

1 Methylene Chloride

2 **5. UNREASONABLE RISK DETERMINATION**

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

8
9 EPA has determined that methylene chloride presents an unreasonable risk of injury to health
10 under the conditions of use. This determination is based on the information in previous sections
11 of the Risk Evaluation, the appendices and supporting documents of methylene chloride, in
12 accordance with TSCA section 6(b), as well as TSCA’s best available science (TSCA section
13 26(h)) and weight of scientific evidence standards (TSCA section 26(i)), and relevant
14 implementing regulations in 40 CFR part 702.

15
16 The full list of conditions of use evaluated for are listed in Table 1-4 of the risk evaluation (Ref.
17 1). EPA’s unreasonable risk determination for methylene chloride is driven by risks associated
18 with the following conditions of use, considered singularly or in combination with other
19 exposures:

- 20 • Manufacturing (Domestic Manufacture)
- 21 • Manufacturing (Import)
- 22 • Processing: as a reactant
- 23 • Processing: incorporation into a formulation, mixture, or reaction products
- 24 • Processing: repackaging
- 25 • Processing: recycling
- 26 • Industrial and commercial use as solvent for batch vapor degreasing
- 27 • Industrial and commercial use as solvent for in-line vapor degreasing
- 28 • Industrial and commercial use as solvent for cold cleaning
- 29 • Industrial and commercial use as solvent for aerosol spray degreaser/cleaner
- 30 • Industrial and commercial use in adhesives, sealants and caulks
- 31 • Industrial and commercial use in paints and coatings
- 32 • Industrial and commercial use in paint and coating removers
- 33 • Industrial and commercial use in adhesive and caulk removers
- 34 • Industrial and commercial use in metal aerosol degreasers
- 35 • Industrial and commercial use in metal non-aerosol degreasers
- 36 • Industrial and commercial use in finishing products for fabric, textiles and leather
- 37 • Industrial and commercial use in automotive care products (functional fluids for air
38 conditioners)
- 39 • Industrial and commercial use in automotive care products (interior car care)
- 40 • Industrial and commercial use in automotive care products (degreasers)
- 41 • Industrial and commercial use in apparel and footwear care products

Methylene Chloride – DRAFT FOR PUBLIC COMMENT

- 42 • Industrial and commercial use in spot removers for apparel and textiles
- 43 • Industrial and commercial use in liquid lubricants and greases
- 44 • Industrial and commercial use in spray lubricants and greases
- 45 • Industrial and commercial use in aerosol degreasers and cleaners
- 46 • Industrial and commercial use in non-aerosol degreasers and cleaners
- 47 • Industrial and commercial use in cold pipe insulations
- 48 • Industrial and commercial use as solvent that becomes part of a formulation or mixture
- 49 • Industrial and commercial use as a processing aid
- 50 • Industrial and commercial use as propellant and blowing agent
- 51 • Industrial and commercial use for electrical equipment, appliance, and component
- 52 manufacturing
- 53 • Industrial and commercial use for plastic and rubber products manufacturing
- 54 • Industrial and commercial use in cellulose triacetate film production
- 55 • Industrial and commercial use as anti-splatter welding aerosol
- 56 • Industrial and commercial use for oil and gas drilling, extraction, and support activities
- 57 • Industrial and commercial use in toys, playground and sporting equipment
- 58 • Industrial and commercial use in lithographic printing plate cleaner
- 59 • Industrial and commercial use in carbon remover, wood floor cleaner, and brush cleaner
- 60 • Industrial and commercial use as laboratory chemical
- 61 • Consumer use as solvent in aerosol degreasers/cleaners
- 62 • Consumer use in adhesives and sealants
- 63 • Consumer use in brush cleaners for paints and coatings
- 64 • Consumer use adhesive and caulk removers
- 65 • Consumer use in metal degreasers
- 66 • Consumer use in automotive care products (functional fluids for air conditioners)
- 67 • Consumer use in automotive care products (degreasers)
- 68 • Consumer use in lubricants and greases
- 69 • Consumer use in cold pipe insulation
- 70 • Consumer use in arts, crafts, and hobby materials glue
- 71 • Consumer use in an anti-splatter welding aerosol
- 72 • Consumer use in carbon removers and other brush cleaners
- 73 • Disposal

