

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

## Comments of Safer Chemicals Healthy Families, Environmental Health Strategy Center, Earthjustice and Natural Resources Defense Council on EPA's Draft Risk Evaluation for Carbon Tetrachloride under Section 6(b) of TSCA

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Safer Chemicals Healthy Families (SCHF), Environmental Health Strategy Center, Earthjustice and Natural Resources Defense Council submit these comments on the Environmental Protection Agency (EPA) draft risk evaluation for carbon tetrachloride (CTC) under section 6(b) of the Toxic Substances Control Act (TSCA).<sup>1</sup> Our organizations are committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day. We took a leadership role during the TSCA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today.

In these comments, we identify significant shortcomings in the CTC Evaluation for consideration by EPA's Science Advisory Committee on Chemicals (SACC) during its upcoming meeting to review the draft on February 25-26, 2020. As we discuss more fully below, the evaluation contains serious gaps and flawed analyses that result in an understatement of CTC's risks to human health and the environment:

- The draft evaluation lacks any assessment of releases of CTC to the environment and thus disregards:
  - Large air emissions that are harmful to the ozone layer, global climate, and the health of the general population
  - Widespread contamination of drinking water at levels that present an unacceptable cancer risk, and
  - Extensive soil contamination at inactive and active waste sites with significant potential for air emissions, vapor intrusion into buildings, and migration to surface and ground water.
- The evaluation assumes that there is no consumer exposure to CTC despite its confirmed presence in several consumer products and data demonstrating significant emissions from household bleach and elevated indoor air levels.
- The evaluation identifies but fails to consider three new epidemiological studies that demonstrate that CTC causes brain tumors in children and adults.

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<sup>1</sup> 85 Federal Register 4658 (January 27, 2020); EPA, *Draft Risk Evaluation for Carbon Tetrachloride (Methane, Tetrachloro-)* CASRN: 56-23-5, January 2020, [https://www.epa.gov/sites/production/files/2020-01/documents/1\\_ccl4\\_draft\\_risk\\_evaluation\\_draft\\_public\\_updated.pdf](https://www.epa.gov/sites/production/files/2020-01/documents/1_ccl4_draft_risk_evaluation_draft_public_updated.pdf) (CTC Evaluation).

- The evaluation’s dermal exposure modeling is incomplete and unrealistic and fails to aggregate dermal and inhalation exposures to determine a composite estimate of risk.
- The draft evaluation fails to apply uncertainty factors necessary to account for elevated risks to vulnerable subpopulations and gaps in the CTC database.
- As in previous risk evaluations, EPA determines that CTC’s risks to workers are not unreasonable based on the “expected” use of Personal Protective Equipment (PPE) although this expectation is not grounded in data, departs from established workplace protection policy, and is contrary to the realities of worker exposure to unsafe chemicals.

**I. The Draft Evaluation Ignores Significant Environmental Releases of CTC That Present Serious Health and Environmental Risks**

**A. EPA’s Exclusion of Environmental Releases Will Result in An Incomplete Risk Evaluation and Disregards Previous SACC Recommendations**

Like previous evaluations, the CTC draft lacks any assessment of risks to the general population or to the environment from CTC’s presence in air, water and soil. To justify this exclusion, EPA claims that it need not address “exposure pathways under programs of other environmental statutes” because they “adequately assess and effectively manage exposures” using “long-standing regulatory and analytical processes.”<sup>2</sup>

EPA’s exclusion of all environmental exposure pathways from risk evaluations will defeat the central TSCA goal of providing a comprehensive picture of a chemical’s risks to humans and the environment. Congress wanted EPA to examine the combined impact of all sources and pathways of exposure on affected populations and provided no exemption for environmental releases that might be subject to other environmental laws. Moreover, as CTC illustrates, other laws are not adequately addressing the contribution of air, soil and drinking water to total risk. If these pathways are ignored under TSCA, the result will likely be an incomplete understanding of CTC’s risks and inadequate protection of health and the environment.

The SACC has repeatedly raised concerns about EPA’s failure to consider environmental pathways of human exposure. Thus, in its review of the 1,4-dioxane draft risk evaluation, the SACC said:<sup>3</sup>

“Exposure scenarios that include consumers are important given the known presence of 1,4-Dioxane in plastics, other commercially available products, surface water, drinking water, groundwater, and in sediments. The Committee also had concerns that the omission of these multiple routes of exposure puts workers who inhale or ingest 1,4-Dioxane outside the workplace at even greater risk.”

The SACC added that:<sup>4</sup>

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<sup>2</sup> CTC Evaluation, at 21.

<sup>3</sup> 1,4-Dioxane and HBCD SACC Report, at 18.

<sup>4</sup> Id.

“The Committee discussed that if each program office of the EPA says others are assessing the risks and thus not including them in their assessment, the U.S. public will be left with no overall assessment of risks. If risks have been assessed by other program offices of EPA then the Agency should present them as part of the underlying data to support this TSCA Evaluation—if not, the Agency must gather the data for an assessment or include an assessment based on the assumption of near-worst-case exposures.”

The SACC underscored that “[g]eneral human population and biota exposure must be assessed for inhalation, ingestion, and dermal routes [and that] [d]ifferent sub-populations may have different extents of exposure, but each route must be assessed.”<sup>5</sup> EPA’s narrower approach, it said, “strayed from basic risk assessment principles by omitting well known exposure routes such as water consumption by all occupationally and non-occupationally-exposed humans as well as similar exposures to other biological receptors.”<sup>6</sup>

The SACC review of the 1-BP draft risk evaluation similarly took EPA to task for failing to consider air emissions and other environmental releases:<sup>7</sup>

“The lack of consideration for general population exposures excludes a vast extent of the US population (workers, consumers, school children, and other populations) who are exposed to 1-BP, perhaps on a daily basis. The lack of consideration of the general population exposure is concerning given the strong evidence of widespread exposure to a chemical that may be 1-BP based (from biomonitoring data).”

For CTC, like several other chemicals EPA is evaluating, the exclusion of environmental release pathways is not merely a theoretical concern. There is considerable evidence of CTC’s ubiquitous presence in air, soil and drinking water at levels that likely harm human health and contribute to ozone depletion and climate change.

## **B. Air Emissions of CTC Are Substantial and Are Harmful to the Ozone Layer, Global Climate, and Human Health**

CTC is highly volatile at ambient temperatures and degrades very slowly in the atmosphere, resulting in long-term accumulation in the environment. CTC is broken down by chemical reactions in air, but so slowly that its estimated atmospheric lifetime is between 30 and 100 years, with 50 years generally regarded as the probable value.<sup>8</sup> Ultimately, CTC slowly migrates upward into the stratosphere where it is photodegraded to form the trichloromethyl radical and chlorine atoms.<sup>9</sup>

CTC’s long residence time in the atmosphere has consequences for ozone depletion, climate change, and human health that are ignored in the EPA risk evaluation.

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<sup>5</sup> Id.

<sup>6</sup> Id.

<sup>7</sup> SACC 1-BP Report at 17.

<sup>8</sup> Agency for Toxic Substances and Disease Registry, *Toxicological Profile For Carbon Tetrachloride*, August 2005, <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/carbontetrachloride.pdf>, (ToxProfile), at 185.

