

**Summary of Public Comments received on the Challenge Substance BENPAT /BENTAX (CAS: 68953-84-4 and 68478-45-5) Draft Screening Assessment Report and Risk Management Scope for Batch 11**

Comments on the draft screening assessment report and risk management scope for BENPAT and BENTAX to be addressed as part of the Chemicals Management Plan Challenge were provided by Lanxess Corporation, Goodyear Tire and Rubber Company, Inuit Tapiriit Kanatami, Canadian Environmental Law Association and Chemical Sensitivities Manitoba.

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

- Physical –Chemical Properties
- Bioaccumulation
- Persistence
- Inherent Toxicity and Health Effects
- Uses
- Exposure
- Data Gaps and Deficiencies
- Risk Assessment Conclusion
- Proposed Risk Management
- Risk Management Scope
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TOPIC	COMMENT	RESPONSE
<b>Physical – Chemical Properties</b>	<p>Use of additional physical-chemical properties data that was submitted during the public comment period was recommended.</p> <p>The fugacity modelling estimates are not realistic given the physical/chemical properties of the structures. It is believed that if released to the environment, BENPAT will partition primarily to soil and sediment, not water.</p> <p>Experimental physical chemical properties should be used as model inputs.</p>	<p>Data from two newly submitted studies on physical chemical properties were incorporated into the final screening assessment.</p> <p>Use patterns of the substance including releases from manufacturing processes and from products indicate that water is one of the receiving environmental compartments. Therefore, fugacity scenarios presented in the final screening assessment are realistic and results are consistent between those obtained for the whole substance and the components. Fugacity modelling results were presented as a range for each environmental compartment, based on physical chemical properties available for the substance as a whole and for individual components. The model was run several times to accommodate the combination of model inputs.</p> <p>Modeled values were used as inputs when experimental values were not available.</p>

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	<p>Intrinsic properties of the substance should be considered to limit the receiving environmental compartments.</p>	<p>The screening assessment carefully considers the intrinsic properties of BENPAT. This includes consideration of experimental and modelled physical chemical properties of the substance, and high adsorptive properties of the substance. Based on the uses and manufacturing processes of products containing BENPAT, the aquatic environment is considered to be a receiving environmental compartment.</p>
<p><b>Bioaccumulation</b></p>	<p>Using the highest mean bio-concentration factor value for a representative structure of BENPAT to represent the bioaccumulation potential of the whole substance is inappropriate. A weighted average of BCF values for the three representative structures should be considered as well as additional evidence from animal studies.</p>	<p>BENPAT is mainly composed of components 1, 2 and 3 identified in the screening assessment at a distribution of approximately 25%, 50% and 25%, respectively. The empirical aquatic data indicates the bioaccumulation potential of an individual component.</p> <p>However, the conclusion for the bioaccumulation potential of BENPAT was revised in the final screening assessment. It was determined that the results from the available aquatic bioaccumulation study were uncertain. Additional information including experimental depuration rates, experimental log K<sub>ow</sub> values, and mammalian studies that were submitted during the public comment period, were considered in the final screening assessment of BENPAT. While it is acknowledged that the substance has a significant potential to bioaccumulate in aquatic organisms, it is concluded based on the available weight of evidence, that it does not meet the bioaccumulation criteria as set out in the <i>Persistence and Bioaccumulation Regulations</i> of the <i>Canadian Environmental Protection Act, 1999</i> (CEPA, 1999).</p>
	<p>Bioaccumulation and biomagnification of these substances should be directly linked to potential health effects.</p>	<p>Although these products have been identified as having the potential to bioaccumulate, no evidence of their presence in food consumed by humans was found. Based on their use patterns, these substances are not expected to be found in food or beverages in Canada. Therefore health effects in human populations are not likely.</p>
<p><b>Persistence</b></p>	<p>The biodegradation potential does not consider a weight of evidence approach and inappropriate conclusions have been drawn from models of ultimate biodegradation.</p>	<p>Evidence of several degradation processes of BENPAT based on reliable studies is considered in the screening assessment. Conclusion on persistence is based on the weight of evidence approach, taking into account reliable studies of different degradation pathways as well as modelled results. Modelled results were found to be reliable.</p>
	<p>There are issues regarding the degradation potential of BENPAT through oxidation, selected biodegradation models, water as the receiving medium, and estimation of the half life in water used to model long range</p>	<p>The conclusion regarding persistence was reached based on the weight of evidence which considered a variety of degradation pathways and reliable biodegradation modelled results. The applicability of model inputs, including the modelled half-life in water, to determine the long range transport potential was re-evaluated. Revisions did not change the conclusion of no long-range transport potential for BENPAT.</p>

