the Danish Environmental Protection Agency. Antimony was detected in jewellery (Strandesen and Poulsen 2008), adult toys (Nielsen et al. 2006), school bags, toy bags, pencil cases and erasers (Svendsen et al. 2007), glitter glue (Hansen et al. 2008), candles (Eggert et al. 2002), baby products including carriers and aprons for perambulators (Tønning et al. 2008), shampoo for children (Poulsen and Schmidt 2007), kohl and henna cosmetics (Bernth et al. 2005), textile colourants such as felt tip pens (Egmose and Pors 2005), toys (Nielsen et al. 2005, Ferdinand et al. 2003; Svendsen et al. 2005), ear plugs (Pors and Fuhlendorff 2003), children's mattresses (Danish Technological Institute 2001), and textiles (e.g., apparel for men/ women/children and dinner napkins) (Ellebaek et al. 2003; Tønning et al. 2009). Further, in Washington State's Children's Safe Product Act (CSPA), antimony was detected in jewellery, arts and crafts materials, footwear, apparel, baby products such as chairs, changing mats, carriers, bibs and playpens, balloons, water toys, games and toys, temporary tattoos, cosmetics, bedding, furniture, kitchen housewares such as knives and dishes (SWDE 2017; Sekerak 2016). In these studies, total antimony was measured and it is not possible to determine the specific antimony-containing substance that is present in the product be tested.

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* or may contravene one or more provisions of the *Cosmetic Regulations*. Antimony and its compounds are identified as being prohibited on the Cosmetic Ingredient Hotlist (Health Canada 2015). Antimony is not an acceptable ingredient in cosmetics yet it may still be found as an impurity, likely from starting materials, due to the persistent nature of these substances and that antimony is found in the natural environment. Health Canada has developed guidance on heavy metal impurities in cosmetics and has established an impurity limit of 5 ppm (or 0.0005%) for antimony. Antimony impurity concentrations in cosmetic products are considered to be technically avoidable when they exceed 5 ppm or 0.0005% (Health Canada 2012d). Antimony has been detected in cosmetics in Canada as part of cyclical compliance testing of cosmetics conducted by Health Canada (Health Canada 2009c, 2011, 2012a). Total antimony was detected in approximately 16% of body and face paint, nail polish, and in tattoo inks at concentrations of up to 0.0009% (Health Canada 2009c, 2012a). Approximately 8% of face paints (typically marketed to children) exceeded the impurity limits of 5 ppm (or 0.0005%) established by Health Canada; compliance action was taken on these products (Health Canada 2012c).

As the antimony containing substances in this group are present in many products available to consumers, for the purpose of this screening assessment, surrogate exposure scenarios were identified to estimate antimony exposure to consumers from the use of products containing the antimony substances in this group. Dermal and oral exposure to antimony from the use of textiles, toys, and lubricants were selected as

sentinel scenarios as these are considered to be representative of typical products that could result in direct exposure to consumers. The substances in this group have low volatility (Appendix A) and no spray products or aerosols were identified, thus inhalation exposure is not expected. Product scenarios that resulted in the highest levels of potential exposure by the oral and dermal routes are presented in Table 6-1, with further details presented in Appendix C.

The presence of antimony-containing substances in building materials, commercial paints, electronics, as a flame retardant in commercial/industrial paper and paper products, and products made with plastic and rubber are more likely to result in indirect exposure to the general public as particulate-bound in household dust or indoor air and are captured in the intake estimates from environmental media presented in section 6.2.2.

