5 UNREASONABLE RISK DETERMINATION

TSCA section 6(b)(4) requires EPA to conduct a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by EPA as relevant to this Risk Evaluation, under the conditions of use.

EPA has determined that methylene chloride presents an unreasonable risk of injury to health under the conditions of use. This determination is based on the information in previous sections of this Risk Evaluation, the appendices and supporting documents of methylene chloride, in accordance with TSCA section 6(b), as well as TSCA's best available science (TSCA section 26(h)) and weight of scientific evidence standards (TSCA section 26(i)), and relevant implementing regulations in 40 CFR part 702.

The full list of conditions of use evaluated for methylene chloride are listed in Table 1-4 of this Risk Evaluation (Ref. 1). EPA's unreasonable risk determination for methylene chloride is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:

- Manufacturing (Domestic Manufacture)
- Manufacturing (Import)
- Processing: as a reactant
- Processing: incorporation into a formulation, mixture, or reaction products
- Processing: repackaging
- Processing: recycling
- Industrial and commercial use as solvent for batch vapor degreasing
- Industrial and commercial use as solvent for in-line vapor degreasing
- Industrial and commercial use as solvent for cold cleaning
- Industrial and commercial use as solvent for aerosol spray degreaser/cleaner
- Industrial and commercial use in adhesives, sealants and caulks
- Industrial and commercial use in paints and coatings
- Industrial and commercial use in paint and coating removers
- Industrial and commercial use in adhesive and caulk removers
- Industrial and commercial use in metal aerosol degreasers
- Industrial and commercial use in metal non-aerosol degreasers
- Industrial and commercial use in finishing products for fabric, textiles and leather
- Industrial and commercial use in automotive care products (functional fluids for air conditioners)

- Industrial and commercial use in automotive care products (interior car care)
- Industrial and commercial use in automotive care products (degreasers)
- Industrial and commercial use in apparel and footwear care products
- Industrial and commercial use in spot removers for apparel and textiles
- Industrial and commercial use in liquid lubricants and greases
- Industrial and commercial use in spray lubricants and greases
- Industrial and commercial use in aerosol degreasers and cleaners
- Industrial and commercial use in non-aerosol degreasers and cleaners
- Industrial and commercial use in cold pipe insulations
- Industrial and commercial use as solvent that becomes part of a formulation or mixture
- Industrial and commercial use as a processing aid
- Industrial and commercial use as propellant and blowing agent
- Industrial and commercial use for electrical equipment, appliance, and component manufacturing
- Industrial and commercial use for plastic and rubber products manufacturing
- Industrial and commercial use in cellulose triacetate film production
- Industrial and commercial use as anti-spatter welding aerosol
- Industrial and commercial use for oil and gas drilling, extraction, and support activities
- Industrial and commercial use in toys, playground and sporting equipment
- Industrial and commercial use in lithographic printing plate cleaner
- Industrial and commercial use in carbon remover, wood floor cleaner, and brush cleaner
- Industrial and commercial use as laboratory chemical
- Consumer use as solvent in aerosol degreasers/cleaners
- Consumer use in adhesives and sealants
- Consumer use in brush cleaners for paints and coatings
- Consumer use adhesive and caulk removers
- Consumer use in metal degreasers
- Consumer use in automotive care products (functional fluids for air conditioners)
- Consumer use in automotive care products (degreasers)
- Consumer use in lubricants and greases
- Consumer use in cold pipe insulation
- Consumer use in arts, crafts, and hobby materials glue
- Consumer use in an anti-spatter welding aerosol
- Consumer use in carbon removers and other brush cleaners
- Disposal

The following condition of use does not drive EPA's unreasonable risk determination for methylene chloride:

- Distribution in commerce

EPA is not making a condition of use-specific risk determination for this condition of use, is not issuing a final order under TSCA section 6(i)(1) for this condition of use, and does not consider the revised risk determination for methylene chloride to constitute a final agency action at this point in time.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory action to the extent necessary so that methylene chloride no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.

5.1 Background

5.1.1 Background on Policy Changes Relating to the Whole Chemical Risk Determination and Assumption of PPE Use by Workers

From June 2020 to January 2021, EPA published risk evaluations on the first ten chemical substances, including for methylene chloride. The risk evaluations included individual unreasonable risk determinations for each condition of use evaluated. The determinations that particular conditions of use did not present an unreasonable risk were issued by order under TSCA section 6(i)(1).

In accordance with Executive Order 13990 ("Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis") and other Administration priorities (Refs. 2, 3, 4, and 5), EPA reviewed the risk evaluations for the first ten chemical substances to ensure that they meet the requirements of TSCA, including conducting decision-making in a manner that is consistent with the best available science and weight of the scientific evidence.

As a result of this review, EPA announced plans to revise specific aspects of certain of the first ten risk evaluations in order to ensure that the risk evaluations appropriately identify unreasonable risks and thereby can help ensure the protection of health and the environment (Ref. 6). To that end, EPA has reconsidered two key aspects of the risk determinations for methylene chloride published in June 2020. First, EPA has determined that the appropriate approach to these determinations is to make an unreasonable risk determination for methylene chloride as a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation. Second, EPA has

determined that the risk determination explicitly state that it does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6; rather, the use of PPE will be considered during risk management. Making unreasonable risk determinations based on the baseline scenario without assuming PPE should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location or that there is widespread noncompliance with applicable OSHA standards. EPA understands that there could be occupational safety protections in place at workplace locations; however, not assuming use of PPE reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, or their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health,"[1] or because the OSHA Permissible Exposure Limit may be inadequate for ensuring protection of worker health, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.