<sup>9</sup> <https://www.atsdr.cdc.gov/toxprofiles/tp30.pdf>, at 185

**Ozone Depletion.** CTC is a significant contributor to ozone depletion, accounting for about 12% of the globally averaged chlorine and bromine in the stratosphere, compared to 14% for CFC-12 in 2012.<sup>10</sup> CTC has an ozone depletion potential (ODP) of 0.82, which makes it nearly as potent as several of the CFCs.<sup>11</sup> Thus, along with CFCs and certain other chemicals, CTC is listed as a Class I Ozone Depleting Substance (ODS) under the 1987 Montreal Protocol (MP) and is subject to the stratospheric ozone protection provisions of Title VI of the Clean Air Act (CAA).<sup>12</sup>

Controls under the MP and CAA regulated many emissive uses of CTC during the 1990s. However, “in spite of the MP controls, “there are large ongoing emissions of [CTC] into the atmosphere.”<sup>13</sup> According to SPARC, “atmospheric levels of [CTC] are currently declining at a rate slightly faster than 1% per year,” 2-3 times slower than would be expected in the absence of significant emissions.<sup>14</sup>

Concern about continuing high levels of CTC in the atmosphere has prompted an international effort by leading experts to better understand the magnitude and sources of global emissions.<sup>15</sup> The EPA draft risk evaluation reports that, according to TRI data, US air emissions for reporting facilities totaled over 176,000 pounds in 2018.<sup>16</sup> However, the 2016 *SPARC Report on the Mystery of Carbon Tetrachloride* by the WMO/ICSU/IOC World Climate Research Programme concludes that the scale of emissions of CTC is several orders of magnitude higher than the TRI data suggest.

The SPARC report summarizes the result of a scientific workshop convened to better understand the large discrepancy between “top down” estimates of global emissions based on atmospheric measurements and “bottom up” emissions data based on country-by-country reports to the United Nations Environment Program (UNEP).<sup>17</sup> As explained in the report:<sup>18</sup>

“Estimates of emissions from various techniques ought to yield similar numbers. However, the recent WMO/UNEP Scientific Assessment of Ozone Depletion [WMO, 2014] estimated a 2007-2012 CCl<sub>4</sub> bottom-up emission of 1-4 Gg/year (1-4 kilotonnes/year), based on country-by-country reports to UNEP, and a global top-down emissions estimate of 57 Gg/year, based on atmospheric measurements.”

Seeking to understand and narrow this huge gap, the SPARC report found that, because the atmospheric lifetime of CTC was longer than previously calculated, top down emission estimates were modestly

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<sup>10</sup> SPARC (2016) [SPARC Report on the Mystery of Carbon tetrachloride](#). Q. Liang, P.A. Newman, and S. Reimann (Eds.), SPARC Report No. 7, WCRP-13/2016.

<sup>11</sup> U.S. Environmental Protection Agency, Ozone Layer Protection: Ozone-Depleting Substances. <https://www.epa.gov/ozone-layer-protection/ozone-depleting-substances>.

<sup>12</sup> Id.

<sup>13</sup> SPARC Report at xi.

<sup>14</sup> Id. at 30.

<sup>15</sup> The 2014 WMO UNEP Scientific Assessment of Ozone Depletion -- Assessment for Decision-Makers states that: “Over the past decade, the (top-down) emissions of CCl<sub>4</sub> estimated from the observed atmospheric abundances and the estimated lifetime are much larger than the (bottom-up) emissions derived from reported production and usage (see Figure ADM 2-1). New evidence indicates that poorly quantified sources, distinct from reported production, could contribute to the currently unaccounted emissions.”

[https://www.esrl.noaa.gov/csd/assessments/ozone/2014/assessment\\_for\\_decision-makers.pdf](https://www.esrl.noaa.gov/csd/assessments/ozone/2014/assessment_for_decision-makers.pdf), at 15.

<sup>16</sup> CTC Evaluation, at 238.

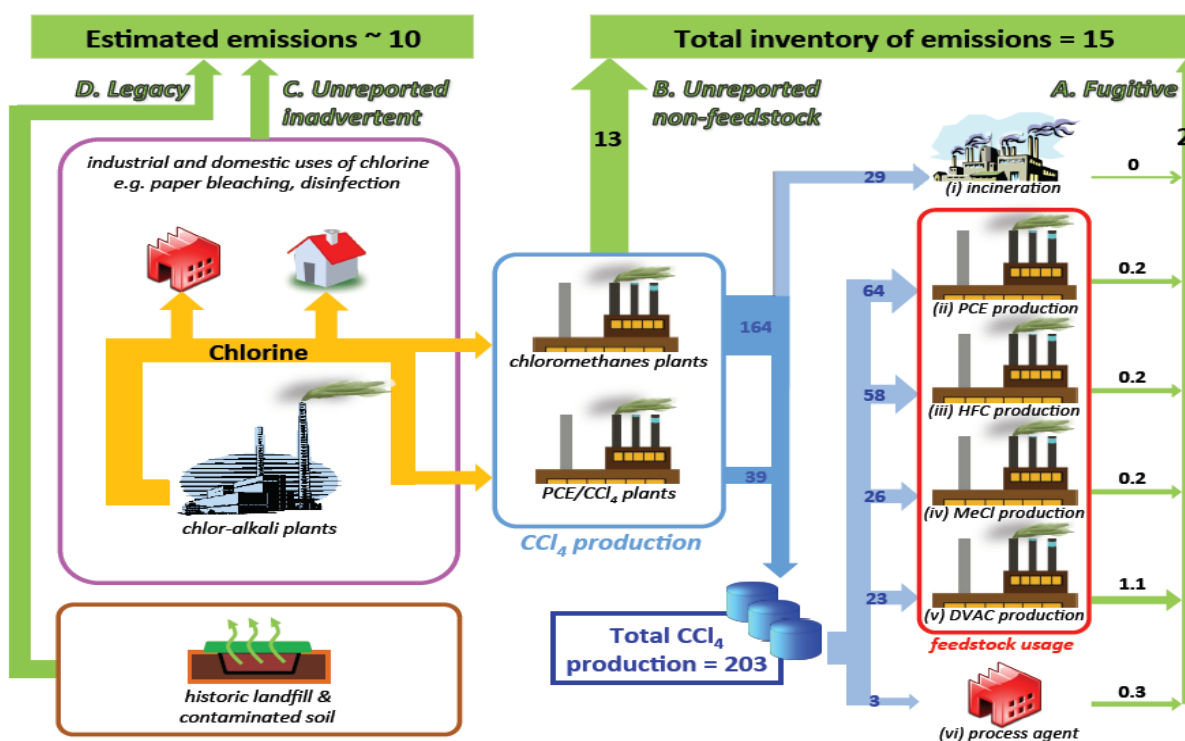
<sup>17</sup> Note 9.