Textiles

Antimony-containing compounds are used in textiles as synergists in flame-retardant finishes, as a pigment, mordant or in the polymerization of PET fibers during manufacture. APT is used as a mordant for dyes in textiles (Environment Canada 2009). As a mordant, the highly soluble APT is used as a source of antimony, where it converted to an insoluble form so that the antimony ion will form a complex with the dye and bind to the fabric. As such, antimony is no longer present in the APT form in the fabric (Baker 1958). Antimony could be present in textiles as a result from any or all these uses. It was estimated that more than 90% of PET is manufactured using antimony-based catalysts (Danish EPA 2003). During the manufacture polyester, fibers contain 160-240 mg/kg (0.016 to 0.024%) antimony of which a large quantity would be washed out during the wet finishing process (Hansen 2002). Based upon the type of fabric, concentrations of antimony ranged from 0 to 60,000 mg/kg (0 to 6%) (Appendix C). Health Canada has determined the antimony concentration of various types of children's sleepwear material available in the Canadian market using ICP-MS and XRF. Concentrations ranged from <LOD to 205 mg/kg (< LOD to 0.0205%) with a median of 72 mg/kg (0.0072%) (Health Canada 2017; personal communication, emails from the Consumer Product Safety Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated July 24, 2017; unreferenced). Another study conducted on PET-containing polyester garment textiles purchased from a German market, which consisted of mixed-fibers materials with different PET fiber proportions and textiles made from pure PET fiber materials, reported a maximum concentration of 270 mg/kg (0.027%) in 100% PET material.

Three sentinel exposure scenarios were identified for textiles: oral exposure from mouthing textiles by infants; dermal exposure from the transfer of antimony from a sleeper to an infant; and dermal transfer from a mattress cover to a sleeping infant. Migration rates based upon the results of migration studies conducted by the Danish EPA (2003) were incorporated into the assessment. Fractional release rates of antimony via artificial saliva and sweat of 0.7% and 10% per day were used. These results are supported by data from other studies. In a German study, a migration rate of

8.5% over 30 minutes via synthetic sweat was measured (BfR 2012) and in a study by Jenkins et al. (1998), a fractional release rate of 0.027% was determined from artificial saliva. For all dermal scenarios, a relative dermal to oral absorption factor of 10% was used as described in the toxicokinetics section.

Toys

Total antimony concentrations were measured in toys available in North America, using techniques such as ICP-MS and XRF; concentrations ranged from 0.000102 to 1300 ppm (1.2×10^{-8} to 0.13%) (Health Canada 2009a, 2009b, 2012b, 2014; Gunney et al. 2014; Sekerak 2016). Antimony had been tested in toys under Health Canada's Cyclical Enforcement of Heavy Metals in Applied Surface Coatings Materials for several years (Health Canada 2009a, 2009b, 2011, 2012b, 2014). Toys are prohibited that have a surface coating material applied to them containing antimony if more than 0.1% of antimony dissolves in 5% hydrochloric acid after being stirred for 10 minutes at 20ºC (Health Canada 2012c). None of the toys tested had leachable antimony levels exceeding the limit of 0.1% (w/w). Gunney et al. (2014) measured total and bioaccessible (via saliva) antimony in metallic toys, jewellery, plastic toys, toys with paint or coating and brittle or pliable toys purchased in North America. Total antimony was measurable, but bioaccessible antimony was below the limit of detection (Gunney et al. 2014). Potential exposure to antimony from mouthing of metallic toys, jewellery, plastic toys, toys with paint or coating and brittle or pliable toys by 0 to 0.5 year old infants was modeled.

Lubricants and greases

Of the 11 antimony-containing substances in this group, trivalent antimony compounds are used in do-it-yourself or automotive lubricants and greases (see Table 4-2). Dermal exposure was estimated based upon a thin film approach (US EPA 2007).

Table 6-2 summarizes the highest exposure estimates to antimony from the sentinel product scenarios: textiles, toys, and lubricants and greases. The algorithms and inputs used to derive these exposure estimates are outlined in Appendix C.

Table 6-2. Estimated potential exposures to antimony-containing substances from the use of products

Product scenario	Age Group	Daily Exposure (mg Sb/kg-bw/day)
Textiles – Oral; mouthing	Infant (0-0.5 years)	3.0×10^{-6}
Textile – Dermal[a]; Baby sleeper	Infant (0-0.5 years)	2.0×10^{-2}
Textiles – Dermal[a]; mattress cover	Infant (0-0.5 years)	5.8×10^{-2}
Children's Toys – Oral	Infant (0-0.5 years)	8.8×10^{-4}

Product scenario	Age Group	Daily Exposure (mg Sb/kg-bw/day)
Lubricants and greases – Dermal[a]	Adult (20-59 yrs)	1.7 $X10^{-2}$

[a] Dermal exposure estimates were refined with a dermal to oral relative absorption factor of 10% (Health Canada 2004). See section 6.1.1 for further details.

