

Charge Questions for the Peer Review of the draft Workplan Risk Assessment for Methylene Chloride (DCM)

August 2013

OPPT focused its risk assessment on the use of DCM in paint stripping. There are human health concerns for both cancer and non-cancer effects with DCM use-application. Only the inhalation route of exposure was evaluated and risk estimates were calculated for consumers and workers using DCM-based paint strippers. Risks also were estimated for individuals physically near the residential user and who are not using the DCM-based product (also referred as called bystanders or non-users).

General Question on the Risk Assessment Document

Issue 1. This risk assessment is divided into three chapters with eight appendices. The first two chapters describe the scoping exercise EPA used and background information on DCM that sets the stage for the information available and used in the risk assessment. Chapter 3 includes the exposure, hazard assessment and risk characterization and a section on uncertainties of the risk assessment. The risk assessment is intended to provide a clear and transparent summary of the Agency's analysis.

Question 1-1: Please comment on whether the risk assessment provides a clear and logical summary of EPA's analysis. Please provide specific suggestions for improving the clarity and transparency of the risk assessment document.

Question 1-2: Please comment on whether appropriate background information is provided and accurately characterized. Please provide any other relevant literature, reports, or data that would be useful to support the risk assessment.

Questions on the Exposure Assessment

Issue 2: Workplace exposure estimates were developed for adults using DCM-based paint strippers. EPA found limited published data for DCM air concentrations in workplace settings during use of DCM-based paint strippers. These data were used for estimating occupational inhalation exposures.

Question 2-1 Please comment on the approach used, and provide any specific suggestions or recommendations for alternative approaches, models or information that should be considered by the Agency for improving its assessment of DCM workplace exposures, including specific citations (if available) of other data sources characterizing occupational inhalation exposures,

Issue 3. Inhalation exposures from consumer uses of DCM-based paint strippers were estimated using the EPA's Multi-Chamber Concentrations and Exposure Model (MCCEM). EPA conducted a sensitivity analysis of selected model parameters to identify

critical parameters essential to the modeling approach used to estimate inhalation exposures. This analysis guided the selection of exposure scenarios and provided the most sensitive input parameters for generating central tendency and upper-end DCM air concentrations.

Question 3-1. Please comment on the approach used and provide any specific suggestions or recommendations for alternative approaches, models, or information that should be considered by the Agency in developing the exposure assumptions and estimates for the consumer use of DCM-based paint strippers and for the bystander/non-users (e.g., children, women of childbearing age). As part of the review, please comment on the strengths and weaknesses of the evaluation of different exposure scenarios and the choice of assumptions/input parameters for generating central tendency and upper-end DCM air concentrations.

Questions on the Hazard Assessment

Issue 4. The inherent hazards of DCM have been well characterized. EPA used a range of acute or chronic human health hazard values to evaluate potential non-cancer risks in workplace and consumer settings. For instance, EPA used the point of departures (PODs) from the California EPA's reference exposure level (Cal EPA REL) and the Spacecraft Maximum Allowable Concentration (SMAC) to evaluate potential acute risks for residential users and bystanders/non-users (e.g., children and women of childbearing age). Harmful concentrations of DCM, leading to death, have been reported in enclosed environments where DCM-based paint strippers were used during bathroom tub refinishing projects. Based on this concern, EPA also included the acute exposure guideline levels (AEGLs) in the analysis to determine if DCM air concentrations would be exceeding the AEGL thresholds for disability (AEGL-2) and lethality (AEGL-3). EPA's Integrated Risk Information System (IRIS) program has recently developed reference concentration (RfC) and inhalation unit risk (IUR) values for DCM. This assessment used the POD from the EPA's IRIS RfC to evaluate chronic non-cancer risks. The EPA's IRIS IUR was used to evaluate cancer risks in this assessment.

Question 4-1. Please comment on EPA's use of the acute PODs that were identified from the technical documents supporting the Cal EPA REL, SMAC and AEGL derivations. As part of the review, please provide your input on the appropriateness of the approach, including its underlying assumptions, strengths and weaknesses. Please provide any specific suggestions or recommendations for alternative approaches that should be considered by the Agency in characterizing the acute inhalation risks. Please provide relevant data or documentation and rationale for including other studies and endpoints for consideration.

Question 4-2: Please comment on EPA's choice of PODs and IUR for evaluating the non-cancer and cancer risks, respectively for chronic exposures to DCM-based paint strippers. As part of the review, provide your input on the appropriateness of the approach, including its underlying assumptions, strengths and weaknesses. Please

provide any specific suggestions or recommendations for alternative approaches that should be considered by the Agency in characterizing the chronic inhalation risks to workers. Please provide relevant data or documentation and rationale for including other studies and endpoints for consideration.

Questions on the Risk Assessment

Issue 5. The margin of exposure (MOE) is the ratio of the hazard value to the exposure. The MOE approach used the PODs identified in the Cal EPA REL and SMAC to evaluate potential acute risks in residential users and bystanders/non-users (e.g., children, women of childbearing age). Benchmark MOEs of 60 and 10 were used to determine acute risks based on the uncertainty analysis conducted in the Cal EPA REL and SMAC assessments, respectively. Hazard quotients (HQs) were used to evaluate potential acute risks in residential settings by comparing the AEGL values with the acute exposure estimates. HQs greater than 1 were interpreted as a potential acute risk. For chronic occupational risks, the POD from the EPA's IRIS RfC was chosen as the basis for the non-cancer MOE calculations. A benchmark MOE of 30 was used to interpret chronic risks for workers based on the uncertainty analysis in the EPA's DCM IRIS assessment. The EPA's IRIS IUR was used to evaluate potential chronic risks to cancer endpoints for the worker exposure scenarios. The risk characterization also provides a discussion of the uncertainties surrounding the risk calculations.

Question 5-1: Please comment on the assumptions, strengths and weaknesses of the MOE and HQ approaches used to estimate the acute non-cancer risks to consumers of DCM-based products, including bystanders/non-users (e.g., children, women of childbearing age). Please also comment on the selection of composite uncertainty factors that were used as benchmark MOEs to determine the acute risks.

Question 5-2: Please comment on the assumptions, strengths and weaknesses of the MOE approach used to estimate the chronic non-cancer risks for workplace exposures. Please also comment on the selection of composite uncertainty factors that were used as benchmark MOEs to determine the chronic risks.

Question 5-3: Please comment on the assumptions, strengths and weaknesses of the cancer estimation risk approach used for the workplace exposures.

Question 5-4: Please comment on whether the risk assessment document has adequately described the uncertainties and data limitations in the methodology used to assess risks to allow the EPA to reduce risks to human health from DCM. Please comment on whether this information is presented in a transparent manner.