74
75 EPA will initiate risk management for methylene chloride by applying one or more of the
76 requirements under TSCA section 6(a) to the extent necessary so that methylene chloride no
77 longer presents an unreasonable risk. Under TSCA section 6(a), EPA is not limited to regulating
78 the specific activities found to drive unreasonable risk and may select from among a suite of risk
79 management options related to manufacture, processing, distribution in commerce, commercial
80 use, and disposal in order to address the unreasonable risk. For instance, EPA may regulate
81 upstream activities (e.g., processing, distribution in commerce) in order to address downstream

82 activities driving unreasonable risk (e.g., consumer use) even if the upstream activities are not
83 unreasonable risk drivers.

84 **5.1 Background**

85 **5.1.1 Background on Policy Changes Relating to the Whole Chemical Risk** 86 **Determination and Assumption of PPE Use by Workers**

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

92
93 In accordance with Executive Order 13990 (“Protecting Public Health and the Environment and
94 Restoring Science to Tackle the Climate Crisis”) and other Administration priorities (Refs. 1, 2,
95 3, and 4), EPA reviewed the risk evaluations for the first ten chemical substances to ensure that
96 they meet the requirements of TSCA, including conducting decision-making in a manner that is
97 consistent with the best available science and weight of the scientific evidence.

98
99 As a result of this review, EPA announced plans to revise specific aspects of certain of the first
100 ten risk evaluations in order to ensure that the risk evaluations appropriately identify
101 unreasonable risks and thereby can help ensure the protection of health and the environment
102 (Ref. 6). To that end, EPA is reconsidering two key aspects of the risk determination for
103 methylene chloride published in June 2020. First, EPA proposes that the appropriate approach to
104 these determinations is to make an unreasonable risk determination for methylene chloride as a
105 whole chemical substance, rather than making unreasonable risk determinations separately on
106 each individual condition of use evaluated in the risk evaluation. Second, EPA proposes that the
107 risk determination shall explicitly state that it does not rely on assumptions regarding the use of
108 personal protective equipment (PPE) in making the unreasonable risk determination under TSCA
109 section 6; rather, the use of PPE will be considered during risk management. Making
110 unreasonable risk determinations based on the baseline scenario without assuming PPE should
111 not be viewed as an indication that EPA believes there are no occupational safety protections in
112 place at any location or that there is widespread noncompliance with applicable OSHA
113 standards. EPA understands that there could be occupational safety protections in place at
114 workplace locations; however, not assuming use of PPE reflects EPA’s recognition that
115 unreasonable risk may exist for subpopulations of workers that may be highly exposed because
116 they are not covered by OSHA standards, or their employers are out of compliance with OSHA
117 standards, or because many of OSHA’s chemical-specific permissible exposure limits largely
118 adopted in the 1970’s are described by OSHA as being “outdated and inadequate for ensuring

119 protection of worker health,”¹ or because the OSHA Permissible Exposure Limit may be
120 inadequate for ensuring protection of worker health.

121
122 Separately, EPA is conducting a screening approach to assess potential risks from the air and
123 water pathways for several of the first 10 chemicals, including this chemical. For methylene
124 chloride, the exposure pathways that were or could be regulated under another EPA administered
125 statute were excluded from the final risk evaluation (see section 1.4.2 of the June 2020
126 methylene chloride risk evaluation). This resulted in the surface water, drinking water, ambient
127 air, and sediment pathways for methylene chloride not being assessed for human health
128 exposures or the general population. The goal of the recently-developed screening approach is to
129 remedy this exclusion and to identify if there are risks that were unaccounted for in the
130 methylene chloride risk evaluation. While this analysis is underway, EPA is not incorporating
131 the screening-level approach into this draft revised unreasonable risk determination. If the results
132 suggest there is additional risk, EPA will determine if the risk management approaches being
133 contemplated for methylene chloride will protect against these risks or if the risk evaluation will
134 need to be formally supplemented or revised.