6.3 Characterization of risk to human health

Canadians may be exposed to the 11 antimony-containing substances in this group, that includes both trivalent and pentavalent antimony-containing substances, from environment media, food, and drinking water, and from their presence in products available to consumers. On the basis of environmental media exposure estimates, the primary sources of daily intake of antimony for the general population are from food (including breast milk and beverages), and to a lesser extent from drinking water.

Trivalent and pentavalent antimony-containing products available to consumers may result in dermal and oral exposure in the general population. Oral and dermal sentinel exposure scenarios to trivalent and pentavalent antimony-containing substances were derived, which included mouthing a textile or a children's toy by infants, dermal transfer of antimony from a sleeper or from a mattress cover to a sleeping infant, and dermal exposure from applying a lubricant to a car.

The relevant endpoints extracted from studies conducted with pentavalent or trivalent antimony compounds were used to characterize risks to the general public. While APT and antimony trichloride, which are trivalent antimony substances, have been reported to have a greater toxicity via the oral route than most of other antimony compounds (likely due to an increased bioavailability) (OEHHA 2016), there is no anticipated exposure to APT or antimony trichloride from environmental media, food, drinking water or products available to consumers. Thus, studies conducted using APT or antimony trichloride were not considered relevant for risk characterization.

The NOAEL of 49 mg Sb/kg-bw/day based upon a slight delay in fetal skeletal development at 148 mg Sb/kg-bw/day was reported in a developmental toxicity study conducted with a pentavalent antimony substance, sodium hexahydroxoantimonate, (ECHA 2014a). This was the lowest NOAEL in the health effects database for the trivalent and pentavalent antimony-containing substances in this group for which there is an oral exposure. This endpoint is considered relevant for risk characterization to women of child-bearing age; it is also considered to be the most sensitive endpoint for the risk characterization of oral exposures for the general population for either valency.

The lowest relevant point of departure for trivalent antimony compounds was the LOEL of 418 mg Sb/kg-bw/day from Sunagawa (1981) and this endpoint was not used in the risk characterization for trivalent antimony because the NOAEL of 49 mg Sb/kg-bw/day reported in the above noted study (ECHA 2014a) was considered to be a more conservative endpoint for both trivalent and pentavalent antimony substances.

In the absence of adequate dermal toxicity studies, the oral NOAEL of 49 mg Sb/kg-bw/day was selected for the risk characterization of dermal exposure to both trivalent and pentavalent antimony substances. A relative dermal to oral absorption value of 10% was applied to the dermal exposure estimates to account for differences in oral and dermal absorption. This endpoint was also used to characterize risk following exposure via the oral route (food, drinking water, soil, dust) and the inhalation route.

Table 6-3 presents the highest exposure estimates derived from environmental media, food and drinking water and from sentinel exposure scenarios. The margin of exposure (MOE) for each exposure scenario was derived by comparing the daily exposure level with the critical NOAEL of 49 mg/kg-bw/day.

Table 6-3. Oral, dermal and inhalation exposure estimates for antimony-containing substances and margins of exposure

Exposure Scenario	Daily Exposure (mg/kg-bw/day)	MOE
Oral and inhalation exposure from environmental media, food and water Infant (0 - 0.5 yrs)	2.7×10^{-4}	181,500
Oral exposure from textiles – mouthing Infant (0-0.5 yrs)	7.7×10^{-5}	640,200
Dermal exposure from textile – baby sleeper/apparel Infant (0 - 0.5 yrs)	2.0×10^{-2}	2,300
Dermal exposure from textiles – mattress cover Infant (0 - 0.5 yrs)	5.8×10^{-2}	840
Oral exposure from children's toys – mouthing Infant (0 - 0.5 yrs)	8.8×10^{-4}	56,600
Dermal exposure from lubricants and greases Adult (20 - 59 yrs)	1.7×10^{-2}	3,100

While antimony trioxide is not included in this assessment, in the absence of studies conducted with an antimony substance from the grouping, the inhalation toxicity studies conducted by NTP (2016) and Newton et al. (1994) were used as surrogate data in the risk characterization of chronic inhalation exposure to both trivalent and pentavalent antimony substances by the general population.

