

## Summary of Public Comments received on the Challenge substance Ethyl Acrylate (CAS 140-88-5) Draft Screening Assessment Report for Batch 11

Comments on the draft screening assessment report for ethyl acrylate to be addressed as part of the Chemicals Management Plan Challenge were provided by Dow Chemical Canada, and the Basic Acrylic Monomer Manufacturers.

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

- Physical-Chemical Properties
- Exposure
- Risk Assessment Conclusion
- Environment
- General

| TOPIC                        | COMMENT   | RESPONSE   |
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| Physical-Chemical Properties | In the physical and chemical properties table of the draft risk assessment, there is generally good agreement for the parameters. However, there are notable differences for vapour pressure, Henry's law constant and water solubility. These differences should be reconciled and values be established for the assessment. | <p>Explanation for the differences in the physical-chemical properties is outlined below.</p> <p>The vapour pressure (3800 Pa) that was selected for modeling purpose is an experimental value at ambient temperature. The vapour pressure of 4132 Pa was removed as the temperature was not cited in the reference.</p> <p>The two experimental Henry's Law Constant values (25.3 Pa·m<sup>3</sup>/mol) are identical. The modeled values differ by an order of magnitude for the Group estimation but the result for the Bond method is comparable to the experimental values.</p> <p>The differences between the experimental water solubilities are the result of the temperature variations and the modeled value is comparable to the experimental values.</p> |

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| Exposure | The odour threshold for ethyl acrylate (EA) is stated as approximately 1 ppb in various credible sources. The physical limitation of exposure created by odour/physical property should be significantly highlighted in any assessment.   | The odour threshold is stated in the sources section of the assessment. The potential physical limitation of exposure created by the odour/physical property of EA was not more significantly highlighted in the assessment due to the possibility of habituation to EA odour.   |
|          | While residual EA is found in products the concentration is very low and the polymer matrix often retards migration. A realistic perception of the situation could be facilitated with the addition of a descriptor in the Use section.   | The description in the Use section accurately portrays that ethyl acrylate is only found as a residual in consumer products, and that using the word residual implies very low concentrations. This is explained in the exposure section.  |
|          | Extensive efforts were undertaken to provide information on EA in consumer products to HC. This is not evident in the references.   | The source of the voluntary submissions has been added to the body of the assessment in a footnote. As well, some additional descriptive information of products that was received has been included in the text of the exposure assessment. This information does not affect the outcome of the assessment.   |
|          | In the absence of data, the assessment assumes EA is present in some fruits. This could inappropriately stigmatize or elevate concerns in the Canadian public. The assessment should present a rationale to justify assuming a presence and if a presence is assumed, it should be at most ½ the limit of detection or measured data. The use of EA as a food flavour in the USA should not be presented as a concern because of the natural occurrence of EA in some fruits, the literature describing the decreasing usage of EA as a food flavour in the USA over time, and because Canada is proportionally smaller in population than the USA. | We recognize that the assumptions made in the exposure scenario are conservative; however, given that even with conservative assumptions, there is no indication of risk, no further refinements to the exposure assessment will be made at this time.   |
|          | The concentration used to derive indoor air exposure is higher than the odour threshold. It is recommended that the concentration used for ambient air estimation be reduced to below the odour threshold.  | If conservative assumptions produce model results that indicate risk, the exposure scenario is revised using more realistic assumptions when the data are available to carry out this refinement. However, in the case of ethyl acrylate in indoor/outdoor air, we would prefer to maintain using the limit of detection from the literature study due to the possibility of |