<sup>18</sup> SPARC Report, at xi.

overstated. At the same time, it concluded that industry emission reports did not account for substantial emission sources and bottom up emissions were substantially understated.<sup>19</sup>

The report recognized that industry was generally reporting fugitive emissions from incineration and use of CTC as a feedstock and process agent, with these emissions totaling 2 Gg/year globally. However, it found that sizeable non-feedstock emissions from the release of CTC during manufacture of chloromethanes and perchloroethylene (PCE) were not being reported and could account for releases of 13 Gg/year globally. It also found that “unreported inadvertent emissions of [CTC] into the atmosphere occur during the production of chlorine gas in chlor-alkali plants or industrial and domestic use of chlorine, e.g., paper bleaching or disinfection.”<sup>20</sup> As the report explained, “this is due to the relative ease with which hydrocarbons are chlorinated; thus, [CTC] may be formed in many chlorination procedures and released into the environment, atmosphere, or surface water.”<sup>21</sup> Finally, the report concluded that “[l]egacy emissions (i.e., emissions from old industrial sites and landfills) also can be important” and, together with chlorine-related emissions, likely total 10 Gg/year globally.<sup>22</sup>

The report illustrated the breakdown of CTC global emission sources as follows:<sup>23</sup>



**Figure 12:** Schematic of CCl<sub>4</sub> routes from pre-CCl<sub>4</sub> production of chlorine gas in chlor-alkali plants (left), and production (middle), usage (right), and emissions of CCl<sub>4</sub> (top) (in Gg). Production and use of

<sup>19</sup> Id. at xii.

<sup>20</sup> Id. at 21-22.

<sup>21</sup> Id.

<sup>22</sup> Id.

<sup>23</sup> Id. at 22.

chlorine gas are shown in yellow arrows. The numbers are 2014 estimates for industry production (blue box and arrows) and use (greyish blue arrows), and emissions of CCl<sub>4</sub> (green boxes and arrows)

Overall, the SPARC report estimated total CTC emissions of 20±5 Gg/year, narrowing but not eliminating the gap with top down emission estimates.

Although focusing on global emissions, the report provided a breakdown of CTC emissions by region.<sup>24</sup> (p.30). For North America, this estimate was **4 Gg/year**, which represents nearly **9 million pounds released into the atmosphere**.<sup>25</sup> While an order-of-magnitude approximation, this number illustrates that TRI-reported air emissions (176,000 pounds in 2018) likely account for a small fraction of the CTC emitted from US sources and that actual emissions are far more consequential for the environment and human health than the draft risk evaluation acknowledges. This was the conclusion of an extensive 2016 analysis of CTC air sampling data:<sup>26</sup>

“The national average CCl<sub>4</sub> emission magnitude for 2008–2012 derived from this extensive air sampling network throughout the United States is 4.0 (2.0–6.5) Gg·y<sup>-1</sup>, or substantially larger than the average reported to the US EPA TRI over this same period (0.06 Gg·y<sup>-1</sup>). **The TRI reported emissions can only explain 0.1% of the magnitudes of monthly median enhancements observed in the lower atmosphere (0–500 m agl) for the period of 2008–2012**, and simulated enhancements with the derived emissions account for 90–110% of the observed monthly median enhancements (Fig. 2 and *SI Text*). **These results strongly suggest that some combination of underreported emissions and nonreporting sources currently account for the majority of US CCl<sub>4</sub> emissions.**

The draft risk evaluation cites TRI-reported emission data but nowhere indicates that they dramatically underestimate actual CTC emissions.

Significantly, CTC production in the US is increasing due to growing demand for CTC as a feedstock in the manufacture of hydrofluoroolefin (HFO) refrigerants, marketed as a replacement for hydrofluorocarbons (HFCs) that are being phased out because of global warming concerns.<sup>27</sup> HFCs contain no chlorine and use of CTC in their manufacture has been limited. However, CTC is used to manufacture HFO-1234yf, used for automotive air conditioning to replace HFC-134, and HFO-1234ze, used as a blowing agent for polyurethane, polystyrene and other polymers and as an aerosol propellant

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<sup>24</sup> SPARC Report, at 30.

<sup>25</sup> For equivalent units, a Gigagram (Gg) equals 1 million kilograms or 2.2 million pounds.

<sup>26</sup> Hu, Lei et al, *Continued emissions of carbon tetrachloride from the United States nearly two decades after its phaseout for dispersive uses*, Proc Natl Acad Sci U S A. 2016, found at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4801316/> (emphasis added)

<sup>27</sup> According to CDR reports described in the EPA risk evaluation, US production of CTC increased from 116,658,281 pounds in 2013 to 142,582,067 pounds in 2015. CTC Evaluation at 26. Production data for the last four years are not available but it's noteworthy that Chemours, a major HFO supplier that is investing in increased production capacity, imported 1,042,000 kilograms (2.3 million pounds) of CTC in January 2017. Comments to the U.S. Environmental Protection Agency (EPA) on the Scope of its Risk Evaluation for Carbon Tetrachloride, March 15, 2017, by Safer Chemicals, Healthy Families, Environmental Health Strategy Center and Healthy Building Network 9SCHF Comments), at 12. While greatly understating emissions, TRI reports show that air releases of CTC increased markedly between 2013 and 2018, corresponding to the increase in production. For example, 2018 releases were 176,065 pounds while 2015 releases were 104,838 pounds.

to replace HFC-134a and HFC-152a.<sup>28</sup> With increasing production and use of CTC, rising emissions are likely, adding to the substantial emissions now occurring,

The draft evaluation fails to acknowledge that, despite the expectation that MP and CAA restrictions would drastically reduce CTC emissions, significant emission sources remain unregulated, slowing the decline in atmospheric levels and posing an ongoing threat to the ozone layer and a risk of skin cancer to people exposed to stratospheric ozone. An evaluation that fully accounts for CTC's impacts on health and the environment should highlight this threat and the emission trends underlying it so there is a basis under TSCA or other laws to control significant but currently unrecognized and unregulated emissions of a major contributor to ozone depletion.

**Climate Change.** CTC also has a significant global warming potential (GWP), which makes it 1,730 times more potent than carbon dioxide.<sup>29</sup> Assuming US emissions of CTC are nearly 9 million pounds per year as estimated by SPARC, CO<sub>2</sub> equivalent emissions would be 6.9 million metric tons. This amount is higher than the CO<sub>2</sub> emissions of most coal-fired power plants and equals the annual CO<sub>2</sub> emissions from over 1.5 million cars.<sup>30</sup> The well-known consequences of global warming include far-reaching impacts on human health and the environment that should be addressed in a comprehensive risk evaluation. Yet there is no mention of CTC's GWP in the draft evaluation, let alone any analysis of the significance of its emissions in contributing to climate change.

**Health Effects.** The large air emissions of CTC also raise health concerns for the general population and subpopulations living near emission sources.

ATSDR describes CTC as "ubiquitous in ambient air" and reports that:<sup>31</sup>

"Based on analysis of 4,913 ambient air samples reported in the National Ambient Volatile Organic Compounds Database (including remote, rural, suburban, urban, and source dominated sites in the United States), the average concentration of carbon tetrachloride was 0.168 ppb (1.1 µg/m<sup>3</sup>) (Shah and Heyerdahl 1988)."

ATSDR cites a variety of monitoring studies demonstrating similar or higher air concentrations at numerous locations across the US. It estimates that daily intake from air ranges from 12 to 511 µg/, based on average ambient concentrations of 0.1– 4 ppb (0.64–25.6 µg/m<sup>3</sup>). It calculates that, based on the typical CTC concentration in ambient air of about 1 µg/m<sup>3</sup> and assuming inhalation of 20 m<sup>3</sup> of air per day by a 70-kg adult and 40% absorption of CTC across the lung, daily inhalation exposure is 0.1 µg/kg of body weight.<sup>32</sup>

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<sup>28</sup> SCHF Comments at 5.