ATSDR (2017 (draft)) derived a draft chronic inhalation reference dose for antimony based upon lung inflammation in female rats from Newton et al. (1994). A human equivalent $BMCL_{HEC}$ of 0.008 mg/m^3 was derived for this effect. A comparison of the $BMCL_{HEC}$ for lung inflammation (i.e., 8000 ng/m^3) with the 95th percentile estimate of general population exposure estimated using personal air samples in the $PM_{2.5}$ fraction (i.e., 1.49 ng/m^3 from table 6.1) resulted in a route-specific MOE of 5370. Lung tumours were noted in 2-year animal bioassays conducted by the NTP (2016). These lung tumours were not considered to be relevant to the general population as tumours only occurred at doses that caused lung overload.

On the basis of the conservative parameters used in modeling oral, dermal and inhalation exposure, the use of surrogate total antimony data for CAS specific exposure data, and the use of a pentavalent endpoint for trivalent substances, the calculated margins are considered adequate to address uncertainties in the health effects and exposure databases.

6.4 Uncertainties in evaluation of risk to human health

Substance-specific exposure and toxicity data for each of the 11 antimony-containing substances in this group are not available. Therefore, total antimony concentration data for environmental media, food and drinking water and products were used as surrogate exposure data. However, as a conservative approach in risk characterization, an endpoint from a developmental toxicity study on pentavalent antimony (the lowest critical effect level across the available relevant studies) was compared to general population exposure to both pentavalent and trivalent substances.

There is uncertainty as to which form of antimony people are exposed to from products available to consumers. In the absence of substance specific information, the assessment has assumed that consumers are exposed to trivalent or pentavalent antimony compounds, but not APT or antimony trichloride as these are unlikely to be present in or formed in products available to consumers. Exposure estimates generated using total antimony are considered to be conservative (see sections 6.2.3 and 6.3).

In the absence of dermal toxicity studies, a dermal to oral absorption factor of 0.1 (10%) was used (as recommended by Health Canada) for antimony risk characterization (Health Canada 2004).

7. Conclusion

Considering all available lines of evidence presented in this screening assessment, there is low risk of harm to the environment from the 11 antimony-containing substances. It is concluded that these 11 antimony-containing substances do not meet the criteria under paragraphs 64(*a*) or (*b*) of CEPA as they are 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.

On the basis of the information presented in this screening assessment, it is concluded that the 11 antimony-containing substances 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 concluded that the 11 substances in the Antimony-Containing Substances Group do not meet any of the criteria set out in section 64 of CEPA.

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Appendix A. Physical and chemical properties

Table A-1. Physical and chemical properties[a,b]

CAS RN	Common Name (Oxidation state)	Water Solubility (mg/L)	Reference	Vapor Pressure (mm Hg)	Reference
1314-60-9	Antimony pentoxide (+5)	594 (read across) (moderately solubility)	ATSDR 1992; ECHA 2014b	NA	N/A
1327-33-9	Antimony oxide (+3)	slightly soluble in water	O'Neil 2006	1 at 574 °C	Sax 1979
1345-04-6	Antimony trisulfide (+3)	1.75 (low solubility)	Lide 1996	NA	N/A
10025-91-9	Antimony trichloride (+3)	100 000 mg/L (very high solubility) (reacts with water)	HSDB 2016	1 at 49.2 °C	Lewis 1996
15432-85-6	Sodium antimonate (+5)	594 (read across) (moderate solubility)	NRC 2000; ECHA 2014c	NA	N/A
15874-48-3	Phosphorodithioic acid, O,O-dipropyl ester, antimony(3+) salt (+3)	NA	N/A	0.0122 (predicted)	US EPA 2017a
15890-25-2	Antimony diamyldithiocarbamate (+3)	3.7×10^{-10} predicted (very low solubility)	US EPA 2017b	NA	N/A
15991-76-1	Antimony, tris[bis(2-ethylhexyl)carbamodithioato-S,S']-, (*OC*-6-11)- (+3)	NA	N/A	NA	N/A