Separately, EPA is conducting a screening approach to assess potential risks from the air and water pathways for several of the first 10 chemicals, including this chemical. For methylene chloride the exposure pathways that were or could be regulated under another EPA-administered statute were excluded from the final risk evaluation (see section 1.4.2 of the June 2020 methylene chloride risk evaluation). This resulted in the surface water, drinking water, and ambient air pathways for methylene chloride not being assessed for human health exposures or the general population. The goal of the recently-developed screening approach is to remedy this exclusion and to identify if there are risks that were unaccounted for in the methylene chloride risk evaluation. The screening-level approach has gone through public comment and independent external peer review through the SACC. The Agency received the final peer review report on May 18, 2022, and has reviewed public comments and SACC comments. EPA expects to describe its findings regarding the chemical-specific application of this screening-level approach in the forthcoming proposed rule under TSCA section 6(a) for methylene chloride.

Further discussion of the rationale for the whole chemical approach is found in the Federal Register Notice in the docket accompanying this revised methylene chloride unreasonable risk determination and further discussion of the decision to not rely on assumptions regarding the use of PPE is provided in the Federal Register Notice and in Section 5.2.4 below. With respect to the methylene chloride risk evaluation, EPA did not amend, nor does a whole chemical approach or change in assumptions regarding PPE require amending, the underlying scientific analysis of the risk evaluation in the risk characterization section of the risk evaluation.

[1] As noted on OSHA's Annotated Table of Permissible Exposure Limits: "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time" (Ref. 7).

With regard to the specific circumstances of methylene chloride, as further explained below, EPA has determined that a whole chemical approach is appropriate in order to protect health and the environment. The whole chemical approach is appropriate for methylene chloride because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (including import), processing, commercial and consumer use, and disposal) for human health and the health effects associated with methylene chloride exposures are irreversible. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, and a substantial amount of the conditions of use drive the unreasonable risk, it is therefore appropriate for the Agency to make a determination that the whole chemical presents an unreasonable risk. In addition, as discussed below in Section 5.2.4, in making this risk determination, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. EPA is revising the assumption for methylene chloride that workers always and properly use PPE, although it does not question the public comments received regarding the occupational safety practices often followed by industry respondents.

As explained in the Federal Register Notice, the revisions to the unreasonable risk determination (Section 5 of this Risk Evaluation) follow the issuance of a draft revision to the TSCA methylene chloride unreasonable risk determination (87 FR 39824, July 5, 2022) (Ref. 8) and the receipt of public comment. A response to comments document is also being issued with this final revised unreasonable risk determination for methylene chloride (Ref. 9). As noted in the Federal Register Notice, the revisions to the unreasonable risk determination are based on the existing risk characterization section of this Risk Evaluation (Section 4), and do not involve additional technical or scientific analysis. The discussion of the issues in this revision to the risk determination supersedes any conflicting statements in the prior methylene chloride risk evaluation (June 2020) and the response to comments document (*Summary of External Peer Review and Public Comments and Disposition for Methylene Chloride (MC), June 2020*). EPA also views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence, per TSCA sections 26(h) and (i).

5.1.2 Background on Unreasonable Risk Determination

In each risk evaluation under TSCA section 6(b), EPA determines whether a chemical substance presents an unreasonable risk of injury to health or the environment, under the conditions of use. The unreasonable risk determination does not consider costs or other nonrisk factors. In making the unreasonable risk determination, EPA considers relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any potentially exposed or susceptible subpopulations (PESS)); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties. EPA also takes into consideration the Agency's confidence in the data

used in the risk estimate. This includes an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization. This approach is in keeping with the Agency's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017).[2]

This section describes the revised unreasonable risk determination for methylene chloride, under the conditions of use in the scope of the Risk Evaluation for methylene chloride. This revised unreasonable risk determination is based on the risk estimates in the final Risk Evaluation, which may differ from the risk estimates in the draft Risk Evaluation due to peer review and public comments.

5.2 Unreasonable Risk to Human Health

5.2.1 Human Health

EPA's methylene chloride Risk Evaluation identified non-cancer adverse effects from acute and chronic inhalation and dermal exposures to methylene chloride, and cancer from chronic inhalation and dermal exposures to methylene chloride. In the methylene chloride risk characterization, neurotoxicity effects (CNS depression) were identified as the most sensitive endpoint for non-cancer adverse effect from acute inhalation, and dermal exposures, and liver effects were identified as the most sensitive endpoint for non-cancer adverse effects from chronic inhalation and dermal exposures for all conditions of use. Additional risks associated with other adverse effects (e.g., other nervous system effects, immune system effects; reproductive and developmental effects; and irritation/burns) were identified for acute and chronic exposures. The health risk estimates for all conditions of use are in Tables 4-2 of Section 4.1.2 of this Risk Evaluation.

In developing the exposure assessment for methylene chloride, EPA identified the following groups as Potentially Exposed or Susceptible Subpopulations (PESS): workers and occupational non-users (ONUs)[3] (including men and women of reproductive age, and adolescents); consumer users and bystanders (of any age group, including infants, toddlers, children, and elderly) (Section 2.4.1 and Tables 4-2 and 4-3 of this Risk Evaluation).

