

Summary of Public Comments received on the Challenge substance MAPBAP (CAS 72102-55-7) Draft Screening Assessment Report and Risk Management Scopes for Batch 8

Comments on the draft screening assessment report for MAPBAP to be addressed as part of the Chemicals Management Plan Challenge were provided by Chemical Sensitivities Manitoba, the Canadian Environmental Law Association (CELA), and the importer of MAPBAP acetate (identity is confidential business information).

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

- Data gaps and deficiencies
- Exposure/ releases
- Risk assessment conclusion
- Proposed risk management

TOPIC	COMMENT	RESPONSE
Data gaps and deficiencies	The government should apply the precautionary approach.	The conclusions from the screening assessments adhere to a precautionary approach because where there are uncertainties (such as volumes in commerce or being released, where models are used to predict exposure or effects, or where the risk characterization is derived), conservative approaches are used. In the case of the risk characterization, the conservative nature of the assumptions used in this derivation takes into account uncertainties in effects and exposure databases.
	<p>There is a need to address data gaps and uncertainties. We recommend that Environment Canada gathers the following information from stakeholders:</p> <ul style="list-style-type: none"> • The quantities of MAPBAP acetate in products imported to Canada, with particular emphasis on paper and paper products. • Identification of all potential uses for this substance. 	<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. The conservative nature of the risk characterization in the screening assessment takes into account uncertainties in the effects and exposure databases, including data gaps and deficiencies, for MAPBAP acetate.</p> <p>With respect to some of the specific recommendations for</p>

	<ul style="list-style-type: none"> • Improved hazard data that would rely on the generation and use of experimental data so that there could be a more accurate reflection of bioaccumulation. • Investigation on the level of toxicity to soil and sediments that may receive biosludge products that contain MAPBAP acetate and similar substances. • The level of MAPBAP acetate used as dyes that have the potential to be adsorbed to waste and eventually end up in water treatment plant sludge, which may be subsequently applied to agricultural lands. There is a need to further investigate soil/sediment toxicity data for this substance. • Identification and consideration of all by-products of MAPBAP acetate in the scope of the assessment report, with a focus on waste disposal sites and other disposal methods. • Since MAPBAP acetate is persistent in water and is capable of being ionized in water, there is a need to establish if any metabolites from this product have toxic properties. 	<p>additional data:</p> <ul style="list-style-type: none"> • Current uses identified in Canada have been addressed in the assessment. • The existing hazard and exposure data and application of precaution are sufficient to conclude that MAPBAP acetate meets the criteria for toxicity under s.64(a) of CEPA 1999. • The exposure assessment has identified which by-product streams (e.g., pulp mill biosludge) are relevant to the assessment. • A thorough investigation of metabolites and their potential toxicity was not conducted because MAPBAP acetate itself meets the criteria for toxicity under s.64 of CEPA 1999. Therefore, it is expected that potential risks posed by metabolites will be addressed indirectly through the management of MAPBAP acetate. <p>In addition, and where relevant, research and monitoring will support verification of assumptions used during the screening assessment.</p>
Exposure/ Releases	<p>The release rate used in the draft Screening Assessment Report (18.3%) does not represent the actual amount of MAPBAP acetate released in pulp mill wastewater. The SAR also does not consider recycling of wastewater within the pulp mill. A lab study, conducted by the importer, found that only 0.08% of MAPBAP acetate was found in experimental wastewater.</p>	<p>The lab study provided by the importer was analyzed and found to contain a number of deficiencies that render the data unusable, including the failure to accurately simulate actual paper-dyeing operations, unacceptable analytical detection limits, and misinterpretation of test results. The conservative release rate used in the site-specific exposure scenario (revised to 8.3% following the public comment period) is based on information in an Organization for Economic Cooperation and Development</p>