CAS RN	Common Name (Oxidation state)	Water Solubility (mg/L)	Reference	Vapor Pressure (mm Hg)	Reference
28300-74-5	Antimony potassium tartrate (APT) (+3)	8.3 x 10^5 (very high solubility)	HSDB 2016	1.3 x 10^{-9} at 25 °C modelled	US EPA 2017c
29638-69-5	Potassium antimonite (+5)	NA	N/A	NA	N/A
33908-66-6	Sodium hexahydroxoantimonate (+5)	594 (moderate solubility)	ECHA 2014a	NA	N/A

NA = Not available, N/A = Not applicable
[a] Experimental and predicted physical and chemical property values at standard temperature, unless otherwise stated
[b] Octanol–water partition coefficient (K_{ow}) data not available

Appendix B: Human exposure to environmental media and food

Table B-1. Mean and 95th percentile of all persons[a] dietary intake of antimony for the Canadian general population based on food and beverage[b]

Age/ sex	Mean (µg/kg-bw/day) (95% CI)	95% (µg/kg-bw/day) (95% CI)
6-11 months (M & F)	0.130 (0.110 - 0.148)	0.270 (0.232 - 0.278)
1-3 yrs. (M & F)	0.075 (0.072 - 0.077)	0.140 (0.134 - 0.148)
4-8 yrs. (M & F)	0.042 (0.041 - 0.043)	0.076 (0.072 - 0.080)
9-13 yrs. (M)	0.026 (0.025 - 0.026)	0.053 (0.047 - 0.056)
9-13 yrs. (F)	0.022 (0.021 - 0.023)	0.040 (0.038 - 0.045)
14-18 yrs. (M)	0.018 (0.017 - 0.018)	0.035 (0.032 - 0.036)
14-18 yrs. (F)	0.016 (0.015 - 0.016)	0.033 (0.030 - 0.034)
19-30 yrs. (M)	0.016 (0.015 - 0.016)	0.031 (0.028 - 0.033)
19-30 yrs. (F)	0.015 (0.014 - 0.016)	0.028 (0.026 - 0.031)

Age/ sex	Mean (µg/kg-bw/day) (95% CI)	95% (µg/kg-bw/day) (95% CI)
31-50 yrs. (M)	0.013 (0.012 - 0.013)	0.023 (0.022 - 0.025)
31-50 yrs. (F)	0.013 (0.012 - 0.013)	0.024 (0.023 - 0.028)
51-70 yr. (M)	0.013 (0.012 - 0.013)	0.024 (0.023 - 0.028)
51-70 yrs. (F)	0.013 (0.012 - 0.013)	0.025 (0.023 - 0.026)
71+ yrs. (M)	0.013 (0.012 - 0.013)	0.026 (0.024 - 0.027)
71+ yrs. (F)	0.013 (0.013 - 0.014)	0.025 (0.024 - 0.026)

CI = Confidence interval

[a]All persons' exposure estimates are generated by taking the total number of survey respondents into consideration.

[b] Infant formula was included and appropriate reconstitution factors were applied, as required. In cases where at least 20% of the samples in a given food category reported antimony concentrations greater than the LOD, concentrations below the LOD were conservatively assumed to be equal to half the LOD; otherwise, samples with antimony concentrations reported as being below the LOD were set to zero.