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	transport predictions.	
<b>Health Effects</b>	Occupational exposure has not been considered.	Hazard information obtained from occupational settings, in particular data from epidemiological investigations, is considered in the screening assessment. The information developed through the Chemicals Management Plan process may be used to inform decisions concerning additional actions to minimize exposure to workers. The Government of Canada is working to communicate results to appropriate occupational health and safety groups.
<b>Uses</b>	An explanation for the changes in use patterns and volumes used over time is required. Past uses may contribute to historic, long-term contamination due to the persistence and bioaccumulation characteristics associated with these substances.	Information regarding substance quantities that are sold, manufactured or imported into Canada obtained through surveys for different years informs conclusions on whether quantities in use are increasing or decreasing. Substances that have persistence and bioaccumulation potential can build up in the environment and biota. This is recognized and accounted for in the screening assessment.
<b>Exposure</b>	The Mass Flow Tool results were provided in percentages, rather than quantities and do not indicate actual amount of releases to the environment. The actual mass of the substance lost from each of the life cycle stages may be higher than the provided.	<p>Releases to the environment from the Mass Flow Tool estimation are provided in percentages. These can be applied to the quantity range of BENPAT imported in 2006, resulting in lower and upper estimates of the potential quantities released into the environment.</p> <p>The estimates of potential releases into the environment provided in the screening assessment for BENPAT and BENTAX are based on section 71 of CEPA 1999 survey results. Response to this survey was mandatory for industries involved in the manufacture, import and use of these substances above the reporting thresholds. The exact import quantities provided to the government are considered confidential business information and cannot be disclosed.</p>
	Releases of BENPAT from industrial processes are unlikely. The water compartment may not be a relevant receiving medium.	Estimations of releases from industrial processes were submitted as part of the public comments. Substantiated information was considered in the industrial release scenarios included in the final screening assessment. Based on the available information on the manufacturing processes of products containing BENPAT, the water compartment is considered a valid receiving medium.

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	<p>The environmental exposure assessment significantly overestimated the release of BENPAT to air, water, soil and sediment from tire wear.</p>	<p>Estimations of environmental concentrations of antidegradants based on a tire marker study were provided in the draft screening assessment since information on the environmental levels of antidegradants including BENPAT stemming from tire wear was not available. These semi-quantitative estimations were removed from the final screening assessment. Revisions considered in the final screening assessment included site specific industrial release scenarios, consumer release scenarios, risk quotient analysis and additional information (e.g., reliability of tire markers and detection of BENPAT in tire particles).</p> <p>Information provided in the public comments submissions was reviewed and incorporated in the final assessment when deemed appropriate. Assumptions presented without supporting documentation or referencing were not incorporated as it was not possible to review their basis. All available information, including that submitted during the public comment period, was considered in determining the most appropriate approach to estimate environmental exposure resulting from tire wear.</p>
<p><b>Data gaps and deficiencies</b></p>	<ol style="list-style-type: none"> <li>1) Data gaps and deficiencies along with claims of confidentiality weaken the argument that general population exposure to consumer products is unlikely.</li> <li>2) Reproductive and developmental effects should be researched further.</li> <li>3) Exposures in vulnerable populations should be considered.</li> <li>4) Synergistic effects of chemical mixtures needs to be examined.</li> <li>5) Water solubility should be experimentally evaluated to determine modeled toxicity accurately.</li> <li>6) Lack of information on environmental releases and concentrations in Canada needs to be addressed and quantified.</li> <li>7) There is an absence of toxicity data for soil or sediment organisms for both substances.</li> </ol>	<ol style="list-style-type: none"> <li>1) Data gaps and deficiencies were associated with modeled estimates of environmental exposure in the SAR. However, these estimates were based on conservative assumptions, and margins between upper-bounding estimates of exposure were considered adequate to address uncertainties in the health effects and exposure databases. With regards to consumer products exposure, information was available but not reported in the SAR for confidentiality reasons. Based on this information, general population exposure to consumer products is considered unlikely.</li> <li>2) Reproductive and developmental effects were taken into consideration in the risk characterization and margins of exposure were considered to be adequate to address uncertainties in the health effects and exposure databases.</li> <li>3) Exposure scenarios assessed in the screening assessment are considered conservative enough to be protective of vulnerable populations in Canada.</li> <li>4) The synergistic effects of chemical mixtures are not precluded from screening assessments as long as sufficient information is available. This information was not available for BENPAT and BENTAX, so the assessment focused on the substances' inherent ability to elicit adverse effects.</li> <li>5) Solubility of BENPAT that was determined experimentally was described in the screening assessment. Since several reliable aquatic toxicity studies are available for BENPAT,</li> </ol>