<sup>29</sup> EPA, Ozone Depleting Substances, <https://www.epa.gov/ozone-layer-protection/ozone-depleting-substances>

<sup>30</sup> According to EPA, a typical passenger vehicle emits about 4.6 metric tons of carbon dioxide per year. <https://www.epa.gov/greenvehicles/greenhouse-gas-emissions-typical-passenger-vehicle>

<sup>31</sup> ToxProfile, at 187.

<sup>32</sup> Id., at 187-88.

EPA's 2010 IRIS assessment for CTC determines that it poses an inhalation cancer risk of 1-in-a-million at ambient air levels of 0.17 µg/m<sup>3</sup>.<sup>33</sup> Since large segments of the general population are exposed to higher concentrations of CTC, **the cancer risk to most Americans from airborne CTC is above this level.**

EPA's 2014 National Air Toxics Assessment (NATA), released in 2018, reached a similar conclusion.<sup>34</sup> The NATA estimates cancer risks to the general population from exposure to 180 Hazardous Air Pollutants (HAPs) identified in the CAA, including CTC. These risk estimates are based on the 2014 National Emissions Inventory (NEI), which compiles comprehensive emission data on the HAPs from sources across the country. EPA used the NEI to estimate ambient concentrations of air toxics across the United States and determine population exposures at a county, state and national level. The Agency then estimated cancer risk by applying available toxicological and human data and related dose-response curves to determine a URE, representing the upper-bound lifetime cancer risk from continuous exposure to the pollutant at a concentration of 1 µg/m<sup>3</sup>.

For CTC, EPA estimated a **cancer risk of 3.18 in a million** at the national level and similar cancer risks for nearly all of the many individual tracts it assessed across the country. The only chemical with a higher estimated cancer risk was formaldehyde. The cancer risk for CTC was greater than for numerous other recognized carcinogens, such as 1,3-butadiene, benzene, ethylene oxide, and vinyl chloride. In fact, given the significant underestimation of CTC emissions described above, it is likely that the actual cancer risk from CTC exposure exceeds the NATA estimate.

As described in EPA's draft evaluation, the Agency uses a 1-in-a-million lifetime risk level as its benchmark for determining cancer risks of significant concern for the general population.<sup>35</sup> Both the 2010 IRIS assessment and the 2014 NATA show that the risk to most American from ambient air exposure to CTC exceeds this benchmark. Yet EPA's risk evaluation ignores this evidence of excess cancer risk to the general population based on its exclusion of all air emissions from the evaluation's scope. EPA also fails to consider the impacts of these background CTC concentrations on the workers and occupational non-users studied in the risk evaluation, and thus understates the risks to this population from aggregate exposure to CTC.

### **C. Drinking Water Exposure to CTC Is Significant and Occurs at Levels of Health Concern**

CTC is a recognized drinking water contaminant. EPA set a National Primary Drinking Water Regulation (NPDWR) for CTC in 1987, establishing a maximum contaminant level goal (MCLG) of zero and an enforceable maximum contaminant level (MCL) of 5 ug/L (5 ppb).<sup>36</sup> The MCL was based on the limit of detection for CTC in drinking water at the time; subsequently developed analytical methods can detect CTC at lower concentrations. Some states recognize that the MCL should be much more health protective. For example, in 2000, California's Office of Environmental Health Hazard Assessment (OEHHA) set a public health goal (PHG) of 0.1 ug/L (or 0.1 ppb) for CTC in drinking water.<sup>37</sup> In addition,

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<sup>33</sup> EPA Integrated Risk Information System (IRIS), *Chemical Assessment Summary for Carbon Tetrachloride*, 2010, [https://cfpub.epa.gov/ncea/iris/iris\\_documents/documents/subst/0020\\_summary.pdf](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0020_summary.pdf), (IRIS Summary) at 25.

<sup>34</sup> National Air Toxics Assessment, *2014 NATA: Assessment Results*, <https://www.epa.gov/national-air-toxics-assessment/2014-nata-assessment-result>

<sup>35</sup> CTC Evaluation, at 174.

<sup>36</sup> 52 Federal Register 25690 (July 8, 1987).

<sup>37</sup> Office of Environmental Health Hazard Assessment, *Public Health Goal for Carbon Tetrachloride*, September 2000, at [https://oehha.ca.gov/media/downloads/water/chemicals/phg/carbtet\\_0.pdf](https://oehha.ca.gov/media/downloads/water/chemicals/phg/carbtet_0.pdf).



the 2010 IRIS assessment for CTC determines that drinking water exposures over a lifetime to only 0.5 ug/L – a tenth of the MCL – pose a cancer risk of 1 in a million.<sup>38</sup>

Because it is subject to an MCL, EPA requires periodic monitoring of drinking water for the presence of CTC. The CTC Problem Formulation describes the results of this monitoring as follows:<sup>39</sup>

“SDWA requires EPA to review each national primary drinking water regulation at least once every six years and revise as necessary. As part of the “Six-Year Review (SYR), EPA evaluates any newly available data, information and technologies to determine if any regulatory revisions are needed. Internal analysis for SYR3 (2006-2011) data, not yet published, show that 118 systems of 55,735 systems (0.212%) have mean concentrations greater than the Minimum Reporting Level (MRL) of 0.5 µg/L. SYR 2 (1998-2005) data showed 650 systems or 1.289% of 50,446 systems had detects greater than 0.5 µg/L. Of those, over 75% of the detections were in groundwater (versus surface water systems). In addition, only 57 (0.113%) systems had detects of carbon tetrachloride greater than the Maximum Contaminant Level (MCL) of 5 µg/L.”

In short, extensive monitoring required by EPA showed exceedances of the EPA MCL and also demonstrated widespread contamination at levels that, according to the IRIS assessment, pose a cancer risk of more than 1 in one million and exceed the California PHG. In separate monitoring of public water systems, the United States Geological Service (USGS) likewise detected CTC in source water and finished water at levels above the PHG.<sup>40</sup>

The 2019 Update of the Environmental Working Group (EWG) Tap Water Database reports that CTC has been detected in the drinking water of 256 water suppliers in 34 states, serving a total population of 3.1 million people. EWG further found that 167 drinking water utilities serving 1.1 million people had CTC concentrations above the California PHG.<sup>41</sup>

Citing several studies, ATSDR concludes that “about 99% of all groundwater supplies and about 95% of all surface water supplies contain <0.5 µg/L of carbon tetrachloride.” It notes that some studies show drinking water concentrations well above the MCL (i.e. at 16 ug/L and 29 ug/L) and that “based on an analysis of data from the STORET database, carbon tetrachloride was detectable in 12% of 8,858 ambient water samples”, with a median concentration in all samples of 0.1 µg/L.<sup>42</sup>

ATSDR concludes that “[i]ngestion via contaminated drinking water is an important route of exposure for the general population not living in areas where carbon tetrachloride is extensively used” and that the general population may also inhale CTC “from volatilization of contaminated water during showering or bathing.”<sup>43</sup> Indeed, the EPA Problem Formulation itself notes that “inhalation of carbon tetrachloride, due to its volatilization, during household use of contaminated water (e.g., during bathing/showering, dishwashing) could be a source of exposure to the general population” and references a study from the

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<sup>38</sup> IRIS Summary at 21.