Table B-2. Average estimates daily Intake (µg/kg-bw/day) of antimony by the general population in Canada by various age groups through environmental media, food, and water

Route of exposure	0 - 0.5 year breast fed[a,b]	0.5 - 4 year[c]	5 - 11 year[d]	12 - 19 year[e]	20 - 59 year[f]	60 + year[g]
Air[h]	8.1E-05	1.7E-04	1.4E-04	7.7E-05	6.6E-05	5.8E-05
Drinking Water[i]	NA	1.1E-02	8.9E-03	5.1E-03	5.3E-03	5.6E-03
Food (and beverages)	2.6E-01	4.2E-02	4.2E-02	1.8E-02	1.6E-02	1.3E-02
Dust[j]	6.1E-03	3.2E-03	1.2E-03	4.5E-05	4.3E-05	4.2E-05
Soil[k]	0.0	1.4E-04	1.1E-04	3.7E-06	3.5E-06	3.3E-06
Total Intake	0.270	0.057	0.052	0.023	0.021	0.019

NA: not applicable

[a] Assumed to weigh 7.5 kg, to breathe 2.1 m^3 of air per day (Health Canada 1998) and to ingest 38 mg of household dust per day (Wilson et al. 2013).

[b] Breastfed infants are assumed to consume solely breast milk for six months. Assumed to consume a median (127.95 µg/kg-bw/day) of breast milk (Arcus-Arth et al. 2005). In the absence of Canadian breast milk data, mean concentration of 0.0020 µg/g (wet weight) was obtained from the scientific literature (Abdulrazzaq et al. 2008; Clemente et al. 1982; Iyengar et al. 1982; Kosta et al. 1983; Krachler et al. 1998; WHO 1989). As no information is available to suggest which of these studies is most representative of the typical range of antimony concentrations in the milk of Canadian women, the arithmetic mean concentration reported over all studies was used to estimate exposure to antimony from human milk in Canada.

[c] Assumed to weigh 15.5 kg, to breathe 9.3 m^3 of air per day to drink 0.7 L of water per day (Health Canada 1998) and to ingest 14 mg of soil and 41mg of household dust per day (Wilson et al. 2013). Mean dietary intake (food and beverage) for 1-3 years, as presented in the Appendix Table B-1 was used to represent the dietary intake for this age group.

[d] Assumed to weigh 31.0 kg, to breathe 14.5 m^3 of air per day, to drink 1.1 L of water per day (Health Canada 1998) and to ingest 21 mg of soil and 31 mg of household dust per day (Wilson et al. 2013). Mean dietary intake (food and beverage) for 4-8 years, as presented in the Appendix Table B-1 was used to represent the dietary intake for this age group.
[e] Assumed to weigh 59.4 kg, to breathe 15.8 m^3 of air per day, to drink 1.2 L of water per day (Health Canada 1998) and to ingest 1.4 mg of soil and 2.2 mg of household dust per day (Wilson et al. 2013). Mean dietary intake (food and beverage) for 14-18 years, as presented in the Appendix Table B-2 was used to represent the dietary intake for this age group.
[f] Assumed to weigh 70.9 kg, to breathe 16.2 m^3 of air per day, to drink 1.5 L of water per day (Health Canada 1998) and to ingest 1.6 mg of soil per day and 2.5 mg of household dust per day (Wilson et al. 2013). Mean dietary intake (food and beverage) for 19-30 years, as presented in the Appendix Table B-2 was used to represent the dietary intake for this age group.
[g] Assumed to weigh 72.0 kg, to breathe 14.3 m^3 of air per day, to drink 1.6 L of water per day (Health Canada 1998) and to ingest 1.5 mg of soil per day and 2.5 mg of household dust per day (Wilson et al. 2013). Mean dietary intake (food and beverage) for 51-70 years, as presented in the Appendix Table B-2 was used to represent the dietary intake for this age group.
[h] Intake estimated using median 24-hr personal air sample $PM_{2.5}$ concentration of 0.29 ng/m^3 (n = 445), measured in Windsor, Ontario (personal air data are considered to be most representative of air concentrations in the breathing zone (Rasmussen 2016).
[i] Intake estimated using median concentration of antimony identified from Canadian Drinking Water Database was 0.25 µg/L (Tugulea 2016).
[j] Intake based upon the median national baseline concentration of bioaccessible antimony of 8.5 ppm measured in 1025 homes in the Canadian House Dust Study (Rasmussen 2016)
[k] Intake based upon the median concentration of antimony of 1.1 mg/kg at 0.05 cm depth from Port Colborne study (ON MOE 2002). This is higher than background median concentrations from provincial data. Bioaccessibility factor of 14% obtained for dust was used (Rasmussen 2016).