135
136 Further discussion of the rationale for the whole chemical approach is found in the Federal
137 Register notice in the docket accompanying this revised methylene chloride unreasonable risk
138 determination and further discussion of the proposed decision to not rely on assumptions
139 regarding the use of PPE is provided in the Federal Register Notice and in Section 5.2.4 below.
140 With respect to the methylene chloride risk evaluation, EPA did not amend, nor does a whole
141 chemical approach or change in assumptions regarding PPE require amending, the underlying
142 scientific analysis of the risk evaluation in the risk characterization section of the risk evaluation.

143
144 With regard to the specific circumstances of methylene chloride, as further explained below,
145 EPA proposes that a whole chemical approach is appropriate for methylene chloride in order to
146 protect health and the environment. The whole chemical approach is appropriate for methylene
147 chloride, because there are benchmark exceedances for multiple conditions of use (spanning
148 across most aspects of the chemical lifecycle – from manufacturing (including import),
149 processing, commercial and consumer use, and disposal) for human health and the health effects
150 associated with methylene chloride exposures are irreversible. Because these chemical-specific
151 properties cut across the conditions of use within the scope of the risk evaluation, and a
152 substantial amount of the conditions of use drive the unreasonable risk, it is therefore appropriate
153 for the Agency to make a determination that the whole chemical presents an unreasonable risk.
154 As explained in the Federal Register Notice, the revisions to the unreasonable risk determination
155 would be based on the existing risk characterization section of the risk evaluation (section 4 of
156 this risk evaluation) and do not involve additional technical or scientific analysis. The discussion
157 of the issues in this draft revision to the risk determination supersedes any conflicting statements

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).

158 in the prior methylene chloride risk evaluation (June 2020) and the response to comments
159 document (*Summary of External Peer Review and Public Comments and Disposition for*
160 *Methylene Chloride (MC), June 2020*). In addition, as discussed below in Section 5.2.4., in
161 making this risk determination, EPA believes it is appropriate to evaluate the levels of risk
162 present in baseline scenarios where PPE is not assumed to be used by workers. EPA is revising
163 the assumption for methylene chloride that workers always or properly use PPE, although the
164 Agency does not question the information received regarding the occupational safety practices
165 often followed by many industry respondents and notes the existing requirements under the
166 methylene chloride standard from the Occupational Safety and Health Administration (OSHA) at
167 29 CFR 1910.1052. EPA also views the peer reviewed hazard and exposure assessments and
168 associated risk characterization as robust and upholding the standards of best available science
169 and weight of the scientific evidence, per TSCA sections 26(h) and (i).

170 **5.1.2 Background on Unreasonable Risk Determination**

171 In each risk evaluation under TSCA section 6(b), EPA determines whether a chemical substance
172 presents an unreasonable risk of injury to health or the environment, under the conditions of use.
173 The unreasonable risk determination does not consider costs or other non-risk factors. In making
174 the unreasonable risk determination, EPA considers relevant risk-related factors, including, but
175 not limited to: the effects of the chemical substance on health and human exposure to such
176 substance under the conditions of use (including cancer and non-cancer risks); the effects of the
177 chemical substance on the environment and environmental exposure under the conditions of use;
178 the population exposed (including any potentially exposed or susceptible subpopulations
179 (PESS)); the severity of hazard (including the nature of the hazard, the irreversibility of the
180 hazard); and uncertainties. EPA also takes into consideration the Agency’s confidence in the data
181 used in the risk estimate. This includes an evaluation of the strengths, limitations, and
182 uncertainties associated with the information used to inform the risk estimate and the risk
183 characterization. This approach is in keeping with the Agency’s final rule, *Procedures for*
184 *Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July
185 20, 2017).²

186
187 This section describes the draft revised unreasonable risk determination for methylene chloride,
188 under the conditions of use in the scope of the Risk Evaluation for methylene chloride.
189 This draft revised unreasonable risk determination is based on the risk estimates in the final Risk
190 Evaluation, which may differ from the risk estimates in the draft Risk Evaluation due to peer
191 review and public comments.