<sup>39</sup> EPA, *Problem Formulation of the Risk Evaluation for Carbon Tetrachloride*, May 2018, [https://www.epa.gov/sites/production/files/2018-06/documents/ccl4\\_problem\\_formulation\\_05-31-18.pdf](https://www.epa.gov/sites/production/files/2018-06/documents/ccl4_problem_formulation_05-31-18.pdf). (Problem Formulation) at 35.

<sup>40</sup> USGS, *Anthropogenic Organic Compounds in Ground Water and Finished Water of Community Water Systems near Dayton, Ohio, 2002–04, 2007*, at [https://pubs.usgs.gov/sir/2007/5035/pdf/sir2007-5035\\_web.pdf](https://pubs.usgs.gov/sir/2007/5035/pdf/sir2007-5035_web.pdf).

<sup>41</sup> <https://www.ewg.org/tapwater/contaminant.php?contamcode=2982>.

<sup>42</sup> ToxProfile, at 189.

<sup>43</sup> Id. at 13.

New Jersey Department of Environmental Protection that finds that the “acceptable shower water criteria for carbon tetrachloride is 0.15 ug/L and the associated shower air concentration of carbon tetrachloride would be acceptable at 1.5 x 10-5ug/m3.”<sup>44</sup> The risk evaluation makes no effort to assess whether these “acceptable” concentrations are being exceeded in homes with CTC-contaminated drinking water, but the Agency’s own drinking water data indicates that such exceedances are in fact occurring.

Although EPA claims that evaluation of drinking water risks under TSCA is unnecessary because the Safe Drinking Water Act (SDWA) is adequately protecting consumers, the CTC MCL is now over 30 years out-of-date, does not take into account health effects data on which EPA now relies in its TSCA draft evaluation and was based on an assumed limit of detection that no longer reflects available analytic methods. Moreover, while required to review drinking water standards every six years, EPA has declined to modify the CTC MCL because IRIS and other assessments are underway.<sup>45</sup> Yet even though the IRIS assessment was completed in 2010, the EPA drinking water program has not conducted an assessment of cancer and non-cancer risk from CTC-contaminated drinking water based on current science and has no plans to do so despite extensive evidence that CTC levels in drinking water exceed EPA’s threshold for acceptable cancer risk. Thus, EPA’s exclusion of drinking water from its TSCA evaluation creates a serious and unjustified gap in health protection that SACC should urge EPA to address.

#### **D. CTC’s Presence at Inactive and Active Waste Sites Is A Significant Source of Exposure**

As noted above, old industrial sites and landfills are believed to be a significant source of CTC air emissions. The EPA Problem Formulation notes that the “volatility of carbon tetrachloride makes inhalation exposures a likely exposure pathway when it is released . . . as a result of waste disposal.”<sup>46</sup>

According to ATSDR, it “is likely that trace levels of carbon tetrachloride are present in surface soils around the globe.”<sup>47</sup> ATSDR indicates that “[c]arbon tetrachloride was detected in soil at 103 NPL [National Priority List] hazardous waste sites, and in sediment at 23 NPL hazardous waste sites.” It further reports that “based on information from the STORET database, carbon tetrachloride was detected in 0.8% of sediment samples across the United States.”<sup>48</sup> Soil and sediment contamination at waste sites is also contaminating groundwater and surface water. ATSDR indicates that CTC has been detected in groundwater at 310 NPL hazardous waste sites and in surface water at 53 NPL sites.<sup>49</sup>

CTC is also managed at numerous active disposal facilities, on-site and off-site. According to 2017 TRI data,<sup>50</sup> total CTC production-related waste totaled 36,838,580 pounds, of which 26,838,850 underwent treatment. Numerous off-site landfills and other waste-treatment operations reported environmental releases, which accounted for 34 percent of total CTC releases. The second highest releases, mainly to

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<sup>44</sup> Problem Formulation, at 37-38.

<sup>45</sup> It appears that the last six-year review was completed in 2003. At that time, a decision whether to revise the CTC MCL was deferred because CTC was “currently undergoing an EPA health risk assessment.”

<https://www.epa.gov/dwsixyearreview/six-year-review-1-drinking-water-standards#frn>.

<sup>46</sup> Problem Formulation at 37.

<sup>47</sup> Toxprofile at 189.

<sup>48</sup> Id 189-90.

<sup>49</sup> Id at 189.

<sup>50</sup> TRI Carbon Tetrachloride Fact Sheet for 2017,

<https://enviro.epa.gov/triexplorer/chemical.html?pLoc=000056235&pYear=2017&pParent=TRI&pDataSet=TRIQ2&pPrint=1>

air, were reported by Chemtron, a large hazardous waste disposal and treatment concern. Thus, active as well as historical disposal sites are responsible for environmental releases of CTC.

As the CTC Problem Formulation notes, due to evaporation of CTC from contaminated soil and groundwater, “[v]apor intrusion is an additional source of exposure in indoor environments. . . there is a potential for carbon tetrachloride from TSCA conditions of use (see Table 2-7) to migrate from groundwater to indoor air via vapor intrusion.”<sup>51</sup> Vapor intrusion may provide a partial explanation for the widespread detection of CTC in indoor air. As ATSDR notes, “[s]tudies have revealed that carbon tetrachloride is also a common contaminant of indoor air. Typical concentrations in homes in several U.S. cities were about 1 µg/m<sup>3</sup> (0.16 ppb), with some values up to 9 µg/m<sup>3</sup> (1.4 ppb).”<sup>52</sup> For the general population, indoor air exposure would be additive to exposure via ambient air, drinking water and contaminated soil.

In sum, CTC emissions from manufacturing and processing and legacy disposal sites are far larger than EPA has recognized and pose a significant threat to the ozone layer and global climate. There is also extensive evidence of pervasive general population exposure to CTC from releases to air, water and soil and this exposure is at levels in ambient air and drinking water that present significant cancer risks. These risks are not being effectively reduced under other environmental laws despite EPA’s insistence that such laws eliminate the need to address them under TSCA. The absence of any consideration of environmental releases and general population exposure is a major and unjustified gap in the draft CTC risk evaluation.

## **II. EPA Unjustifiably Excludes Consumer Product Exposures from the Scope of Its Evaluation**

As EPA states, “there are no consumer uses of carbon tetrachloride within the scope of the risk evaluation.”<sup>53</sup> To justify this exclusion, EPA indicates that “direct use of carbon tetrachloride as a reactant or additive in the formulation” of consumer products is prohibited under the MP and Consumer Product Safety Commission (CPSC) regulations.<sup>54</sup> However, the Agency recognizes that CTC is used as a reactant or processing aid in the manufacture of many chemical products that do have consumer uses and may contain residual amounts of CTC to which consumers may be exposed. There is no prohibition on the presence of such residual CTC in consumer products. For example, the CPSC regulations banning intentional use of CTC as a consumer product ingredient allow “unavoidable manufacturing residues of carbon tetrachloride in other chemicals that under reasonably foreseen conditions of use do not result in an atmospheric concentration of carbon tetrachloride greater than 10 parts per million.” 16 CFR 1500.17(a)(2). Nonetheless, EPA maintains that this residual CTC is only “present in consumer products at trace levels resulting in de minimis exposures or otherwise insignificant risks and therefore that consumer uses do not warrant inclusion in the risk evaluation.”<sup>55</sup>

EPA cites no data on CTC levels in consumer products and provides no analysis demonstrating that such residual CTC is without any potential for harm. However, since CTC causes acute and chronic central nervous system (CNS) effects at low doses and extremely small concentrations in ambient air and

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<sup>51</sup> Problem Formulation at 38.