Appendix C: Human exposure estimates from use of products

Table C-1. Concentrations of antimony in textiles

Textile Type	Antimony Concentration (mg/kg)	Reference
Polyester	160-700	HealthyStuff.org 2009
Polyester	0.6- 25	Sorensen et al. 2005
Textile (flame retardants) type not specified	2,000-5,000	HealthyStuff.org 2009
Textile (flame retardants) type not specified	40,000- 60,000	EU 2008
Polyester (PET) Apparel	2 – 200	Danish EPA 2003
Apparel (type not specified)	87 - 147	BFR 2012
100% PET(Apparel	270	BFR 2012
Apparel (Skin contact) type not specified	<0.05 – 204	Rovira et al. 2015
Children's sleepwear type not specified	113 – 205	Health Canada 2017
Upholstery (PET / Cotton/ Rayon) Back-coated with FR	16,000 - 28,000	CPSC 2006b
Car seat canopy	82	Miller and Jeff (2016)

Upholstery/carpets/rugs/pillows	90 – 9,922	Turner and Filella (2017)
Carpet material	<LOD – 40	Health Canada 2017

Table C-2. Exposure to antimony from textiles

Scenario	Total surface area (cm^2)	Area weight (mg/cm^2)	Antimony concentration	Fractional release/ migration rate (Sb/day)	Exposure (mg/kg-bw/day)
Oral: Infant (0-0.5 yrs) mouthing textile	20[a]	20[b]	205 mg/kg[c]	0.007[d]	$7.7 X10^{-5}$[e]
Dermal: Infant (0-0.5 yrs) wearing a sleeper	3680[f]	20[b]	205 mg/kg[c]	0.1[g]	$2.0 X10^{-2}$[h]
Dermal: Infant (0-0.5 yrs) sleeping on a mattress cover	1620[i]	NA	NA	2.7 $\mu g/cm^2/day$[j]	$5.8 X 10^{-2}$[k]

NA: not applicable

[a] Surface area of object mouthed (SA): 20 cm^2 (Zeilmaker et al. 2000). Considered to be a conservative input as the US EPA Residential SOPs recommend to use 10 cm^2 (US EPA 2012).

[b] The area weight of textiles can vary greatly depending on the type of material. An area weight of 20 mg/cm^2 for cotton textiles is recommended by the US EPA in "Standard Operating Procedures for Residential Pesticide Exposure Assessment" (US EPA 2012).

[c] Measured maximum concentration in sleepwear textiles available in the Canadian market (Health Canada 2017)

[d] Antimony-specific extraction via artificial saliva; 0.7% (Danish EPA 2003).

[e] Oral exposure to antimony is based upon a scenario assuming that the child is mouthing a textile object (e.g., blanket, garment or a textile toy) that may release antimony. Based upon screening assessment: Aromatic Azo and Benzidine-based Substance Grouping; Certain Azo Disperse (ECCC, HC 2017) Estimated Daily Exposure via Oral Route from Mouthing Textile Object (mg/kg-bw/day) = Total surface area (cm^2) * Area weight (mg/ cm^2) * Antimony concentration (mg/kg) * Fractional release rate of Sb/day * conversion factor 1 kg/1,000,000 mg/ Default mean body weight; 7.5 kg body weight for infants (Health Canada 1998).

[f] Surface area of skin contact: Total body surface area; 3680 cm^2 for an infant baby sleeper (Health Canada 1995). This is considered to be a conservative input as parts of the body will not be in contact with the sleeper (e.g., head).

[g] Antimony-specific extraction via artificial sweat; 10% (Danish EPA 2003).

[h] Dermal exposure to antimony is based upon exposure from a baby sleeper. A conservative exposure estimate to antimony is based upon full body coverage from wearing clothing, assuming to account for exposures from multiple pieces of apparel that cover the entire surface area of the body (Based on Danish EPA 2014). Estimated Daily Exposure via dermal route from wearing baby sleeper (mg/kg-bw/day) = Total area of skin contact area (cm^2) * Area weight (mg/cm^2) * Antimony concentration (mg/kg) * Extracted fraction (per day) * Relative dermal to oral absorption fraction (0.1) * conversion factor 1 kg/1,000,000 mg/ Default mean body weight; 7.5 kg body Weight (Health Canada 1998).