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.

192 **5.2 Unreasonable Risk to Human Health**

193 **5.2.1 Human Health**

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

205
206 In developing the exposure assessment for methylene chloride, EPA identified the following
207 groups as Potentially Exposed or Susceptible Subpopulations (PESS): workers and occupational
208 non-users (ONUs)³ (including men and women of reproductive age, and adolescents); consumer
209 users and bystanders (of any age group, including infants, toddlers, children, and elderly)
210 (Section 2.4.1 and Tables 4-2 and 4-3 of this Risk Evaluation).

211
212 EPA evaluated exposures to workers, ONUs, consumer users, and bystanders using reasonably
213 available monitoring and modeling data for inhalation and dermal exposures as applicable. For
214 example, EPA assumed that ONUs and bystanders do not have direct contact with methylene
215 chloride; therefore, non-cancer effects and cancer from dermal exposures to methylene chloride
216 were not evaluated. The description of the data used for human health exposure is in Section 2.4
217 of this Risk Evaluation. Uncertainties in the analysis are discussed in Section 4.4 of this Risk
218 Evaluation and are considered in the unreasonable risk determination, including the fact that the
219 dermal model used for occupational exposures does not address variability in exposure duration
220 and frequency. An additional uncertainty includes the use of exposure data generated before the
221 OSHA Methylene Chloride standard was updated in 1997.

222
223 EPA currently is examining whether there are risks not accounted for in the risk evaluation by
224 analyzing exposures to fenceline communities. As described earlier (in Section 5.1.1), while this
225 analysis is underway, EPA is not incorporating the screening-level approach into this draft
226 revised unreasonable risk determination.

227 **5.2.2 Non-Cancer Risk Estimates**

228 The risk estimates for non-cancer effects (expressed as margins of exposure or MOEs) refer to
229 adverse health effects associated with health endpoints other than cancer, including to the body’s

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).

230 organ systems, reproductive/developmental effects, cardiac and lung effects, and kidney and
231 liver effects. The MOE is the point of departure (POD) (an approximation of the no-observed
232 adverse effect level (NOAEL) or benchmark dose level (BMDL)) and the corresponding human
233 equivalent concentration (HEC) for a specific health endpoint divided by the exposure
234 concentration for the specific scenario of concern. Section 3.2.5 of this Risk Evaluation presents
235 the PODs for acute and chronic non-cancer effects for methylene chloride and Section 4.3 of this
236 Risk Evaluation presents the MOEs for acute and chronic non-cancer effects.

237
238 The MOEs are compared to a benchmark MOE. The benchmark MOE accounts for the total
239 uncertainty in a POD, including, as appropriate: (1) the variation in sensitivity among the
240 members of the human population (i.e., intrahuman/intraspecies variability); (2) the uncertainty
241 in extrapolating animal data to humans (i.e., interspecies variability); (3) the uncertainty in
242 extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure
243 (i.e., extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating
244 from a lowest observed adverse effect level (LOAEL) rather than from a NOAEL. A lower
245 benchmark MOE (e.g., 30) indicates greater certainty in the data (because fewer of the default
246 uncertainty factors (UFs) relevant to a given POD as described above were applied). A higher
247 benchmark MOE (e.g., 1000) would indicate more uncertainty for specific endpoints and
248 scenarios. However, these are often not the only uncertainties in a risk evaluation. The
249 benchmark MOE for acute non-cancer risks for methylene chloride is 30 (accounting for
250 intraspecies and LOAEL to NOAEL variability for an effect of small magnitude in a human
251 study). The benchmark MOE for chronic non-cancer risks for methylene chloride is 10
252 (accounting for interspecies and intraspecies variability in toxicodynamics); toxicokinetic
253 differences are accounted for in the PBPK modeling.). Additional information regarding the
254 non-cancer hazard identification is in Section 3.2.3.1 and the benchmark MOE is in Section 4.3.
255 of this Risk Evaluation.