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|             |  | habituation to odour. This conservative assumption produced model results that indicate no risk so there is no need to revise the exposure scenario.   |
|             | The current approach of using the limit of detection or single data points to establish exposures when no or limited data were available produces an estimate that is overly conservative.   | If conservative assumptions produce model results that indicate risk, the exposure scenario is revised using more realistic assumptions when the data are available to carry out this refinement. In the case of ethyl acrylate, conservative assumptions produce model results that indicate no risk so there is no need to revise the exposure scenario.   |
|             | Questioning the validity of the model assumptions:<br>i) 100% dermal absorption<br>ii) task frequency for caulk and paint<br>iii) ventilation rate for paint and caulk   | If conservative assumptions produce model results that indicate risk, the exposure scenario is revised using more realistic assumptions when the data are available to carry out this refinement. However, in the case of ethyl acrylate as a residual in consumer products, conservative assumptions produce model results that indicate no risk so there is no need to revise the exposure scenario. |
| Environment | The draft risk assessment for ethyl acrylate indicates that the substance rapidly degrades in water which challenges subsequent analysis in the risk assessment.   | Although both empirical and modeling results indicate that ethyl acrylate degrades rapidly (ranging from 52% after 14 days to 90% after 28 days), these values show that the substance is not completely degraded. Therefore, ethyl acrylate still could occur in the Canadian environment.  |
|             | If ethyl acrylate degrades quickly, it does not exist long enough to be reported by NPRI.  | Facilities have reported ethyl acrylate releases and disposes for a number of years indicating that it exists long enough to be reported by NPRI.  |
|             | In the industrial release model inputs, the removal rate for water treatment was assumed to be zero. However, if ethyl acrylate does degrade in water, an allowance should be made for removal even for natural processes in the normal retention time. If the original assertion is accepted there are a number of statements in the draft risk assessment that are confusing and should be reconciled. | A removal rate of 0% is used to take into account a conservative estimate of exposure. In the case of ethyl acrylate, the risk quotient analysis based on the predicted environmental concentration from the consumer release scenario indicated that the potential for ecological harm is unlikely, therefore derivation of refined estimates using a higher removal rate was not needed.             |
|             | In the characterization of ecological risk, the draft risk assessment states ethyl acrylate will be found mainly in water. However, this is not consistent   | Fate modeling indicates that ethyl acrylate will be found mainly in water and although empirical data show that ethyl acrylate degrades easily, it does not biodegrade completely.   |

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|         | with the assertion that ethyl acrylate rapidly degrades in water.  |   |
|         | It should be noted that reported emissions from the CMP section 71 survey and the National Pollutant Release Inventory (NPRI) will be different as the reporting criteria and thresholds for each are different. This should be recognized in the assessment and the usage of the data.  | It is acknowledged that the reported emissions from the CMP section 71 survey and the National Pollutant Release Inventory (NPRI) are different. It is stated in the draft risk assessment that the data used for the exposure analysis is based on responses to the CEPA section 71 survey.  |
|         | The discussion indicates there is a possibility of incomplete reporting to the NPRI, including some industrial release to water. It is recommended the assertion of incomplete reporting of water releases be deleted unless there is clear evidence presented to the contrary.  | The discussion in the draft screening assessment strategy notes that there is a possibility of incomplete reporting to the NPRI based on the fact that on a national level, voluntary reporting may lead to emissions data that may be incomplete and inconsistent.   |
|         | <p>Information and input to model used to estimate releases to establish predicted environmental concentrations (PEC) in the ecological exposure assessment of the draft risk assessment are questioned.</p> <p>In the industrial release section, the loss fraction of 5% is considered very high. An order of magnitude less should be considered given the nature of the substance, good handling practices, and economic value concerns for this substance.</p> <p>The consistency between the removal scenarios for the industrial and consumer scenarios are questioned. Minimum removal rates in both scenarios should be at least 10%, to be conservatively realistic.</p> | The data input for the two release scenarios, industrial and consumer release, are based on conservative assumptions. The inputs are considered to represent the level of exposure under realistic worst case release scenarios and the corresponding predicted environmental concentrations and conservative risk quotients suggests that ethyl acrylate is unlikely to cause ecological harm in Canada. |
| General | The Synopsis of the draft Risk Assessment (last paragraph) states that EA will be considered for inclusion in the DSL inventory update. With EA  | Ethyl acrylate would be added to the DSL Inventory Update to monitor trends in quantities used given the substance was identified under the Challenge and to validate assumptions used in   |

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|  | being recommended as not CEPA toxic, why is it being included?   | the SAR   |
|  | In the Introduction, the draft Risk Assessment indicates “key studies were critically evaluated”. In the case of EA, or any CMP substance, it is always good practice to include robust summaries or scoring for the quality of the study with the CMP assessment. | A robust study summary is provided for the chronic aquatic toxicity study used to derive the predicted no effect concentration in the characterization of ecological risk.  |
|  | A balanced, well-rounded and scientific peer review would assist in a risk assessment review and/or the informed development of a Risk Management instrument.  | <p>The Health Canada component of the draft screening assessment for EA underwent external peer review consistent with others in the Challenge. The reviewers are indicated in the last paragraph of the Introduction.</p> <p>The ecological portion of this assessment has undergone external written peer review and consultation. While external comments are taken into consideration, the final content and outcome of the screening assessment report remains the responsibility of the Government of Canada. Additionally, the draft of this screening assessment was subject to a 60-day public comment period and external comments were taken into consideration.</p> |