[i] Total body surface area of skin contact; the surface area of exposure (skin is based upon exposure to back of the head, arms and legs (Health Canada 1995). The surface area of the head was multiplied by a factor of 0.5 to represent exposure to one side of the head only.

[j] Based upon CPSC (2006a); CPSC conducted a sheet migration study using a fabric treated antimony trioxide and simulated sweat. The average concentration of antimony was measured on a filter paper (as surrogate skin) which

was in direct contact with the fabric subject to a pressure of 1 PSI and wetted with 2 mL of simulated sweat. This result which represented the amount expected to migrate from the fabric to the surface of the skin, when subjected to wetting with simulated sweat was 2.7 µg/cm^2/day. This result represents the amount of antimony that is expected to migrate from a barrier to the surface and adsorb to the surface of the skin.

[k] Dermal exposure to antimony: For this scenario, it is assumed that an individual is wearing shorts and a t-shirt and sleeping on an antimony back coated mattress cover. Estimated Daily Exposure via dermal route from sleeping on a mattress cover containing antimony as a flame retardant (mg/kg-bw/day) = Total area of skin contact area (cm^2) * Migration of antimony from fabric over time (or release rate in µg/cm^2/day) * Relative dermal to oral absorption fraction (0.1) * Conversion factor 1mg/1000 µg/ Default mean body weight; 7.5 kg for infants (Health Canada 1998).

Table C-3. Oral exposure to antimony by mouthing children's toys

Scenario	Amount of antimony migrated (µg) in 120 min[a]	Exposure duration (min/day)[b]	Exposure estimate (mg/kg-bw/day)[c]
Infant (0-0.5 years) mouthing a toy	6.61	120	8.8 X 10^{-4}

[a] Amount of antimony at the maximum detection limit of the study conducted on contaminated toys and children's jewelry via saliva mobilization (Gunney et al. 2014, Personal communication, email from Gunney et al. to the Existing Substances Risk Assessment Bureau, Health Canada, dated June 23, 2017; unreferenced).

[b] Exposure Duration: 120min/ day for 0 – 18 months. This duration aligns with the maximum mouthing durations used in the assessment of several phthalates, such as DINP and DIBP (Environment Canada, Health Canada 2015a, 2015b).

[c] Estimated Daily Exposure via oral route; mouthing children's toys (mg/kg-bw/day) = Amount of antimony migrating from various toys and jewelry (µg) per 120 min / * Conversion factor 1mg/1000 µg * bw (kg) Default mean body weight; 7.5 kg for infants (Health Canada 1998).

Table C-4. Dermal exposure to antimony by applying lubricants and greases

Scenario	Skin surface area exposed cm^2)[a]	Antimony concentration range (%)[b]	Film thickness on skin (cm)[c]	Density (g/cm^3)[d]	Exposure frequency	Exposure estimate (mg/kg-bw/day)[e]
Dermal: Adult (20$^+$) applying lubricant to car	12	7	0.0156	0.9	1/day	1.7 X 10 $^{-2}$

[a] Skin surface area exposed: 12 cm^2 (US EPA 2011)

[b] Maximum antimony concentration in lubricant: 7% (SDS 2016; SDS 2002)

[c] Film thickness on skin: 1.56×10^{-2} cm (US EPA 2011)

[d] Density of the Lubricant: 0.9 g/cm^3 (SDS 2002, SDS 2016)

[e] Estimated Daily Exposure via dermal route; applying antimony-containing lubricants (mg/kg-bw/day) = Skin surface area exposed * Antimony Concentration * Film thickness on skin * Density * Relative dermal to oral absorption fraction (0.1) * Exposure frequency * Conversion factor 1,000 mg/g/ body weight (kg). Default mean body weight; 70.9 kg for an adult (Health Canada 1998)