256 **5.2.3 Cancer Risk Estimates**

257 Cancer risk estimates represent the incremental increase in probability of an individual in an
258 exposed population developing cancer over a lifetime (excess lifetime cancer risk (ELCR))
259 following exposure to the chemical. Standard cancer benchmarks used by EPA and other
260 regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000
261 to 1 in 10,000 (i.e., 1×10^{-6} to 1×10^{-4}) depending on the subpopulation exposed. For example, in
262 this risk evaluation, EPA used 1×10^{-4} as the benchmark for the cancer risk to individuals in
263 industrial and commercial work places. The 1×10^{-4} value is not a bright line and EPA has
264 discretion to make an unreasonable risk determination for the chemical substance based on other
265 benchmarks as appropriate. Additional information regarding the cancer benchmark is in Section
266 4.3.1 of this Risk Evaluation.

267 **5.2.4 Determining Unreasonable Risk of Injury to Health**

268 Calculated risk estimates (MOEs or cancer risk estimates) can provide a risk profile of methylene
269 chloride by presenting a range of estimates for different health effects for different conditions of
270 use. A calculated MOE that is less than the benchmark MOE supports a determination of
271 unreasonable risk of injury to health, based on noncancer effects. Similarly, a calculated cancer
272 risk estimate that is greater than the cancer benchmark supports a determination of unreasonable

273 risk of injury to health from cancer. These calculated risk estimates alone are not bright-line
274 indicators of unreasonable risk. Whether EPA makes a determination of unreasonable risk for the
275 chemical substance depends upon other risk-related factors, such as the endpoint under
276 consideration, the reversibility of effect, exposure-related considerations (e.g., duration,
277 magnitude, or frequency of exposure, or population exposed), and the confidence in the
278 information used to inform the hazard and exposure values.

279
280 In the methylene chloride risk characterization, neurotoxicity effects (CNS depression) were
281 identified as the most sensitive endpoint for non-cancer adverse effect from acute inhalation and
282 dermal exposures and liver effects were identified as the most sensitive endpoint for non-cancer
283 adverse effects from chronic inhalation and dermal exposures for all conditions of use. However,
284 additional risks associated with other adverse effects (e.g., other nervous system effects, immune
285 system effects; reproductive and developmental effects; and irritation/burns) were identified for
286 acute and chronic exposures. Addressing unreasonable risk by using CNS and liver effects will
287 also address the unreasonable risk from other endpoints resulting from acute or chronic
288 inhalation and dermal exposures.

289
290 In accordance with EPA’s Guidelines for Carcinogen Risk Assessment, methylene chloride is
291 considered “likely to be carcinogenic to humans” and EPA calculated cancer risk estimates with
292 a linear model. The cancer analysis is described in Section 3.2. EPA considered cancer risks
293 estimates from chronic dermal or inhalation exposures in the unreasonable risk determination.

294
295 When making a determination of unreasonable risk for the chemical substance, the Agency has a
296 higher degree of confidence where uncertainty is low. For example, EPA has high confidence in
297 the hazard and exposure characterizations when the basis for characterizations is measured data
298 or representative monitoring data or a robust model and the hazards identified for risk estimation
299 are relevant for conditions of use. This Risk Evaluation discusses major assumptions and key
300 uncertainties; for example, where EPA has made assumptions in the scientific evaluation,
301 whether or not those assumptions are “conservative” (that is the degree to which these
302 assumptions err on the side of protection) is also a consideration. Additionally, EPA considers
303 the central tendency and high-end exposure levels when determining unreasonable risk. The high
304 volatility of methylene chloride and potentially severe effects from short term (1-hr) exposure
305 are considerations when weighing the role of uncertainties in decision making for methylene
306 chloride. For the human health risk estimation, key assumptions and uncertainties are related to
307 the estimates for ONU inhalation exposures, because monitoring data were not reasonably
308 available for many of the conditions of use evaluated. An additional source of uncertainty is the
309 inhalation to dermal route-to-route extrapolations, which is a source of uncertainty in the dermal
310 risk assessment for dermal cancer and non-cancer risk estimates. Similarly, for assessing cancer
311 risks, although EPA chose to model the combination of liver and lung tumor results from a
312 cancer bioassay using mice, there is uncertainty regarding the modeling of these tumor types for
313 humans. Important assumptions and key sources of uncertainty in the risk characterization are
314 described in more detail in Section 4.4 of this Risk Evaluation.