EPA evaluated exposures to workers, ONUs, consumer users, and bystanders using reasonably available monitoring and modeling data for inhalation and dermal exposures as applicable. For example, EPA assumed that ONUs and bystanders do not have direct contact with methylene chloride; therefore, non-cancer effects and cancer from dermal exposures to methylene chloride

[2] This risk determination is being issued under TSCA section 6(b) and the terms used, such as unreasonable risk, and the considerations discussed are specific to TSCA. Other EPA programs have different statutory authorities and mandates and may involve risk considerations other than those discussed here.

[3] ONUs are workers who do not directly handle methylene chloride but perform work in an area where methylene chloride is present. (Executive Summary of this Risk Evaluation).

were not evaluated. The description of the data used for human health exposure is in Section 2.4 of this Risk Evaluation. Uncertainties in the analysis are discussed in Section 4.4 of this Risk Evaluation and are considered in the unreasonable risk determination, including the fact that the dermal model used for occupational exposures does not address variability in exposure duration and frequency. An additional uncertainty includes the use of exposure data generated before the OSHA Methylene Chloride standard was updated in 1997.

5.2.2 Non-Cancer Risk Estimates

The risk estimates of non-cancer effects (expressed as margins of exposure or MOEs) refer to adverse health effects associated with health endpoints other than cancer, including to the body's organ systems, such as reproductive/developmental effects, cardiac and lung effects, and kidney and liver effects. The MOE is the point of departure (POD) (an approximation of the no-observed adverse effect level (NOAEL) or benchmark dose level (BMDL)) and the corresponding human equivalent concentration (HEC) for a specific health endpoint divided by the exposure concentration for the specific scenario of concern. Section 3.2.5 of this Risk Evaluation presents the PODs for acute and chronic non-cancer effects for methylene chloride and Section 4.3 of this Risk Evaluation presents the MOEs for acute and chronic non-cancer effects.

The MOEs are compared to a benchmark MOE. The benchmark MOE accounts for the total uncertainty in a POD, including, as appropriate: (1) the variation in sensitivity among the members of the human population (i.e., intrahuman/intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (i.e., interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating from a lowest observed adverse effect level (LOAEL) rather than from a NOAEL. A lower benchmark MOE (e.g., 30) indicates greater certainty in the data (because fewer of the default uncertainty factors (UFs) relevant to a given POD as described above were applied). A higher benchmark MOE (e.g., 1000) would indicate more uncertainty for specific endpoints and scenarios. However, these are often not the only uncertainties in a risk evaluation. The benchmark MOE for acute non-cancer risks for methylene chloride is 30 (accounting for intraspecies and LOAEL to NOAEL variability for an effect of small magnitude in a human study). The benchmark MOE for chronic non-cancer risks for methylene chloride is 10 (accounting for interspecies and intraspecies variability in toxicodynamics); toxicokinetic differences are accounted for in the PBPK modeling). Additional information regarding the non-cancer hazard identification is in section 3.2.3.1 and the benchmark MOE is in Section 4.3 of this Risk Evaluation.

5.2.3 Cancer Risk Estimates

Cancer risk estimates represent the incremental increase in probability of an individual in an exposed population developing cancer over a lifetime (excess lifetime cancer risk (ELCR)) following exposure to the chemical. Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (i.e., $1x10^{-6}$ to $1x10^{-4}$) depending on the subpopulation exposed. For example, in this risk evaluation, EPA used $1x10^{-4}$ as the benchmark for the cancer risk to individuals in industrial and commercial workplaces. The $1x10^{-4}$ value is not a bright line and EPA has discretion to make an unreasonable risk determination for the chemical substance based on other benchmarks as appropriate. Additional information regarding the cancer benchmark is in Section 4.3.1 of this Risk Evaluation.

5.2.4 Determining Unreasonable Risk of Injury to Health

Calculated risk estimates (MOEs or cancer risk estimates) can provide a risk profile of methylene chloride by presenting a range of estimates for different health effects for different conditions of use. A calculated MOE that is less than the benchmark MOE supports a determination of unreasonable risk of injury to health, based on noncancer effects. Similarly, a calculated cancer risk estimate that is greater than the cancer benchmark supports a determination of unreasonable risk of injury to health from cancer. Whether EPA makes a determination of unreasonable risk for the chemical substance depends upon other risk-related factors, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values.

In the methylene chloride risk characterization, neurotoxicity effects (central nervous system (CNS) depression) were identified as the most sensitive endpoint for non-cancer adverse effect from acute inhalation and dermal exposures and liver effects were identified as the most sensitive endpoint for non-cancer adverse effects from chronic inhalation and dermal exposures for all conditions of use. However, additional risks associated with other adverse effects (e.g., other nervous system effects, immune system effects; reproductive and developmental effects; and irritation/burns) were identified for acute and chronic exposures. EPA expects that addressing the unreasonable risk presented by methylene chloride for acute CNS and chronic liver effects would also address the risk from other endpoints resulting from acute or chronic inhalation and dermal exposures.

In accordance with EPA's Guidelines for Carcinogen Risk Assessment, methylene chloride is considered "likely to be carcinogenic to humans" and EPA calculated cancer risk estimates with a linear model. The cancer analysis is described in Section 3.2. EPA considered cancer risks estimates from chronic dermal or inhalation exposures in the unreasonable risk determination.