		Emission Scenario Document that was developed in consultation with the pulp and paper sector. Therefore, this rate is deemed acceptable for exposure purposes. The exposure scenario takes water recycling within the pulp mill into account.
	MAPBAP acetate is used in paper imported into Canada and there is concern about the accuracy of data on the releases of this chemical to the environment. These releases will most likely be underestimated without accurate information on the amount of paper containing this chemical that is annually imported into Canada.	<p>In developing the exposure scenario to predict releases to wastewater, conservative assumptions were used.</p> <p>MAPBAP acetate adheres strongly to paper. Consequently, releases from paper and paper products are predicted to be low.</p>
Risk Assessment, Conclusion and Proposed Risk Management	The SAR does not adequately explain how uncertainties about releases (specifically those related to paper production and disposal) and their potential human health impacts (e.g. carcinogenicity) have influenced the decision making process for the management of this chemical.	<p>Risk management actions to protect the environment will focus on releases of MAPBAP acetate into wastewater from facilities manufacturing, processing and using MAPBAP acetate.</p> <p>Assessments recognize that some portion of a substance is expected to end up in landfills, but releases of the specific substance from those sites are generally not quantified. Approaches are currently under development to identify substances for which monitoring, of landfill leachates for example, may be warranted to support risk management activities.</p> <p>The health risks associated with a chemical depend on the hazard (its potential to cause health effects) and the dose (the amount of chemical to which you are exposed). The final Risk Assessment Report concludes that, based on current low to negligible exposure levels of MAPBAP from environmental and consumer product (newsprint dyes) sources, the health risk to the general population is considered low. Therefore the substance was not found to meet the criteria under section 64(c) of CEPA 1999. However, due to the potential health hazards identified, the Government of Canada plans to implement Significant New Activity provisions under CEPA 1999 to this substance. This would require that any proposed new manufacture, import or use be subject to further assessment, and would determine if the new activity requires</p>

		further risk management consideration.
	<p>Based on the calculated risk quotients (>1 for all sites), the Government made the appropriate assumption that MAPBAP acetate could be causing “ecological harm in Canada.” These results focused on only 10 sites and we are concerned about how relevant these findings may be for all of Canada. Because of these limited data, careful consideration should be taken in the development of management options. Concerns around the low confidence in toxicity data for human health effects such as carcinogenicity point to a greater need to prevent exposure. Recommendations are:</p> <ol style="list-style-type: none"> 1) Based on its properties and widespread use, we recommend that MAPBAP acetate be designated as CEPA toxic. 2) We support the recommendation that MAPBAP acetate be added to the List of Toxic Substances (Schedule 1) of CEPA. 3) We urge the government to phase out the use of MAPBAP acetate, targeting industrial applications and the use of MAPBAP acetate in consumer products, including imports. 	<p>The 10 sites used in the calculation of risk quotients are located across Canada (from British Columbia to Newfoundland) and are customers to whom the importer sold dyes containing MAPBAP acetate. Therefore, they are considered representative of potential exposures across Canada.</p> <p>In response to the first two recommendations provided, the screening assessment report concludes that MAPBAP acetate meets one or more of the criteria under section 64 of CEPA 1999. Therefore, it is proposed to recommend the addition of MAPBAP acetate to the List of Toxic Substances in Schedule 1.</p> <p>In response to the third recommendation, the final Risk Assessment Report concludes that, based on current low to negligible exposure levels to MAPBAP acetate from environmental and consumer product sources (newsprint dyes), the health risk to the general population is considered low, therefore the substance was not found to meet the criteria under section 64(c) of CEPA 1999. However, due to the potential health hazards identified, the Government of Canada plans to implement Significant New Activity provisions under CEPA 1999 to this substance. This would require that any proposed new manufacture, import or use be subject to further assessment, and would determine if the new activity could be permitted or requires further risk management consideration. In addition, the risk management being considered for MAPBAP acetate is an environmental release guideline (ERG) to limit releases to water from facilities manufacturing, processing and using MAPBAP acetate or products containing MAPBAP acetate.</p>