315

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

323
324 As shown in Section 4 of this Risk Evaluation, when characterizing the risk to human health
325 from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate
326 to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used
327 by workers, notwithstanding the current requirements under the OSHA methylene chloride
328 standard. It should be noted that, in some cases, baseline conditions may reflect certain
329 mitigation measures, such as engineering controls, in instances where exposure estimates are
330 based on monitoring data at facilities that have engineering controls in place. This approach of
331 not assuming PPE use by workers considers the risk to potentially exposed or susceptible
332 subpopulations (workers and ONUs) who may not be covered by OSHA standards, such as self-
333 employed individuals and public sector workers who are not covered by a State Plan. In addition,
334 EPA risk evaluations may characterize the levels of risk present in scenarios considering
335 applicable OSHA requirements (e.g., chemical-specific PELs and/or chemical-specific health
336 standards with PELs and additional ancillary provisions), as well as scenarios considering
337 industry or sector best practices for industrial hygiene that are clearly articulated to the Agency.
338 EPA's evaluation of risk under scenarios that, for example, incorporate use of engineering or
339 administrative controls, or personal protective equipment, serves to inform its risk management
340 efforts. By characterizing risks using scenarios that reflect different levels of mitigation, EPA
341 risk evaluations can help inform potential risk management actions by providing information that
342 could be used to tailor risk mitigation appropriately to address worker exposures where the
343 Agency has found unreasonable risk. In particular, EPA can use the information developed
344 during its risk evaluation to determine whether alignment of EPA's risk management
345 requirements with existing OSHA requirements or industry best practices will adequately
346 address unreasonable risk as required by TSCA.

347
348 When undertaking unreasonable risk determinations as part of TSCA risk evaluations, EPA
349 cannot assume as a general matter that an applicable OSHA requirement (including the
350 methylene chloride standard) or industry practice is consistently and always properly applied.
351 Mitigation scenarios included in the methylene chloride risk evaluation (e.g., scenarios
352 considering use of various personal protective equipment (PPE)) likely represent what is
353 happening already in some facilities. However, the Agency cannot assume that all facilities will
354 have adopted these practices for the purposes of making the TSCA risk determination.

355
356 Therefore, EPA conducts baseline assessments of risk and makes its determination of
357 unreasonable risk from a baseline scenario that is not based on an assumption of compliance with
358 OSHA standards, including any applicable exposure limits or requirements for use of respiratory
359 protection or other PPE. Making unreasonable risk determinations based on the baseline scenario
360 should not be viewed as an indication that EPA believes there are no occupational safety
361 protections in place at any location or that there is widespread noncompliance with applicable

362 OSHA standards. Rather, it reflects EPA’s recognition that unreasonable risk may exist for
363 subpopulations of workers that may be highly exposed because they are not covered by OSHA
364 standards, such as self-employed individuals and public sector workers who are not covered by a
365 State Plan, or because their employer is out of compliance with OSHA standards, or because
366 many of OSHA’s chemical-specific permissible exposure limits largely adopted in the 1970’s are
367 described by OSHA as being “outdated and inadequate for ensuring protection of worker health,”
368 (Ref. 7) or because the OSHA PEL alone may be inadequate to protect worker health, or because
369 EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA
370 requirements.

371
372 The draft revised unreasonable risk determination for methylene chloride is based on the peer
373 reviewed risk characterization (Section 4 of this Risk Evaluation), which was developed
374 according to TSCA section 26(h) requirements to make science-driven decisions, consistent with
375 best available science. Changing the risk determination to a whole chemical approach does not
376 impact the underlying data and analysis presented in the risk characterization of the risk
377 evaluation. Section 4.5.2 and Table 4-27 of this Risk Evaluation summarize the risk estimates
378 with and without PPE, and informed the revised unreasonable risk determination.

