

Summary of Public Comments received on the Challenge substance Antimony trioxide (CAS 1309-64-4) Draft Screening Assessment Report for Batch 9

Comments on the draft screening assessment report for antimony trioxide to be addressed as part of the Chemicals Management Plan Challenge were provided by International Antimony Association, Inuit Tapiriit Kanatami and Canadian Bottled Water Association.

A summary of comments and responses is included below, organized by topic:

- Human exposure assessment
- Human hazard assessment
- Human risk characterization
- Environmental and ecological assessment
- Risk Assessment

TOPIC	COMMENT	RESPONSE
Human exposure assessment	The World Health Organization (WHO) concluded a rise in drinking water guidelines from 5 to 20 µg/L for antimony trioxide was acceptable. Could the guideline acceptable for Health Canada of 6 µg/L be considered over-precautionary?	Based on the scientific information used to develop the drinking water guidelines established by Health Canada and WHO, the Health Canada guideline is not over-precautionary. It is also in line with the Maximum Contaminant Limit established by the U.S. Environmental Protection Agency. It is important to note that the current screening assessment estimated the intake from drinking water using the maximum concentration of antimony found to be leaching from PET plastic bottles into water.
	The European Union (EU) Risk Assessment Report (RAR) oral absorption coefficient of 1% is not used in this assessment; however, it should be considered instead of the 100% proposed in the screening assessment report (SAR). The EU RAR dermal absorption coefficient was 0.26%, which is suggested instead of the proposed 100% in the SAR.	The screening assessments notes the absorption values proposed in the EU RAR. However as adequate margins of exposure were obtained for general population exposure scenarios, additional refinements to the exposure estimates were not warranted
Human hazard assessment	There are gaps in the assessment that need addressing such as a lack of epidemiological studies that may address the uncertainty in the carcinogenic	The confidence in the health effects database for antimony trioxide is considered to be moderate and the derived margins of exposure were considered adequate to account for uncertainties in the health

	potential of antimony trioxide. Long-term toxicity studies should be conducted in species other than rats. Animal inhalation genotoxicity studies are needed and the dermal data set also needs strengthening.	effects and exposure databases. Additional genotoxicity studies via the inhalation route became available during the public comment period and have been included in the final screening assessment report.
Human risk characterization	Given its many adverse effects (carcinogenicity, developmental and reproductive), a precautionary approach should be taken for antimony trioxide with the result of a CEPA toxic designation.	Upper bounding estimates of general population exposure are presented in the screening assessment. On the basis of the adequacy of the margins between these conservative estimates of exposure to antimony trioxide and critical effect levels in experimental animals, it is concluded that antimony trioxide is 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.
	The assessment should consider vulnerable populations such as children, pregnant women, aboriginal communities, individuals with low income and chemical sensitivities.	The Challenge screening assessments are based on consideration of the available data. The various conservative exposure scenarios used are considered to be protective of vulnerable populations in Canada and do incorporate specific exposure estimates for Canadians of different ages. If information is available which suggests that a specific sub-population would be particularly vulnerable, this information is considered in the assessment. In this assessment, it was recognized that use of household products, while common to all age groups, is of more concern to young children, and this is reflected in the screening assessment, exposure to young children was a focus of the exposure assessment for products
Environmental and ecological assessment	It is strongly recommended that a re-evaluation be undertaken of human health risks regarding the gaps in water and sediments monitoring data (ie. in water when antimony trioxide is used as a flame retardant and in soil near roadways where antimony trioxide is emitted from brake pads).	Canadian monitoring data was not available for all environmental media, and general population exposure estimates were derived based on models or surrogate data. It is considered that the margins of exposure are adequate to address uncertainties in the health effects and exposure databases. All substances that have undergone assessment remain subject to future evaluation if new, substantive information is identified that indicates that further consideration is warranted.
	Empirical data suggests that antimony has a	Empirical inherent toxicity data for aquatic, soil and sediment

	<p>“moderate potential to cause harm to aquatic, soil and sediment organisms” whereas the assessment concluded that antimony trioxide does not have the potential to cause ecological harm in Canada.</p>	<p>organisms show that dissolved antimony has a moderate potential to cause harm. However, based on comparison of exposure levels with levels expected to cause a detrimental effect, antimony trioxide is unlikely to cause ecological harm in Canada.</p>
	<p>Long-Range Transport Potential (LRTP) of antimony trioxide was not quantified in the substance profile nor in draft Screening Assessment Report (SAR). However, according to a report by the European Union, human activities may result in LRTP of a portion of the substance emitted to air.</p>	<p>LRTP was not quantified in the draft screening assessment as this source is not expected to contribute significantly to Predicted Environmental Concentrations (PECs), used to determine exposure. This has been further clarified in the final SAR.</p>
Risk Assessment	<p>The Government should consider the potentially synergistic effects of chemical mixtures, given that exposures to several chemicals occur simultaneously.</p>	<p>Consideration of cumulative, synergistic and antagonistic effects is not precluded from a risk assessment. However, in order to be considered, sufficient information to undertake such analyses would be needed. Under the Challenge, the information typically available for assessing effects is representative only of a substance’s inherent ability to elicit adverse effects on its own.</p>