<sup>52</sup> ToxProfile at 188.

<sup>53</sup> CTC evaluation, at 94.

<sup>54</sup> Id at 30.

<sup>55</sup> Id at 94.

drinking water present significant cancer risks according to EPA, it is not implausible that exposures from consumer products are a pathway of concern, particularly in combination with other sources of general population exposure, and for vulnerable populations of reproductive age. EPA’s decision not to evaluate these exposure scenarios was thus arbitrary and unwarranted.

In fact, there is evidence that product-related consumer exposure to CTC may be a significant risk pathway. It is known that sodium hypochlorite (NaOCl) and many organic chemicals contained in household cleaning products may react during use to generate halogenated volatile organic compounds (VOCs), including CTC. Thus, the SPARC report lists use of hypochlorite as bleach in domestic applications as a CTC emissions source.<sup>56</sup> A 2008 study measured VOC emissions from eight different chlorine bleach-containing household products (pure and diluted) before, during, and 30 min after bathroom, kitchen, and floor cleaning applications.<sup>57</sup> The highest emissions were of chloroform and CTC. Concentrations of CTC were 0.25–459 µg m<sup>-3</sup>, clearly levels of health concern.

In a search of retail websites, SCHF identified five consumer sealant products with Safety Data Sheets (SDSs) indicating the presence of CTC at levels of up to 1 percent by weight.<sup>58</sup> Given the low ambient concentrations of CTC linked to cancer and other adverse effects, there is no basis to assume that CTC releases from these products would be without concern, particularly when combined with outdoor air and drinking water exposures by consumers who also use the products.

In a 2017 preliminary survey of CTC’s conditions of use, EPA identified a similar set of CTC-containing products available to consumers:<sup>59</sup>

**Table 2. Products Containing Carbon Tetrachloride Available for Purchase Online**

Product	Description and price	References
Saf-T-Solv	Solvent Carpet Spot Remover (1 quart for \$13.35)	<a href="http://www.baneclene.com/catalog/sts.html">http://www.baneclene.com/catalog/sts.html</a>
Devcon 14385 Straw Plastic Welder Adhesive	Plastic Welder Adhesive 400 mL (pack of 12) \$616.71	<a href="https://www.amazon.com/Devcon-Plastic-Welder-Adhesive-Cartridge/dp/B005YSSFBO#feature-bullets-btf">https://www.amazon.com/Devcon-Plastic-Welder-Adhesive-Cartridge/dp/B005YSSFBO#feature-bullets-btf</a>
Loctite Epoxy Plastic bonder	Adhesive for plastics bonding (.85 oz. for \$7.29, \$7.88)  Note: Is unclear whether the new or old formulas are for sale	<a href="https://www.amazon.com/Loctite-Plastic-0-85-Fluid-Syringe-1363118/dp/B0044FBB8C">https://www.amazon.com/Loctite-Plastic-0-85-Fluid-Syringe-1363118/dp/B0044FBB8C</a>  <a href="https://www.menards.com/main/home-decor/craft-supplies/glue/epoxy-glue/loctite-20-min-plastic-bonder-epoxy-0-85-oz/p-1444432303984.htm">https://www.menards.com/main/home-decor/craft-supplies/glue/epoxy-glue/loctite-20-min-plastic-bonder-epoxy-0-85-oz/p-1444432303984.htm</a>

<sup>56</sup> SPARC Report, at 21.

<sup>57</sup> Odabaşı, M. (2008), *Halogenated volatile organic compounds from the use of chlorine-bleach-containing household products*, Environmental Science & Technology, 42 5, 1445-51.

<sup>58</sup> SCHF Comments, *Consumer Appendix: Consumer Products Containing Carbon Tetrachloride* (attached). Since they were described in comments on the CTC Scoping Document, EPA should be aware of these products, but neither they nor the consumer products earlier identified by EPA itself are discussed in the draft risk evaluation.

<sup>59</sup> EPA, *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Carbon Tetrachloride*, February 2017 at 12, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0733-0003>

RAMUC PRO 2000 Chlorinated Rubber Pool Paint	Rubber Pool Paint (1 gallon for \$84.95, \$196.00)  Note: Only listed as an impurity	<a href="https://www.google.com/webhp?sourceid=chrome-instant&amp;ion=1&amp;espv=2&amp;ie=UTF-8#q=RAMUC+PRO+2000+Chlorinated+Rubber+Pool+Paint">https://www.google.com/webhp?sourceid=chrome-instant&amp;ion=1&amp;espv=2&amp;ie=UTF-8#q=RAMUC+PRO+2000+Chlorinated+Rubber+Pool+Paint</a> <a href="https://www.walmart.com/ip/Pro-2000-Chlorinated-Rubber-Pool-Coating-Dawn-Blue-5-Gallon-Pail-per-Pail/160687567?wmlspartner=wlp&amp;selectedSellerId=1293&amp;adid=2222222227000000000&amp;wl0=&amp;wl1=g&amp;wl2=c&amp;wl3=42423897272&amp;wl4=pla-51320962143&amp;wl5=9061285&amp;wl6=&amp;wl7=&amp;wl8=&amp;wl9=pla&amp;wl10=113137480&amp;wl11=online&amp;wl12=160687567&amp;wl13=&amp;veh=sem">https://www.walmart.com/ip/Pro-2000-Chlorinated-Rubber-Pool-Coating-Dawn-Blue-5-Gallon-Pail-per-Pail/160687567?wmlspartner=wlp&amp;selectedSellerId=1293&amp;adid=2222222227000000000&amp;wl0=&amp;wl1=g&amp;wl2=c&amp;wl3=42423897272&amp;wl4=pla-51320962143&amp;wl5=9061285&amp;wl6=&amp;wl7=&amp;wl8=&amp;wl9=pla&amp;wl10=113137480&amp;wl11=online&amp;wl12=160687567&amp;wl13=&amp;veh=sem</a>
MOTO-SEAL 1 ULTIMATE GASKET MAKER GREY 80 ML	Sealant (2.7 oz. tube for \$4.61, \$8.74)	<a href="http://www.autopartsandstuff.com/permatex-ptx-29132-motoseal1ultimategasketmakergrey27oztube.aspx?gclid=COBvka_mbl9ECFY5WDQodUXkMHA">http://www.autopartsandstuff.com/permatex-ptx-29132-motoseal1ultimategasketmakergrey27oztube.aspx?gclid=COBvka_mbl9ECFY5WDQodUXkMHA</a> <a href="http://www.ebay.com/itm/like/172439663876?lpid=82&amp;chn=ps&amp;ul_noapp=true">http://www.ebay.com/itm/like/172439663876?lpid=82&amp;chn=ps&amp;ul_noapp=true</a>

There is no discussion of these products in the draft risk evaluation and thus no explanation of why the CTC levels they contain would be too low to pose any health concern.