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	<p>8) Exposure estimates need to be more thorough using information derived through environmental monitoring.</p> <p>9) Disposal and legacy issues from the use of these substances need to be addressed.</p>	<p>modelling of aquatic toxicity is not required and, therefore is not considered in the final screening assessment.</p> <p>6) Information regarding measured environmental releases and concentrations for BENPAT and BENTAX is not available. It is recognized that data gaps exist in the environmental monitoring of these substances. It is additionally noted that reliable environmental monitoring is scientifically and technically difficult as these substances are multi-component, complex reaction products. Estimates of environmental releases from manufacturing sites in Canada determined for BENPAT were submitted during the public comment period and substantiated information has been considered as appropriate in the final screening assessment.</p> <p>7) Soil and sediment toxicity studies for BENPAT were submitted to Environment Canada and are considered in the final screening assessment. Soil and sediment toxicity data were not available for BENTAX, and models to address toxicity in soil and sediment are not currently available.</p> <p>8) As reliable environmental monitoring data is not available for BENPAT and BENTAX, exposure assessment is based on appropriate assumptions for release and exposure.</p> <p>9) Disposal sites and contaminated sites are under provincial jurisdiction. The risk management process consults all relevant stakeholders at every stage</p>
<b>Risk Assessment Conclusion</b>	Virtual elimination of releases will have economic and social impacts, for companies that use these substances both nationally and internationally.	Virtual elimination will not be pursued for BENTAX or BENPAT as neither substance meets the criteria for virtual elimination under s. 74 of CEPA, as indicated in the final screening assessment.
<b>Proposed Risk Management</b>	The risk management document does not consider the production of other toxic chemicals that may result from other activities affecting BENPAT/BENTAX substances such as incineration or landfill leaching, and environmental and health risks associated with these activities.	The risk management scope document addresses only risks that are identified in the assessment. No risk was identified for combustion of BENPAT and BENTAX. However, off-gassing or migration of BENPAT and BENTAX from landfills is not expected to be a significant source of release, as both substances have low volatility and adsorb highly to soils.
	There should be safe substitutes for BENPAT/BENTAX such as in tire manufacturing.	Substitutes for BENPAT and BENTAX are not yet assessed for their potential to harm environmental or human health. Therefore alternatives can not be identified in the risk management document.

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	The government is urged to take a preventative and protective approach and phase out these substances.	The proposed risk management objective for BENPAT is to reduce releases of BENPAT to the environment from the rubber products and tire manufacturing, and from consumer products to the greatest extent possible. There is no risk management approach for BENTAX because this substance does not meet any of the criteria set out in section 64 of CEPA 1999.
<b>Risk Management Scope</b>	Levels of Quantification for virtual elimination are difficult to establish when values for releases and all potential sources are not provided.	BENPAT does not meet the criteria for virtual elimination, and there is no need to develop a Level of Quantification.