

Comments on the original draft screening assessment for M4Q to be addressed as part of the Chemicals Management Plan Challenge were submitted by an individual from the Department of Chemistry and Chemical Biology, McMaster University and from Keepers of the Athabasca.

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

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TOPIC	COMMENT	RESPONSE
Bioaccumulation	MDM offers a more effective comparison than PTS for determining the bioaccumulation potential of M4Q.	Analysis of bioaccumulation potential has been expanded to include data from four substances that are structurally and mechanistically similar to M4Q: PTS, L4, L5 and MDM.
Persistence	Degradation products should be considered in the screening assessment.	While screening assessments focus on the evaluation of the categorized substance, potentially harmful degradation products may also be considered. In the case of M4Q, no information on degradation or transformation products was found.
	The proposed conclusion on the persistence of M4Q in the natural environment is unsupported by empirical data and reliable models.	No empirical degradation data for M4Q were found and modelled data, as well as empirical and modelled data for suitable analogue substances, were used to evaluate environmental persistence.
Inherent toxicity	The model estimates of M4Q's toxicity are not reliable.	Models are used routinely in Canada and internationally as part of a weight-of-evidence approach. In the case of the modelled aquatic toxicity estimates for M4Q, they were obtained from the ECOSAR (2008) computer program and are determined by several factors, including the mode of action and partitioning of the substance (rather than its chemical structure). As a result, the fact that only a few similar substances are included in the model does not prevent its use in estimating aquatic toxicity.
	Toxicity data on soil- and sediment-dwelling organisms are needed.	While additional toxicity data for soil- and sediment-dwelling organisms would be useful, their absence did not prevent a decision about potential hazards caused by M4Q. Toxicity data for a substance with a probable similarity in mode of action to M4Q suggest that M4Q is not likely to be hazardous to soil organisms. A sediment study for M4Q found effects in one species, but the conditions used in the study may have influenced the

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		<p>results. As well, it is expected that organisms in the environment would only be exposed to very low levels of M4Q. Most M4Q released to soil would be expected to disperse into the air, with only a small amount staying in the soil. A small quantity of M4Q also may be present in wastewater, but most will be present in products that ultimately end up in landfills.</p>
<p>Data gaps and deficiencies</p>	<p>Gaps in data for M4Q seriously affect the ability to conclude on its potential risk. There are very limited empirical toxicity data for M4Q and its analogues, and limited (or no) genotoxicity data.</p> <p>Mouse studies on MDM, the analogue substance for M4Q, conclude lymphoma cell-mutation.</p>	<p>Screening assessments conducted under section 74 of CEPA 1999 are based on considerations of the available data. In the case of M4Q, the limitations of the databases are recognized, but all available information was considered. Ultimately, that available information—which includes evidence taken from mouse studies for MDM and data from similar substances—was enough to support the proposed conclusion that M4Q is not considered to meet criteria under section 64 of CEPA 1999.</p>
<p>Uses and releases</p>	<p>M4Q should be added to the Domestic Substances List Inventory Update in order to obtain more information on imports and use.</p>	<p>Data on the manufacturing, import, and use of M4Q were collected for the years 2005 and 2006 through two survey Notices under Section 71 of CEPA 1999. These data are included in the screening assessment.</p>
	<p>The survey data used in estimates is insufficient because it only covers two years (2005 and 2006). This is not enough time to establish a trend, and the data compared from each year is significantly different.</p>	<p>Different survey methods were applied in each year. The 2005 survey was designed only to determine the approximate magnitude of the quantity of substances used in Canada for commercial and non-commercial uses, to support forward planning for assessments. It did not ask for specific quantities, but rather required identification of quantities within a few wide ranges (e.g., 1001– 100 000 kg). The 2006 survey, however, required importers to report quantities with more precision. The surveys were designed for different purposes and were not intended to obtain a trend.</p>
	<p>The amount of M4Q contained in products—and how long it is contained—should also be discussed.</p>	<p>A wide range of silicon-based products contain M4Q at low levels, and studies indicate that it remains mostly within these products during use. Releases of M4Q are primarily expected to occur after the product is discarded and starts to break down in the natural environment.</p>
	<p>Exports of M4Q from Canada should not be considered a reduction in the potential for M4Q</p>	<p>In the mass balance model used in the assessment of M4Q, the export of products containing M4Q reduces the initial quantity of the substance that is the starting point of</p>

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	release into the environment.	the estimates. The model is meant to estimate the <i>proportion</i> of the substance lost throughout its lifecycle and can be used to identify environmental compartments into which a substance is most likely to be released.
	The estimates of exposure are uncertain because environmental concentrations were modelled.	Exposure estimates were developed using conservative assumptions and protective margins of exposure. This means that while estimating environmental concentrations in this way can be uncertain, the assumptions are protective enough to account for limitations in the database. The screening assessment now also includes some recent Canadian monitoring data.
Risk assessment conclusion	The proposed regulatory conclusion does a good job of balancing the available data for this substance.	The Government of Canada acknowledges this comment.
Overarching comments	Current standard measurements for a “reasonable” rate of environmental degradation need to be reconsidered because they assume that some compounds (notably those with a low molecular weight) are not undergoing efficient degradation in the environment.	Substances were categorized relative to regulatory criteria in <i>the Persistence and Bioaccumulation Regulations</i> of CEPA 1999 for both environmental persistence and bioaccumulation potential. The Regulations do not distinguish between compounds of different molecular weights; rather, they are applied to all substances based on measured or modelled degradation or bioaccumulation data.
	The assessment did not consider the possibility of cumulative and synergistic effects of exposure. The chemical-by-chemical approach is a serious limitation of risk assessment, and methods for estimating the cumulative effects of exposure to similar substances should be developed further and applied in risk assessments.	Consideration of cumulative and synergistic effects can be part of a screening assessment. However, in order to be considered, sufficient information to undertake such analyses would be needed.
	Environment Canada and Health Canada should develop a method for generating the data for determining if substances meet the criteria under Section 64 of CEPA 1999.	The Government of Canada has committed to concluding on Challenge substances based on the currently available information. That means existing empirical data for the substance (or an analogue), as well as data derived from reliable modelling procedures, form the basis of decision making for screening risk assessments conducted under the Challenge.