When making a determination of unreasonable risk for the chemical substance, the Agency has a higher degree of confidence where uncertainty is low. For example, EPA has high confidence in

the hazard and exposure characterizations when the basis for characterizations is measured data or representative monitoring data or a robust model and the hazards identified for risk estimation are relevant for conditions of use. This Risk Evaluation discusses major assumptions and key uncertainties; for example, where EPA has made assumptions in the scientific evaluation, whether those assumptions are "conservative" (that is the degree to which these assumptions err on the side of protection) is also a consideration. The high volatility of methylene chloride and potentially severe effects from short term (1-hr) exposure are considerations when weighing the role of uncertainties in decision making for methylene chloride. For the human health risk estimation, key assumptions and uncertainties are related to the estimates for ONU inhalation exposures, because monitoring data were not reasonably available for many of the conditions of use evaluated. An additional source of uncertainty is the inhalation to dermal route-to-route extrapolations, which is a source of uncertainty in the dermal risk assessment for dermal cancer and non-cancer risk estimates. Similarly, for assessing cancer risks, although EPA chose to model the combination of liver and lung tumor results from a cancer bioassay using mice, there is uncertainty regarding the modeling of these tumor types for humans. Important assumptions and key sources of uncertainty in the risk characterization are described in more detail in Section 4.4 of this Risk Evaluation.

When determining the unreasonable risk for a chemical substance, EPA considers the central tendency and high-end exposure levels in occupational settings, and low, moderate and high intensity of use for consumer uses. Risk estimates based on high-end exposure levels or high intensity use scenarios (e.g., 95th percentile) are generally intended to cover individuals or sub-populations with greater exposure (PESS) as well as to capture individuals with sentinel exposure, and risk estimates at the central tendency exposure are generally estimates of average or typical exposure (Section 4.4 of this Risk Evaluation).

As shown in Section 4 of this Risk Evaluation, when characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place. This approach of not assuming PPE use by workers considers the risk to potentially exposed or susceptible subpopulations (workers and ONUs) who may not be covered by Occupational Safety and Health Administration (OSHA) standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. In addition, EPA risk evaluations may characterize the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific PELs and/or chemical-specific health standards with PELs and additional ancillary provisions), as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. EPA's evaluation of risk under scenarios that, for example, incorporate use of engineering or administrative controls, or personal protective equipment, serves to inform its risk management efforts. By characterizing risks using scenarios

that reflect different levels of mitigation, EPA risk evaluations can help inform potential risk management actions by providing information that could be used to tailor risk mitigation appropriately to address worker exposures where the Agency has found unreasonable risk. In particular, EPA can use the information developed during its risk evaluation to determine whether alignment of EPA's risk management requirements with existing OSHA requirements or industry best practices will adequately address unreasonable risk as required by TSCA.

When undertaking unreasonable risk determinations as part of TSCA risk evaluations, EPA cannot assume as a general matter that an applicable OSHA requirement or industry practice is consistently and always properly applied. Mitigation scenarios included in the methylene chloride risk evaluation (e.g., scenarios considering use of various personal protective equipment (PPE)) likely represent what is happening already in some facilities. However, the Agency cannot assume that all facilities will have adopted these practices for the purposes of making the TSCA risk determination.

Therefore, EPA conducts baseline assessments of risk and makes its determination of unreasonable risk from a baseline scenario that is not based on an assumption of compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread noncompliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health,"[4] or because the OSHA PEL alone may be inadequate to protect worker health, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

The revised unreasonable risk determination for methylene chloride is based on the peer reviewed risk characterization of the June 2020 Risk Evaluation, which was developed according to TSCA section 26(h) requirements to make science-driven decisions, consistent with best available science. Changing the risk determination to a whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation. Section 4.5.2 and Table 4-27 of this Risk Evaluation summarize the risk estimates with and without PPE, and informed the revised unreasonable risk determination.

[4] As noted on OSHA's Annotated Table of Permissible Exposure Limits: "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time" (Ref. 5).

5.3 Unreasonable Risk to the Environment

5.3.1 Environment

EPA's Risk Evaluation considered the effects of exposures to methylene chloride for aquatic, sediment dwelling, and terrestrial organisms. The environmental hazard threshold is calculated for aquatic, sediment dwelling, and terrestrial organisms.

EPA calculated a risk quotient (RQ) to compare environmental concentrations against an effect level. The environmental concentration is determined based on the levels of the chemical released to the environment (e.g., surface water, sediment, soil, biota) under the conditions of use, based on the fate properties, release potential, and reasonably available environmental monitoring data. The effect level is calculated using concentrations of concern that represent hazard data for aquatic, sediment-dwelling, and terrestrial organisms. Section 4.2 of this Risk Evaluation provides more detail regarding the environmental risk characterization for methylene chloride.

5.3.2 Determining Unreasonable Risk of Injury to the Environment

Calculated risk quotients (RQs) can provide a risk profile by presenting a range of estimates for different environmental hazard effects for different conditions of use. An RQ equal to 1 indicates that the exposures are the same as the concentration that causes effects. An RQ less than 1, when the exposure is less than the effect concentration, generally indicates that there is not risk of injury to the environment that would support a determination of unreasonable risk for the chemical substance. An RQ greater than 1, when the exposure is greater than the effect concentration, generally indicates that there is risk of injury to the environment that would support a determination of unreasonable risk for the chemical substance. Consistent with EPA's human health evaluations, the RQ is not treated as a bright line and other risk-based factors may be considered (*e.g.*, confidence in the hazard and exposure characterization, duration, magnitude, uncertainty) for purposes of making an unreasonable risk determination.