The presence of CTC in indoor air as described above is further evidence of the contribution of consumer products to CTC exposure. As ATSDR comments, “[c]oncentrations in indoor air were usually higher than in outdoor air, indicating that the source of the carbon tetrachloride was building materials or products (pesticides, cleaning agents) inside the home.”<sup>60</sup>

In sum, EPA’s unsupported exclusion of all consumer product exposure to CTC is another serious gap in its draft evaluation that results in a significant understatement of its human health impacts.

### III. EPA Has Identified but Failed to Consider Three New Epidemiological Studies that Demonstrate that CTC Causes Brain Tumors in Children and Adults

The 2010 IRIS assessment concluded that, while there was extensive evidence of CTC’s carcinogenicity in animal studies, available human epidemiological data was inconclusive. However, several additional human studies have subsequently become available. The draft evaluation identifies 11 post-IRIS human studies “that have been found to be of acceptable data quality.”<sup>61</sup> It then indicates that:

“four of these newer studies report results for cancers of the nervous system – as did one study from the IRIS assessment (Heineman et al., 1994). Three of these were specific to astrocytic brain tumors which include astrocytoma, glioma, and glioblastoma and occur in adults. The fourth was a study of neuroblastoma – a childhood cancer of the nervous system.”

<sup>60</sup> ToxProfile at 189.

<sup>61</sup> CTC Evaluation at 116-117.

Our evaluation of these studies confirms EPA’s judgment that the studies were high/medium in quality. The results of three of the studies are significant in several respects: the exposure metrics were well done and generally reliable; the odds ratios (OR) were statistically significant and unusually high; a dose-response relationship was observed; and the measured adverse effect endpoints were medically confirmed. The form of cancer observed – brain tumors – is rare and extremely severe and the fact that this outcome was associated with CTC exposure in three separate studies increases confidence in the results. The elevated occurrence of neuroblastoma in children – a vulnerable population singled out for protection in TSCA – is of particular concern given that the cancer treatments during childhood can themselves contribute to an elevated cancer risk in adulthood.

EPA’s description of the studies is as follows:

**Table 3-8. Acceptable Epidemiological Studies for Cancer Toxicity of Carbon Tetrachloride Not evaluated in EPA IRIS Assessment**

Cancer Endpoint	Study Population	Exposure	Results	Reference	Data Quality Evaluation
Brain (Neuroblastoma)	Children (75 cases, 14602 controls), ages <6 years born in 1990-2007 in California within 5 km of exposure monitoring stations, cases from California Cancer Registry.	Carbon tetrachloride (0.105 ppbV) in ambient air, pollution monitoring stations used to estimate maternal exposure during pregnancy from birth certificate address.	Significant positive association between risk of neuroblastomas per interquartile increase in carbon tetrachloride exposure (OR=2.55; 95% CI: 1.07, 6.53) within a 5 km radius and (OR=7.87; 95% CI: 1.37, 45.34) within a 2.5 km radius of monitors. Significant positive association for the highest quartile of carbon tetrachloride exposure compared to the lowest (OR=8.85; 95% CI: 1.19, 66.0).	( <a href="#">Heck et al., 2013</a> )	Medium
Brain (Glioblastoma)	8,006 men of Japanese descent from the Honolulu Heart Program (HHP) and Honolulu-Asia Aging Study (HAAS) cohorts, aged 45-68 at initial examination (1965-	Usual occupation with no, low-medium, or high exposure to carbon tetrachloride, based on professional judgement; no quantification of exposure available.	Rate ratio of exposed vs unexposed was 10.09 (p=0.012). A positive, statistically significant association was found between glioblastoma and high occupational exposure vs. no exposure to carbon tetrachloride (OR=26.59; 95% CI: 2.9, 243.50).	( <a href="#">Nelson et al., 2012</a> )	Medium

	1968) and followed through 1998. 9 glioblastoma cases.				
Brain (Glioma)	489 glioma cases, 197 meningioma cases, and 799 controls from three USA hospitals in Arizona, Massachusetts and Pennsylvania.	Occupational exposure to carbon tetrachloride via self-reported occupational history and industrial hygienist assigned level of exposure.	Carbon tetrachloride was associated with a significant increase in risk of gliomas with higher average weekly exposure (OR=7.1; 95% CI: 1.1, 45.2; p-value = 0.04) and when further controlling for lead and magnetic fields (OR=60.2; 95% CI: 2.4, 1533.8).	( <a href="#">Neta et al., 2012</a> )	High
Brain (Glioma)	Non-farm workers from the Upper Midwest Health Study (798 cases and 1141 controls from Iowa, Michigan, Minnesota, and Wisconsin 1995-1997).	Carbon tetrachloride use (self-reported occupational history through 1992, using a bibliographic database of published exposure). Of 798 glioma cases, 360 interviews were conducted with proxies because the cases were deceased.  <i>NOTE: this study had no quantitative exposure data</i>	Excluding proxy-only interviews: 'Ever' vs. 'never' having carbon tetrachloride exposure was not associated with a risk of glioma (OR=0.82; 95% CI: 0.64, 1.06) and cumulative exposure was associated with decreased risk of gliomas per ppm-year with borderline significance (OR=0.98; 95% CI: 0.96, 1.00).  Including proxy-only interviews: 'Ever' vs. 'never' having carbon tetrachloride exposure was significantly associated with a decreased risk of glioma (OR=0.79; 95% CI: 0.65, 0.97) and cumulative exposure was associated with a small but significant decrease in risk of gliomas per ppm-year (OR=0.98; 95% CI: 0.96, 0.99).	( <a href="#">Ruder et al., 2013</a> )	High

Despite reviewing and summarizing these studies, EPA does not mention them in its analysis of the weight of the scientific evidence for carcinogenicity, its determination of a cancer inhalation unit risk or its risk estimations for cancer effects. Instead, these portions of the draft evaluation are based entirely on rodent studies, consistent with the 2010 IRIS assessment. Given their high quality, significant results and consistency with each other, the three positive brain cancer studies above should be used in assessing CTC's cancer risks.<sup>62</sup> We urge SACC to recommend that EPA classify CTC as a known human carcinogen based on these studies and use them for quantitative cancer risk estimates along with the animal data on which EPA now relies for that purpose.

#### **IV. EPA Has Failed to Model Realistic Dermal Exposure Scenarios and to Combine Dermal and Inhalation Exposures to Determine a Composite Estimate of Risk**

CTC is a volatile liquid and dermal exposure is expected during manufacturing, processing, use and disposal. Accordingly, EPA developed exposure and risk estimates for dermal as well as inhalation routes of exposure. The basis for the dermal assessment was highly uncertain because of the limited data available. Without test data on dermal absorption rates, EPA assumed that "the calculated retained dose is low for all dermal exposure scenarios as carbon tetrachloride evaporates quickly after exposure."<sup>63</sup> Based on CTC volatilization rates and other physical-chemical properties, it estimated that "approximately four percent of the applied dose is absorbed through the skin" where no gloves are worn and considerably less in instances of glove use. EPA then assumed "one exposure event (applied dose) per workday" for workers and no exposure by Occupational Non-Users (who were believed to lack dermal contact with CTC). To determine Points of Departure (PODs) for estimating risks, EPA relied (pp 132-134) on a single flawed acute toxicity study (classified unacceptable in EPA's systematic review) for acute liver effects and extrapolated a Human Equivalent Dose (HED) for chronic effects and carcinogenicity from inhalation studies since no dermal data for these endpoints was available for CTC.<sup>64</sup>

Using this methodology, EPA estimated that dermal MOEs were above the benchmark MOE for acute and chronic dermal effects but that high end dermal exposures without gloves resulted in a cancer risk greater than EPA's benchmark of  $1 \times 10^{-4}$ .

