

Summary of Public Comments received on the Challenge substance Ethanedial (107-22-2) Draft Screening Assessment Report for Batch 11

Comments on the draft screening assessment report for ethanedial to be addressed as part of the Chemicals Management Plan Challenge were provided by Dow Chemical Canada.

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

- Physical Chemical Properties
- Uses
- Sources
- Exposure

TOPIC	COMMENT	RESPONSE
Physical Chemical Properties	There are notable differences in the values for some physical/chemical properties, (e.g., vapour pressure, Henry's law constant and water solubility). These values should be reconciled. Some of the ecotoxicity predictions may exceed the water solubility. A rationale should be provided for which values are selected and used for modelling.	<p>The consistency of the vapour pressure, Henry's Law constant and water solubility with one another was checked using the method of Beyer et al. (2002). According to this method, these values are all reasonably consistent with one another.</p> <p>Only one modelled water solubility value is given in Table 2 – the same value was obtained using two different models (WKSOW and WATERNT). All of the empirical toxicity values are at least 100 times lower than this water solubility prediction, and nearly all of the modelled toxicity values are more than 10 times less. When there are discrepancies between modelled and empirical data, reliable empirical data are usually selected.</p> <p>All of the empirical Henry's Law constant (HLC) data are similar, and the modelled value is approximately one order of magnitude lower than the empirical values. The value from Ip et al. (2009) was chosen as this study was deemed to be the most robust.</p> <p>The calculated vapour pressure value has been removed from Table 2, as upon review of this method, it was determined that it may not be appropriate for highly soluble substances such as ethanedial. Therefore, only the modelled value is now reported.</p>

		Modelling in the report that has been affected by this change in vapour pressure value (e.g. the EQC modelling in the Environmental Fate section, the ChemCan modelling in the Health Exposure section) has been redone, and changes in the text and tables of the report have been made accordingly.
Uses	While currently ethanediol is not listed on the Cosmetic Ingredient Hotlist, suggestion for further notice and consultations with stakeholders in the event of it being assigned to the Hotlist and thus prohibiting it as an ingredient in consumer products.	Further consultation with stakeholders regarding inclusion of ethanediol to the Cosmetic Ingredient Hotlist is not within the scope of a screening assessment report.
Sources	The assertion that ethylene glycol processes produce ethanediol cannot be substantiated and therefore that reference should be removed to avoid misleading the reader.	Wording in the screening assessment has been changed to reflect that ethanediol is commercially produced from the oxidation of ethylene glycol in the presence of copper or silver catalysts.
Exposure	The report should state that the reason that ethanediol was not found in water in Canada is because it is likely not there because it is quickly degrading.	No studies on levels of ethanediol in the Canadian environment were found during the literature review. One cannot conclude on this basis that it is not present in the environment. Ethanediol has been detected in surface and groundwater samples in the U.S. and Europe at low ($\leq 12 \mu\text{g/L}$) levels (CICAD 2004). Despite the fact that ethanediol degrades relatively quickly, it could still be present in the environment near sources of continuous release, such as industrial sources.
	In the Industrial Release, A - Aquatic Environment section, a nominal removal rate for primary treatment should be assumed rather than 0%.	The 0% removal assumption during primary treatment in the Industrial Release section was made to make the exposure scenarios conservative. Even with this conservative assumption, the risk quotients were still well below one. Therefore, it was not necessary to refine the exposure scenarios to be more realistic.
	The dichotomy between the existence of ethanediol in the environment and a non-stable form only able to be produced in the lab, calls into question its validity for exposure.	The anhydrous ethanediol form is referenced as not existing in a stable form. However, throughout the screening assessment, only the hydrated monomer form (found in the environment) of ethanediol is indicated when determining its risk from exposure.
	More knowledge of the background environmental	Given that this assessment has concluded that ethanediol does not

	<p>levels of ethanedial is needed to identify and quantify any potential risks. The same applies with the background levels of glyoxal in blood plasma, where it is the product of normal cellular metabolism via multiple enzyme-independent pathways.</p>	<p>pose a risk to human life or health, or to the environment or its biological diversity (i.e., it does not meet any of the criteria set out in section 64 of CEPA 1999), it is not necessary to determine background levels to further quantify the potential risks.</p>
	<p>The values used to calculate the exposure from air should be reconsidered, and the average of $0.87 \mu\text{g}/\text{m}^3$ is more representative and superior to the concentration of $1.06 \mu\text{g}/\text{m}^3$ for ambient air.</p>	<p>The study for indoor air is extensive; however, as stated in the screening assessment, the data is from the United States and may not be reflective of indoor air in Canadian homes. Generally indoor air had higher concentration levels of chemicals than the ambient air. In this case, as the ambient air value was derived from a Canadian study and is higher than the indoor air study, using it in the exposure estimate is a more appropriate approach.</p>
	<p>Further explanation is needed as to why there is a large increase between breast milk, formula and non-formula fed infants if beer and wine were discarded from the exposure calculation for children under the age of 11.</p>	<p>Health Canada recommends exclusively breast feeding infants until they are 6 months of age. However, in keeping with the conservative nature of the assessment, a dietary exposure category assuming that some infants are fed only a normal diet (i.e. do not drink formula or breast milk), is included in the exposure assessment. In the exposure assessment, only beer and wine were removed from the exposure assessment for children under 11; yogurt and honey were still included in the exposure assessment. These food categories make up a larger proportion of the diet in the younger age categories, accounting for the differences in the values. Clarification was added to the screening assessment.</p>
	<p>i. The 9kg weight for a stack of paper does not match the weight of commercially sold paper (2.8 kg). The density of the stack of paper is 20 lbs/ 75 kg/m^2, which may have been used in error.</p> <p>ii. Consuming $\frac{1}{4}$ of a sheet of paper may be a lethal dose in children. Perhaps $\frac{1}{10}$ of a sheet be used instead.</p> <p>iii. The frequency of use for acne face wash may be too conservative.</p>	<p>i. The weight of a stack of 500 sheets of multi-purpose paper is listed as 20 lbs for the uncut paper (with dimensions of 17 x 22 inches per sheet). The weight conversion from 17x22 in paper to 8x11 in paper was given in the screening assessment – with the actual weight for one sheet being ~4.5 g. No change.</p> <p>ii. It was determined as an upper-bound scenario for children based on mouthing behaviours. The amount will stay.</p> <p>iii. The face wash scenario is based on the assumption that one would wash their face twice daily as an upper bound scenario.</p>

	<p>iv. Is the amount of 8g a reasonable assumption for the large surface area of 1.69 m².</p> <p>v. The lotion scenario is an over estimate and the frequency of use should be reduced.</p> <p>vi. shaving scenario does not seem to apply to males, clarify.</p> <p>vii. manicure preparation is thought to be less frequent.</p>	<p>iv. This amount is based on information on typical use and is considered reasonable.</p> <p>v. The frequency of use for body lotion is consistent against other previous screening assessments. This amount is based on information on typical use.</p> <p>vi. Given the surface area of 0.582 m² was used, the frequency does apply to typical shaving periods for women.</p> <p>vii. As an upper bound scenario, it was assumed that people would have their nails done 2-3 times per week, whether that was to paint them or remove the nail polish</p>
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