For all conditions of use, EPA has determined based on the RQ values (Table 4-4 and 4-5) in water for acute and chronic exposures to methylene chloride for amphibians, fish, and aquatic invertebrates that the conditions of use do not drive the unreasonable risk by presenting unreasonable risk of injury to the environment. To characterize the exposure to methylene chloride by aquatic organisms, modeled data were used to represent surface water concentrations near facilities actively releasing methylene chloride to surface water, and monitored concentrations were used to represent ambient water concentrations of methylene chloride. EPA considered the biological relevance of the species to determine the concentrations of concern for the location of surface water concentration data to produce RQs, as well as frequency and duration of the exposure. Some site-specific RQs, calculated from modeled release data from facilities conducting recycling, disposal, and wastewater treatment plant activities are greater than or equal to one. Uncertainties related to these particular estimates are discussed in section 4.2.2. Uncertainties in the analysis include limitations in data, since monitoring data were not

available near facilities where methylene chloride is released, and TRI does not capture release data for facilities with fewer than ten employees. As an additional uncertainty, the model does not consider chemical fate or hydrologic transport properties and may not consider dilution in static water bodies. As described in section 4.4.6, additional analysis indicated that model outputs, rather than monitoring estimates, may best represent concentrations found at the point of discharge from the facilities.

Without toxicity data on sediment-dwelling invertebrates, EPA assumed the toxicity of methylene chloride to sediment-dwelling invertebrates is similar to the toxicity to aquatic invertebrates. Methylene chloride is most likely present in the pore waters and not absorbed to the sediment organic matter because methylene chloride has low partitioning to organic matter. The concentrations in sediment pore water are similar to or less than the concentrations in the overlying water, and concentrations in the deeper part of sediment are lower than the concentrations in the overlying water. Therefore, for sediment dwelling organisms the risk estimates from acute and chronic exposures, based on the highest ambient surface water concentration, do not support the inclusion of these risks as drivers of the unreasonable risk determination for methylene chloride. There is uncertainty due to the lack of ecotoxicity studies specifically for sediment-dwelling organisms and limited sediment monitoring data.

Based on its physical-chemical properties, methylene chloride does not partition to or accumulate in soil and thus does not pose risk to terrestrial organisms. Therefore, these physical chemical properties, do not support the inclusion of these exposures as drivers of the unreasonable risk determination.

When making a determination of unreasonable risk, EPA has a higher degree of confidence where uncertainty is low. For example, EPA has high confidence in the hazard and exposure characterizations when the basis for the characterizations is measured or representative monitoring data or a robust model and the hazards identified for risk estimation are relevant for conditions of use. Additionally, EPA considers the central tendency and high-end scenarios when determining the unreasonable risk. High-end risk estimates (*e.g.*, 90th percentile) are generally intended to cover organisms or populations with greater exposure (those inhabiting ecosystems near industries) and central tendency risk estimates are generally estimates of average or typical exposure. For methylene chloride, key assumptions and uncertainties in the environmental risk estimation include the uncertainty around modeled releases that used E-FAST 2014 with 2016 TRI data as well as 2016 DMR data to estimate releases. Some sites that manufacture, process, or use methylene chloride may not report to these datasets, are not included in this analysis and therefore actual environmental exposures may be underestimated. In the measured surface water data and watershed analysis, the WQP Tools contains data from USGS-NWIS and STORET databases, and is one of the largest environmental monitoring databases in the U.S.; however, comprehensive information needed for data interpretation is not always reasonably available. As a result, there are uncertainties in the reported monitoring data that are difficult to quantify with

regard to impacts on exposure estimates. Assumptions and key sources of uncertainty in the risk characterization are detailed in Section 4.4.1. of this Risk Evaluation.

Although various degrees of uncertainty and assumptions were identified in the risk evaluation, EPA did not identify risk of injury to the environment that would drive the unreasonable risk determination for methylene chloride.

5.4 Additional Information Regarding the Basis for the Unreasonable Risk Determination

Table 5-1 and Table 5-2 summarize the basis for the revised determination of unreasonable risk of injury to health presented by methylene chloride. In these tables, a checkmark indicates the type of effect and the exposure route to the population evaluated for each condition of use that drives the unreasonable risk determination. As explained in Section 5.2, for the revised unreasonable risk determination, EPA considered the effects on human health and the environment of exposure to methylene chloride at the central tendency and high-end (or low, moderate, and high intensity use), the exposures from the condition of use, the risk estimates, and the uncertainties in the analysis. See Section 4.1.2 and 4.1.3 of the Risk Evaluation for a summary of risk estimates.