379 **5.3 Unreasonable Risk to the Environment**

380 **5.3.1 Environment**

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

384
385 EPA calculated a risk quotient (RQ) to compare environmental concentrations against an effect
386 level. The environmental concentration is determined based on the levels of the chemical
387 released to the environment (e.g., surface water, sediment, soil, biota) under the conditions of
388 use, based on the fate properties, release potential, and reasonably available environmental
389 monitoring data. The effect level is calculated using concentrations of concern that represent
390 hazard data for aquatic, sediment-dwelling, and terrestrial organisms. Section 4.2 of this Risk
391 Evaluation provides more detail regarding the environmental risk characterization for methylene
392 chloride.

393

5.3.2 Determining Unreasonable Risk of Injury to the Environment

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

405

406 For all conditions of use, the RQ values (Table 4-4 and 4-5) do not support an unreasonable risk
407 determination in water for acute and chronic exposures to methylene chloride for amphibians,
408 fish, and aquatic invertebrates. To characterize the exposure to methylene chloride by aquatic
409 organisms, modeled data were used to represent surface water concentrations near facilities
410 actively releasing methylene chloride to surface water, and monitored concentrations were used
411 to represent ambient water concentrations of methylene chloride. EPA considered the biological
412 relevance of the species to determine the concentrations of concern for the location of surface
413 water concentration data to produce RQs, as well as frequency and duration of the exposure.
414 Some site-specific RQs, calculated from modeled release data from facilities conducting
415 recycling, disposal, and wastewater treatment plant activities are greater than or equal to one.
416 Uncertainties related to these particular estimates are discussed in section 4.2.2. Uncertainties in
417 the analysis include limitations in data, since monitoring data were not available near facilities
418 where methylene chloride is released, and TRI does not capture release data for facilities with
419 fewer than ten employees. As an additional uncertainty, the model does not consider chemical
420 fate or hydrologic transport properties and may not consider dilution in static water bodies. As
421 described in section 4.4.6, additional analysis indicated that model outputs, rather than
422 monitoring estimates, may best represent concentrations found at the point of discharge from the
423 facilities.

424

425 The toxicity of methylene chloride to sediment-dwelling invertebrates is similar to the toxicity to
426 aquatic invertebrates. Methylene chloride is most likely present in the pore waters and not
427 absorbed to the sediment organic matter because methylene chloride has low partitioning to
428 organic matter. The concentrations in sediment pore water are similar to or less than the
429 concentrations in the overlying water, and concentrations in the deeper part of sediment are
430 lower than the concentrations in the overlying water. Therefore, for sediment dwelling organisms
431 the risk estimates, based on the highest ambient surface water concentration, do not support an
432 unreasonable risk determination to sediment-dwelling organisms from acute or chronic
433 exposures. There is uncertainty due to the lack of ecotoxicity studies specifically for sediment-
434 dwelling organisms and limited sediment monitoring data.

435

436 Based on its physical-chemical properties, methylene chloride does not partition to or
437 accumulate in soil. Therefore, the physical chemical properties of methylene chloride do not
438 support an unreasonable risk determination to terrestrial organisms.

439
440 When making a determination of unreasonable risk, EPA has a higher degree of confidence
441 where uncertainty is low. For example, EPA has high confidence in the hazard and exposure
442 characterizations when the basis for the characterizations is measured or representative
443 monitoring data or a robust model and the hazards identified for risk estimation are relevant for
444 conditions of use. Additionally, EPA considers the central tendency and high-end scenarios when
445 determining the unreasonable risk. High-end risk estimates (*e.g.*, 90th percentile) are generally
446 intended to cover organisms or populations with greater exposure (those inhabiting ecosystems
447 near industries) and central tendency risk estimates are generally estimates of average or typical
448 exposure. For methylene chloride, key assumptions and uncertainties in the environmental risk
449 estimation include the uncertainty around modeled releases that used E-FAST 2014 with 2016
450 TRI data as well as 2016 DMR data to estimate releases. Some sites that manufacture, process,
451 or use methylene chloride may not report to these datasets, are not included in this analysis and
452 therefore actual environmental exposures may be underestimated. In the measured surface water
453 data and watershed analysis, the WQP Tools contains data from USGS-NWIS and STORET
454 databases, and is one of the largest environmental monitoring databases in the U.S.; however,
455 comprehensive information needed for data interpretation is not always reasonably available. As
456 a result, there are uncertainties in the reported monitoring data that are difficult to quantify with
457 regard to impacts on exposure estimates. Assumptions and key sources of uncertainty in the risk
458 characterization are detailed in Section 4.4.1. of this Risk Evaluation.

