

Summary of Public Comments received on the Challenge substance DTBSBP (CAS 17540-75-9) Draft Screening Assessment Report and Risk Management Scope for Batch 8

Overarching comments on the draft screening assessment reports for Batch 8 to be addressed as part of the Chemicals Management Plan Challenge were provided by Chemical Sensitivities Manitoba and Canadian Environmental Law Association, Dow Chemical Canada, and Inuit Tapiriit Kanatami (ITK).

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

- Phys-Chem Properties
- Persistence
- Inherent Toxicity
- Risk Management Scope
- Exposure
- Data gaps and deficiencies
- Risk Assessment Conclusion

TOPIC	COMMENT	RESPONSE
Phys-Chem Properties	The two values for the melting point (measured and experimental) presented in Table 2 vary largely. Please identify and justify the value used in the assessment.	The melting point value of 18.9 °C comes from a Material Safety Data Sheet (MSDS) provided by the only North American manufacturer of this substance and is considered to be more reliable than the modelled value of 102 °C.
Persistence	Since DTBSBP is persistent, further investigation on the biodegradation process is required since biodegradation may lead to the formation of metabolites that may have toxic properties.	The metabolites are anticipated to be less toxic than DTBSBP, based on model predictions that were generated for the four most likely metabolites, and are also not bioaccumulative. Based on this no further assessment is required.
Inherent Toxicity	According to a Material Safety Data Sheet this substance may irritate eyes, skin and mucous membranes. This was not discussed in the screening assessment.	Available health effects information is considered in the screening assessment. However, if reliable information identifies additional effects as a concern, this information will be taken into consideration. Hazard information in an MSDS on its own is considered to be insufficient for assessment. Supporting documentation for the hazard information and classification mentioned in the MSDS was searched for but could not be found in other sources.

	<p>Chronic studies on the effects of DTBSBP exposure in various species are required to fully evaluate the impact of it in organisms and the environment. The government should seek chronic toxicity data. Empirical data on possible health effects in humans should also be gathered.</p>	<p>The Government of Canada has stated that the absence of information will not preclude the Ministers from issuing a decision that safeguards human health and the environment. Thus the process being used for the Challenge substances is not to wait until data gaps are filled, but to act on what we know now. As DTBSBP has been determined to be persistent and bioaccumulative, it is targeted for virtual elimination of releases, as specified in CEPA 1999.</p>
Risk Management Scope	<p>It is important to engage stakeholders who will be affected by the proposed implementation of virtual elimination for DTBSBP.</p>	<p>Consultation with stakeholders is an essential part of any risk management process. The Government of Canada intends to consult extensively with all affected stakeholders with regards to the proposed risk management measures.</p>
	<p>DTBSBP should be removed from Canadian commerce.</p>	<p>Risk management measures will be based on strategies to prevent measurable releases of DTBSBP to the environment. If it is determined that measurable releases of DTBSBP as a result of its current uses cannot be prevented, then, the removal of this substance from Canadian commerce will be considered.</p>
	<p>Risk management measures should be tailored to the sources of release and exposure to avoid impacting usages that do not lead to any release. As such, it is suggested that the government add DTBSBP to the <i>Prohibition of Certain Toxic Substances Regulation</i> with a concentration limit and permitted uses.</p>	<p>Various risk management measures will be considered to achieve the risk management objective of eliminating releases of DTBSBP. The <i>Prohibition of Certain Toxic Substances Regulation</i> was identified as one potential risk management instrument.</p>
Exposure	<p>The lack of exposure, as well as experimental or predicted effects data for non-aquatic organisms in sediment and soil is of concern, due to the chemical's ability to partition and persist in soil and sediment, and also due to its bioaccumulative properties.</p>	<p>The Government of Canada has stated that the absence of new information will not preclude the Ministers from issuing a decision that safeguards human health and the environment. Thus the process being used for Challenge substances is not to wait until data gaps are filled, but to act on what we know now. All substances that have undergone assessment remain subject to future evaluation if new, substantive information is identified that indicates that further consideration is warranted.</p> <p>However, because DTBSBP has been found to be persistent and</p>

		bioaccumulative, environmental risk quotients, and hence environmental exposure estimates were not used in the determination of the toxicity of this substance.
	The likelihood of human exposure to DTBSBP being negligible to low is incorrect.	In the screening assessment of DTBSBP, all estimates of human exposure were derived using conservative assumptions and were considered to be over-estimates. The magnitudes of the estimated exposures, coupled with the conservative approach used to derive the estimates, suggest that potential human exposure to DTBSBP is negligible to low.
	There is no consideration for long-term effects of exposure through various products and routes (e.g., dermal, inhalation, ingestion).	There were no empirical data identified for chronic toxicity of DTBSBP. However, available empirical chronic toxicity data from analogues were compared with exposure estimates for DTBSBP in deriving estimated margins of exposures for different routes and products. These margins of exposure thus account for long term effects of exposure through different routes and products.
	The estimates and model assumptions for releases of DTBSBP presented in the Releases to the Environment section of the report (e.g., wastewater emissions) are extremely high and are not realistic.	The losses estimated for DTBSBP in the Releases to the Environment section of the report represent realistic, worst-case scenarios, as described in the report. Assumptions for environmental releases were taken from all information currently available, including Emission Scenario Documents issued by the Organization for Economic Cooperation and Development (OECD).
Data gaps and deficiencies	The total reliance of models in predictions of persistence, bioaccumulation and ecotoxicity and health effects cannot be relied upon to the degree it has without corroboration with empirical, measured or monitored data.	In the ecological risk assessment of DTBSBP, there is empirical data for persistence, and the modelled predictions for bioaccumulation and toxicity are supported by empirical data for the close structural analogue 2,4,6-tri-tert-butylphenol. Empirical studies for the log Kow of this substance, as well as biodegradation, bioaccumulation and toxicity studies were produced by the Chemicals Evaluation and Research Institute (CERI) of Japan, using standard OECD methods.
	The Government should search for safer alternative substances to DTBSBP.	Essential uses of the substance and availability and suitability of potential alternatives will be considered in the risk management process.

	<p>Confidentiality granted to the industry makes it impossible to obtain information critical to understanding the extent of use, release levels and potential for exposure. In fact, because of CBI, the extent of the use of DTBSBP in Canada is virtually unknown to the public, and it is not clear what information has been provided to the government.</p>	<p>Most usage information for DTBSBP was non-confidential, and is provided in the SAR. This information includes the total quantity of DTBSBP used in Canada, as well as the number of companies involved, uses of the substance, including food contact uses, and the concentration range in which it is used.</p>
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