Table 5-1. Supporting Basis for the Revised Unreasonable Risk Determination for Human Health (Occupational Conditions of Use)[5]

Life Cycle Stage	Category [a]	Subcategory [b]	Population [c]	Exposure Route [d]	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Manufacturing	Domestic manufacturing	Manufacturing	Worker	Inhalation 8-Hr TWA						
				Inhalation 15-Minute TWA	✓					
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
				Inhalation 15-Minute TWA	n/a		n/a		n/a	
Manufacturing	Import	Import	Worker	Inhalation 8-Hr TWA	✓		✓	✓		
				Inhalation 1-Hr TWA	✓	✓				
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a	✓	n/a	
				Inhalation 1-Hr TWA	n/a	✓	n/a		n/a	
Processing	Processing as a reactant	Intermediate in industrial gas manufacturing (e.g., manufacture of fluorinated gases used as refrigerants)	Worker	Inhalation 8-Hr TWA	✓		✓			
				Inhalation 15-Minute TWA	✓					
		Intermediate for pesticide, fertilizer, and other agricultural chemical manufacturing		Dermal	✓	✓	✓	✓		
		Petrochemical manufacturing	ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
		Intermediate for other chemicals		Inhalation 15-Minute TWA	✓					

[5] The checkmarks indicate the type of effect and the exposure route to the population evaluated for each condition of use that support the revised unreasonable risk determination for methylene chloride. This table is based on Table 4-2 of this Risk Evaluation.

Life Cycle Stage	Category [a]	Subcategory [b]	Population [c]	Exposure Route [d]	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Processing	Incorporation into formulation, mixture or reaction products	Solvents (for cleaning or degreasing), including manufacturing of:All other basic organic chemical; Soap, cleaning compound and toilet preparation	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
		Solvents (which become part of product formulation or mixture), including manufacturing of: All other chemical product and preparation; paints and coatings		Inhalation 15-Minute TWA	✓					
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	
				Inhalation 15-Minute TWA	✓					
		Propellants and blowing agents for all other chemical product and preparation manufacturing								
		Propellants and blowing agents for plastics product manufacturing								
		Paint additives and coating additives not described by other codes								
		Laboratory chemicals for all other chemical product and preparation manufacturing								
		Laboratory chemicals for other industrial sectors								
		Processing aid, not otherwise listed for petrochemical manufacturing								
		Adhesive and sealant chemicals in adhesive manufacturing								
		Oil and gas drilling, extraction, and support activities								

Life Cycle Stage	Category [a]	Subcategory [b]	Population [c]	Exposure Route [d]	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Processing	Repackaging	Solvents (which become part of product formulation or mixture) for all other chemical product and preparation manufacturing. All other chemical product and preparation manufacturing.	Worker	Inhalation 8-Hr TWA	✓		✓	✓		
				Inhalation 1-Hr TWA	✓	✓				
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a	✓	n/a	
				Inhalation 1-Hr TWA	n/a	✓	n/a		n/a	
Processing	Recycling	Recycling	Worker	Inhalation 8-Hr TWA	✓		✓			
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
Distribution in commerce	Distribution	Distribution	Worker	Inhalation 8-Hr TWA						
				Dermal						
			ONU	Inhalation 8-Hr TWA						
Industrial / commercial use	Solvents (for cleaning or degreasing)	Batch vapor degreaser (e.g., open-top, closed-loop)	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
Industrial / commercial use	Solvents (for cleaning or degreasing)	In-line vapor degreaser (e.g., conveyorized, web cleaner)	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	✓
Industrial / commercial use	Solvents (for cleaning or degreasing)	Cold cleaner	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	✓

Life Cycle Stage	Category [a]	Subcategory [b]	Population [c]	Exposure Route [d]	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Industrial / commercial use	Solvents (for cleaning or degreasing)	Aerosol spray degreaser/cleaner	Worker	Inhalation 8-Hr TWA	✓		✓		✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
Industrial / commercial use	Adhesives and Sealants	Single component glues and adhesives and sealants and caulks (spray and non-spray).	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	
Industrial / commercial use	Paints and coatings and paint and coating removers, including furniture refinisher	Paints and coatings	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	
Industrial / commercial use	Paints and coatings and paint and coating removers, including furniture refinisher	Paints and coating removers	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	✓
				Dermal						
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	✓
Industrial / commercial use	Adhesive / caulk remover	Adhesive / caulk removers.	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	✓
Industrial / commercial use	Metal products not covered elsewhere	Degreasers – aerosol degreasers and cleaners.	Worker	Inhalation 8-Hr TWA	✓		✓		✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
Industrial / commercial use	Metal products not covered elsewhere	Degreasers –non-aerosol degreasers and cleaners.	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	

Life Cycle Stage	Category [a]	Subcategory [b]	Population [c]	Exposure Route [d]	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Industrial / commercial use	Fabric, textile and leather products not covered elsewhere	Textile finishing and impregnating/ surface treatment products.	Worker	Inhalation 8-Hr TWA	✓		✓	✓		
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a	✓	n/a	
Industrial / commercial use	Automotive care products	Function fluids for air conditioners: refrigerant, treatment, leak sealer.	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	
Industrial / commercial use	Automotive care products	Interior car care – spot remover.	Worker	Inhalation 8-Hr TWA	✓		✓		✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
Industrial / commercial use	Automotive care products	Degreasers: gasket remover, transmission cleaners, carburetor cleaner, brake quieter/cleaner.	Worker	Inhalation 8-Hr TWA	✓		✓		✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
Industrial / commercial use	Apparel and footwear care products	Post-market waxes and polishes applied to footwear e.g., shoe polish.	Worker	Inhalation 8-Hr TWA	✓		✓		✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
Industrial / commercial use	Laundry and dishwashing products	Spot remover for apparel and textiles.	Worker	Inhalation 8-Hr TWA	✓		✓		✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
Industrial / commercial use	Lubricants and greases	Liquid lubricants and greases.	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	

