# Summary of Public Comments Received on the Draft Screening Assessment Report for Acetone (CAS RN 67-64-1)

Comments on the draft screening assessment report (SAR) for acetone.

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



| Topic | Comment | Response |
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| Introduction | The term “Gradient” and what it represents should be clarified, as should the nature of its role in the external peer review. | The final Screening Assessment (SAR) now clarifies that Gradient is a consulting company that assisted in selecting and directing external peer reviews for the human health portion of the assessment. |
| Uses and Releases | The most recent regulatory proposals for volatile organic compounds (VOCs) from Environment Canada should be cited. | The pertinent paragraph has been updated in the final SAR. Reference to the proposed regulation on VOC concentration limits has been removed because the legislation will not apply to acetone (as it is already excluded under the VOC definition). |
| Uses and Releases | The use of acetone in polyethylene resin food packaging should be clarified. | The text in the final SAR was revised to clarify the presence of acetone. |
| Uses and Releases | In the “Canadian Releases” discussion on page 10 of the SAR, the reduction in total releases of | The text in the final SAR has been corrected to indicate “24.7%.” |

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| | acetone should be “24.7%” (where the percentage sign currently is missing). | |
| Uses and Releases | It is our understanding that a reduction in economic activity in Ontario is the primary cause of this reduction in the use (and subsequent emission) of acetone. | The sentence has been edited to reflect the information provided. |
| Uses and Releases | The OECD model for long-range transport presents a characteristic travel distance (CTD) for acetone of 5394 km (versus the threshold of 5098 km). It is questionable if this difference is significant given that it’s only a 6% difference. | The wording in the final SAR has been revised to state that the CTD indicates acetone has *potential* for long-range atmospheric transport (rather than *significant* potential). |
| Sources | The risk assessment protocols should give special consideration to the natural and anthropogenic contributions of substances that have significant natural presence in the environment or the human body. | A discussion about the contribution of natural sources to background levels of acetone has been added to the ecological portion of the final SAR. Despite this, the contribution of natural sources to ambient levels is expected to be low, and therefore it did not affect the calculation of the risk quotients.<br><br>In the health portion of the assessment naturally occurring and anthropogenic sources are identified and considered whenever possible. In many cases, however, data are not available to distinguish what proportion of background concentrations occurs from natural sources and what is from anthropogenic sources. |
| Exposure | The draft SAR use some overly conservative assumptions that are unrealistic (*e.g.* use of maximum values for outdoor air concentration and in tomatoes, or the assumption of zero wastewater removal efficiency). More realistic inputs in future will build credibility for the process. | The conclusions from the screening assessments adhere to a precautionary approach, using conservative assumptions where there are uncertainties.<br><br>For efficiency in conducting assessments, a tiered approach is used in the development of exposure scenarios. If very conservative estimates of release and exposure that are based on worst-case assumptions do not indicate levels of potential concern to biota or human health, then refinement of the scenarios is unnecessary. Decisions that a substance is harmful to the environmental or human health are not based on worst-case scenarios. |

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| Exposure | Given the robust data set available, the 95$^{th}$ percentile outdoor air concentration value should be used as the predicted environmental concentration (PEC) instead of the maximum air concentration measured. This also would be consistent with the health portion of the assessment. | The 95th percentile outdoor air concentration is now being used in the ecological assessment. |
| Exposure | Confidence in the exposure database is indicated as moderate-to-low. Given the amount of data and its quality, it is surprising the confidence is not higher. | Conservative assumptions were used in the assessment to account for data gaps relating to product use and associated exposure potential. While there was high uncertainty in some of the exposure scenarios due to lack of data, there is high confidence that intake was not underestimated. |
| Ecotoxicity | Should an ecotoxicity study (Schubert et al. 1995) that was deemed not to be fully reliable (or that was of low quality) be used to derive a Critical Toxicity Value (CTV)? | Changes have been made in the final SAR to justify the use of this study. |
| Ecotoxicity | The assessment should provide a conclusion on the inherent toxicity of acetone. | Ecological hazard information is presented in the screening assessment, and it is concluded that low concentrations of acetone, as would be found in the environment, are not hazardous to aquatic organisms, terrestrial plants or mammals. |
| Human Health Effects | The treatment-related hematological effects reported in the 90-day study (American Biogenics Corporation, 1986) should be listed. | The hematological effects have been added to the final SAR. |
| Human Health Effects | Clarification is needed about the relationship between bolus administration and the observed higher toxicity in the oral gavage study (American Biogenics Corporation, 1986). | The wording has been revised in the final SAR to improve clarity. |
| Human Health Effects | The conclusion by the study authors of Mast *et al.* (1988) should be included in the final screening assessment. | The conclusion was added to the final SAR. |
| Human Health Effects | The fact that the cited epidemiological studies (Mitran *et al.*, 1977; Grampella *et al.*, 1987; Oglesby *et al.*, 1949; and Soden, 1993) did not show an association between acetone exposure and hematological or kidney-related biochemical changes should be included. | The studies and relevant text were re-examined, and it is believed that the epidemiology data were adequately documented in the assessment. No changes were made to the SAR. |

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| Robust Study Summaries | Robust study summaries of all key studies should be included in the appendix. | The removal of the robust study summaries for the ecotoxicity studies is consistent with recent changes to the format of SARs. The study summaries are available upon request from Environment Canada.<br><br>For the human health studies, robust summaries were not included as it is believed that the criteria for selecting critical studies were adequately documented in the SAR. |
| Risk Assessment Conclusions | The commenter supports and agrees with the proposed conclusion. | Noted |
| General Comments | The draft Screening Assessment for acetone is clearly written, comprehensive and represents a broad assessment of the environmental and human health risk associated with exposure to acetone. This assessment may serve as a very useful reference for stakeholders. | Noted |
| General Comments | A number of technical and process changes are possible that would increase clarity and improve both the assessment and/or the Chemical Management Plan processes that create and deliver assessments. The commenter extends our thanks to the Government of Canada for the continuing efforts to produce the best scientific decision possible (through the inclusion of peer review and consultations across the technical/professional communities). | Noted |