459
460 Although various degrees of uncertainty and assumptions were identified in the risk evaluation,
461 EPA did not identify risk of injury to the environment that would drive the unreasonable risk
462 determination for methylene chloride.

463 **5.4 Additional Information regarding the Basis for the Unreasonable Risk** 464 **Determination**

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

Table 5-1. Supporting Basis for the Draft Revised Unreasonable Risk Determination for Human Health (Occupational Conditions of Use)⁴

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		✓				
				Dermal	✓	✓	✓	✓		
		Petrochemical manufacturing	ONU	Inhalation 8-Hr TWA	n/a		n/a		n/a	
				Inhalation 15-Minute TWA		✓				

⁴ The checkmarks indicate the type of effect and the exposure route to the population evaluated for each condition of use that support the draft 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	✓	✓	✓	✓	✓	
				Inhalation 15-Minute TWA	✓					
				Dermal	✓	✓	✓	✓		
		Solvents (which become part of product formulation or mixture), including manufacturing of: All other chemical product and preparation; paints and coatings	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										

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
		Oil and gas drilling, extraction, and support activities								
Processing	Repackaging	Solvents (which become part of product formulation or mixture) for all other chemical product and preparation manufacturing.	Worker	Inhalation 8-Hr TWA	✓		✓	✓		
				Inhalation 1-Hr TWA	✓	✓				
				Dermal	✓	✓	✓	✓		
		All other chemical product and preparation manufacturing.	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	
Industrial /		Aerosol spray degreaser/cleaner	Worker	Inhalation 8-Hr TWA	✓		✓		✓	

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
commercial use	Solvents (for cleaning or degreasing)			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	
Industrial /			Worker	Inhalation 8-Hr TWA	✓		✓	✓		

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
commercial use	Fabric, textile and leather products not covered elsewhere	Textile finishing and impregnating/ surface treatment products.		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	
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 /			Worker	Inhalation 8-Hr TWA	✓		✓		✓	

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
commercial use	Lubricants and greases	Degreasers – aerosol degreasers and cleaners.		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	✓
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 /	Other Uses		Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	

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
commercial use		Electrical equipment, appliance, and component manufacturing.	ONU	Dermal	✓	✓	✓	✓		
				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	✓		✓			
Industrial / commercial use	Other Uses	Anti-adhesive agent - anti-spatter welding aerosol.	ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	✓
				Dermal	✓	✓	✓	✓		
Industrial / commercial use	Other Uses	Oil and gas drilling, extraction, and support activities.	Worker	Inhalation 8-Hr TWA	✓	✓	✓	✓	✓	
				Dermal	✓	✓	✓	✓		
Industrial / commercial use	Other Uses	Toys, playground, and sporting equipment - including novelty articles (toys, gifts, etc.)	ONU	Inhalation 8-Hr TWA	n/a	✓	n/a	✓	n/a	
				Dermal	✓	✓	✓	✓		
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	

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	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 Draft 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	Adhesive/caulk removers	Consumer user	Inhalation 1-hour	✓	✓	
				Inhalation 8-hour	✓		
				Dermal	✓	✓	✓
			Bystander	Inhalation 1-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
	coating removers			Inhalation 8-hour	✓		
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	✓	✓	

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
				Inhalation 8-hour	✓	✓	
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.

5.1 References

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