Life Cycle Stage	Category [a]	Subcategory [b]	Population [c]	Exposure Route [d]	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Industrial / commercial use	Lubricants and greases	Spray lubricants and greases.	Worker	Inhalation 8-Hr TWA	✓		✓		✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
Industrial / commercial use	Lubricants and greases	Degreasers – aerosol degreasers and cleaners.	Worker	Inhalation 8-Hr TWA	✓		✓		✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
Industrial / commercial use	Lubricants and greases	Degreasers - non-aerosol degreasers and cleaners.	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	
Industrial / commercial use	Building/ construction materials not covered elsewhere	Cold pipe insulation.	Worker	Inhalation 8-Hr TWA	✓		✓		✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
Industrial / commercial use	Solvents (which become part of product formulation or mixture)	All other chemical product and preparation manufacturing.	Worker	Inhalation 8-hr TWA	✓	✓	✓	✓	✓	
				Inhalation 15-Minute TWA	✓					
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	
				Inhalation 15-Minute TWA	✓		✓			
Industrial / commercial use	Processing aid not otherwise listed	In multiple manufacturing sectors.	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	✓
Industrial / commercial use	Propellants and blowing agents	Flexible polyurethane foam manufacturing.	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	✓

Life Cycle Stage	Category [a]	Subcategory [b]	Population [c]	Exposure Route [d]	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Industrial / commercial use	Other Uses	Laboratory chemicals - all other chemical product and preparation manufacturing.	Worker	Inhalation 8-Hr TWA	✓		✓			
				Inhalation 15-Minute TWA	✓					
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
				Inhalation 15-Minute TWA	n/a		n/a		n/a	
Industrial / commercial use	Other Uses	Electrical equipment, appliance, and component manufacturing.	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	
Industrial / commercial use	Other Uses	Plastic and rubber products.	Worker	Inhalation 8-Hr TWA	✓		✓	✓	✓	
				Inhalation 15-Minute TWA	✓	✓				
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA			✓	✓		
Industrial / commercial use	Other Uses	Cellulose triacetate film production.	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	✓
				Dermal	✓		✓			
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	✓
Industrial / commercial use	Other Uses	Anti-adhesive agent - anti-spatter welding aerosol.	Worker	Inhalation 8-Hr TWA	✓		✓		✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
Industrial / commercial use	Other Uses	Oil and gas drilling, extraction, and support activities.	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	

Life Cycle Stage	Category [a]	Subcategory [b]	Population [c]	Exposure Route [d]	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Industrial / commercial use	Other Uses	Toys, playground, and sporting equipment - including novelty articles (toys, gifts, etc.)	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	
Industrial / commercial use	Other Uses	Lithographic printing cleaner.	Worker	Inhalation 8-Hr TWA	✓		✓	✓	✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
Industrial / commercial use	Other Uses	Carbon remover, Wood floor cleaner, and Brush cleaner.	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	
Disposal	Disposal	Industrial pre-treatment Industrial wastewater treatment Publicly owned treatment works (POTW) Underground injection Municipal landfill Hazardous landfill Other land disposal Municipal waste incinerator Off-site waste transfer	Worker	Inhalation 8-Hr TWA	✓		✓			
				Dermal	✓	✓	✓	✓		
			ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	

[a] These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent additional information regarding all conditions of use of methylene chloride.
[b] These subcategories reflect more specific information regarding the conditions of use of methylene chloride.
[c] When the difference between ONUs' exposures and workers' exposures could not be quantified, EPA assumed that ONU inhalation exposures are lower than inhalation exposures for workers directly handling the chemical substance, and considered the central tendency risk estimate when determining ONU risk.
[d] 15-min TWA are shown for conditions of use that had available exposure data and when risks from acute exposure indicated were different from 8-hr TWA. See Section 4.2.2.1 of this risk evaluation for details of 15-min TWAs for each occupational exposure scenario.

Table 5-2. Supporting Basis for the Revised Unreasonable Risk Determination for Human Health (Consumer Conditions of Use)

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route and Duration	Human Health		
					Acute Non-cancer		
					High Intensity Use	Moderate Intensity Use	Low Intensity Use
Consumer use	Solvents (for cleaning and degreasing)	Aerosol spray degreaser/cleaner	Consumer user	Inhalation 1-hour	✓	✓	✓
				Inhalation 8-hour	✓	✓	✓
				Dermal	✓	✓	✓
			Bystander	Inhalation 1-hour	✓	✓	
				Inhalation 8-hour	✓	✓	
Consumer use	Adhesives and Sealants	Single component glues, adhesives, sealants, and caulk	Consumer user	Inhalation 1-hour	✓	✓	
				Inhalation 8-hour	✓	✓	
				Dermal	✓	✓	
			Bystander	Inhalation 1-hour	✓	✓	
				Inhalation 8-hour	✓	✓	
Consumer use	Paints and coatings Including paint and coating removers	Brush cleaner for paints and coatings	Consumer user	Inhalation 1-hour			
				Inhalation 8-hour			
				Dermal	✓		
			Bystander	Inhalation 1-hour			
				Inhalation 8-hour			
Consumer use	Paints and coatings Including paint and coating removers	Adhesive/caulk removers	Consumer user	Inhalation 1-hour	✓	✓	
				Inhalation 8-hour	✓		
				Dermal	✓	✓	✓
			Bystander	Inhalation 1-hour	✓		
				Inhalation 8-hour	✓		

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route and Duration	Human Health		
					Acute Non-cancer		
					High Intensity Use	Moderate Intensity Use	Low Intensity Use
Consumer use	Metal products not covered elsewhere	Degreasers - aerosol and non-aerosol degreasers (metal degreasers)	Consumer user	Inhalation 1-hour	✓	✓	✓
				Inhalation 8-hour	✓	✓	✓
				Dermal	✓	✓	✓
			Bystander	Inhalation 1-hour	✓	✓	
				Inhalation 8-hour	✓	✓	
Consumer use	Automotive care products	Functional fluids for air conditioners	Consumer user	Inhalation 1-hour	✓	✓	
				Inhalation 8-hour	✓	✓	
				Dermal	✓	✓	✓
			Bystander	Inhalation 1-hour	✓		
				Inhalation 8-hour	✓		
Consumer use	Automotive care products	Degreasers: gasket remover, transmission cleaners, carburetor cleaner, brake quieter/cleaner	Consumer user	Inhalation 1-hour	✓	✓	✓
				Inhalation 8-hour	✓	✓	✓
				Dermal	✓	✓	✓
			Bystander	Inhalation 1-hour	✓	✓	
				Inhalation 8-hour	✓	✓	
Consumer use Consumer use	Lubricants and greases Lubricants and greases	Degreasers - Aerosol and non-aerosol degreasers and cleaners	Consumer user	Inhalation 1-hour	✓	✓	✓
				Inhalation 8-hour	✓	✓	✓
				Dermal	✓	✓	✓
			Bystander	Inhalation 1-hour	✓	✓	
				Inhalation 8-hour	✓	✓	

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route and Duration	Human Health		
					Acute Non-cancer		
					High Intensity Use	Moderate Intensity Use	Low Intensity Use
Consumer use	Building / construction materials not covered elsewhere	Cold pipe insulation	Consumer user	Inhalation 1-hour	✓	✓	✓
				Inhalation 8-hour	✓	✓	
				Dermal	✓	✓	
			Bystander	Inhalation 1-hour	✓	✓	
				Inhalation 8-hour	✓	✓	
Consumer use	Arts, crafts, and hobby materials	Crafting glue and cement/concrete	Consumer user	Inhalation 1-hour	✓	✓	
				Inhalation 8-hour	✓	✓	
				Dermal	✓	✓	
			Bystander	Inhalation 1-hour	✓		
				Inhalation 8-hour	✓		
Consumer use	Other Uses	Anti-adhesive agent	Consumer user	Inhalation 1-hour	✓	✓	✓
				Inhalation 8-hour	✓	✓	✓
				Dermal	✓	✓	
			Bystander	Inhalation 1-hour	✓	✓	
				Inhalation 8-hour	✓	✓	

[a] These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent additional information regarding all conditions of use of methylene chloride.

[b] These subcategories reflect more specific information regarding the conditions of use of methylene chloride.

5.5 Order Withdrawing TSCA Section 6(i)(1) Order

The June 2020 risk evaluation for methylene chloride included individual risk determinations for each condition of use evaluated. The determinations that particular conditions of use did not present unreasonable risk were issued by order under TSCA section 6(i)(1). Section 5.4.1 of the June 2020 Risk Evaluation stated: "This subsection of the final Risk Evaluation … constitutes the order required under TSCA section 6(i)(1), and the 'no unreasonable risk' determinations in this subsection are considered to be final agency action effective on the date of issuance of this order."

In this revised risk determination, EPA has determined that methylene chloride as a whole chemical substance presents an unreasonable risk of injury to health under the conditions of use. This revised risk determination supersedes the no unreasonable risk determinations in the June 2020 Risk Evaluation that were premised on a condition of use-specific approach to determining unreasonable risk. This subsection of the revised risk determination also constitutes an order withdrawing the TSCA section 6(i)(1) order in the June 2020 Risk Evaluation. EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the to the extent permitted by law and supported by reasoned explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Further explanation and justification for this action can be found in the Federal Register Notice announcing the availability of the draft revised risk determination for methylene chloride, 87 Fed. Reg. 39824 (July 5, 2022) (Ref. 8), and in the Federal Register Notice accompanying this revised risk determination.

5.6 References

1. EPA. Risk Evaluation for Methylene Chloride (MC). June 2020. https://www.regulations.gov/document/ EPA-HQ-OPPT-2019-0437-0107.

2. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register* (86 FR 7009, January 25, 2021).

3. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register* (86 FR 7037, of January 25, 2021).

4. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal Register* (86 FR 7619, February 1, 2021).

5. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. *Federal Register* (86 FR 8845, February 10, 2021).

6. EPA Press Release. EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 30, 2021. https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations

7. Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. https://www.osha.gov/annotated-pels

8. Notice. Methylene Chloride; Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment. *Federal Register* (87 Fed. Reg. 39824 (July 5, 2022).

9. EPA. Methylene Chloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination: Response to Public Comments. October 2022. *Available at*: docket EPA–HQ–OPPT–2016–0742.