As EPA itself acknowledged, several of the steps in this analysis were based on debatable assumptions that resulted in an underestimation of dermal exposure and risk. For example, rapid volatilization after skin contact would not occur in all situations:<sup>65</sup>

"dermal exposure may be significant in cases of occluded exposure, repeated contacts, or dermal immersion. For example, work activities with a high degree of splash potential may result in carbon tetrachloride liquids trapped inside the gloves, inhibiting the evaporation of carbon tetrachloride and increasing the exposure duration."

Similarly:<sup>66</sup>

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<sup>62</sup> The one study by Ruder et al that failed to identify a cancer risk should not be relied upon, as it lacked detailed information on exposures, and instead assumed that workplace levels were within the ranges reported in the literature, making it too limited to support a no-risk finding.

<sup>63</sup> CTC Evaluation at 92.

<sup>64</sup> Id. at 132-134.

<sup>65</sup> Id at 91.

<sup>66</sup> Id at 92



“Due to increased area of contact and reduced skin barrier properties, repeated skin contact with chemicals could have even higher than expected exposure if evaporation of the chemical occurs and the concentration of chemical in contact with the skin increases. In the workplace the wearing of gloves could have important consequences for dermal uptake. If the worker is handling a chemical without any gloves, a splash of the liquid or immersion of the hand in the chemical may overwhelm the skin contamination layer so that the liquid chemical essentially comprises the skin contamination layer. If the material is undiluted, then uptake could proceed rapidly as there will be a large concentration difference between the skin contamination layer and the peripheral blood supply.”

However, EPA did not develop alternate estimates of dermal exposure showing higher levels of absorption in these scenarios.

EPA also admitted that its dermal “model assumes one exposure event per day, which likely underestimates exposure as workers often come into repeat contact with the chemical throughout their work day.”<sup>67</sup> However, EPA did not model any repeat contact scenarios involving higher levels of dermal exposure.

Of greatest concern is EPA’s failure to aggregate dermal and inhalation exposure and derive composite risk estimates even though the draft risk evaluation indicates that “[i]nhalation and dermal exposures are assumed to occur simultaneously for workers.”<sup>68</sup> EPA’s rationale for failing to combine exposure routes is that:<sup>69</sup>

“carbon tetrachloride is a skin irritant and sensitizer, which suggests that workers are persuaded on their own (in addition to the workplace industrial hygiene program and OSHA regulations) to wear gloves when handling the chemical. Based on this assumption, the occurrence of aggregate exposures including dermal exposures without gloves is expected to be highly unlikely especially for chronic aggregate exposures.”

EPA does not provide any information on the severity of skin irritation for CTC but ATSDR indicates that “direct dermal contact with undiluted carbon tetrachloride causes a mild burning sensation with mild erythema.”<sup>70</sup> Moreover, EPA acknowledges that its “glove protection factors are based on . . . ‘what-if’ assumptions and are highly uncertain” and that it “does not know the actual frequency, type, and effectiveness of glove use in specific workplaces of the occupational exposure scenarios.”<sup>71</sup> Given these admissions, it is hard to understand how EPA can dismiss aggregate inhalation and dermal exposure as “highly unlikely.”

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<sup>67</sup> Id. at 168

<sup>68</sup> Id. at 20

<sup>69</sup> Id. At 171

<sup>70</sup> ToxProfile at 91.

<sup>71</sup> CTC Evaluation at 168

The SACC should recommend that EPA (1) model a broader range of dermal contact scenarios based on its own analysis of variations in dermal exposure conditions and (2) aggregate dermal and inhalation exposures since these two routes of exposure occur simultaneously and EPA has no plausible basis to conclude that use of gloves will prevent dermal contact with CTC.

## **V. The Draft Evaluation Inadequately Addresses Risks to Vulnerable Populations and Fails to Apply Sufficient Uncertainty Factors**

There are two significant ways in which the draft risk evaluation uses insufficiently protective uncertainty factors (UFs) and understates risks as a result.

First, consistent with its 2010 IRIS assessment, EPA notes that “[m]etabolism of carbon tetrachloride to reactive metabolites by cytochrome p450 enzymes (particularly CYP2E1 and CYP3A) is hypothesized to be a key event in the toxicity of this compound.”<sup>72</sup> As it explains, “[d]ifferences in the metabolism due to alcohol consumption, exposure to other chemicals, age, nutritional status, genetic variability in CYP expression, or impaired liver function due to liver disease can increase susceptibility to carbon tetrachloride.” Thus, “[c]ases of acute toxicity from occupational exposures indicate that heavy drinkers are more susceptible to carbon tetrachloride and this observation has been verified in numerous animal studies.” In addition, “reduced kidney function and increased CYP3A activity in the liver (indicated by animal studies) suggest that older populations could be at greater risk of carbon tetrachloride-associated kidney damage.”

EPA recognizes that these groups comprise “potentially exposed or susceptible subpopulations” for which it must make specific determinations of unreasonable risk under TSCA. It accounted for the increased risk to these susceptible subpopulations by applying a default intraspecies uncertainty/variability factor (UF) of 10.<sup>73</sup> However, this UF is customarily used by EPA to account for normal expected variations in sensitivity within the healthy population.<sup>74</sup> Here, by contrast, EPA has identified specific subgroups with biological characteristics that make it likely that they will experience adverse effects from CTC at lower concentrations than healthy adults.<sup>75</sup> To provide protection to these groups, a UF beyond the default intraspecies 10X factor should be applied, as EPA has previously done

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<sup>72</sup> Id at 137

<sup>73</sup> Id at 130.

<sup>74</sup> For instance, in its draft Pigment Violet 29 risk evaluation EPA used an intraspecies UF of 10 despite finding “no evidence of increased susceptibility for any single group relative to the general population.” Draft Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline- 1,3,8,10(2H,9H)-tetrone) (Nov. 2018), found at [https://www.epa.gov/sites/production/files/2018-11/documents/draft\\_pv29\\_risk\\_evaluation\\_public.pdf](https://www.epa.gov/sites/production/files/2018-11/documents/draft_pv29_risk_evaluation_public.pdf) (PV29 Risk Evaluation).

<sup>75</sup> Thus, EPA guidance provides that “a 10-fold factor may sometimes be too small because of factors that can influence large differences in susceptibility, such as genetic polymorphisms.” EPA-630-P02-002F, A Review of the Reference Dose and Reference Concentration Processes, at 4-44 (Dec. 2002) <https://www.epa.gov/risk/review-reference-dose-and-reference-concentration-processes-document>. (RD and RC Review).

for other susceptible groups such as infants and children.<sup>76</sup> The SACC should recommend that EPA apply a UF of 20X.<sup>77</sup>

Second, EPA guidance also calls for application of a UF where the absence of adequate data creates uncertainty in determining a chemical's health effects:<sup>78</sup>

"The database UF is intended to account for the potential for deriving an underprotective RfD/RfC as a result of an incomplete characterization of the chemical's toxicity. In addition to identifying toxicity information that is lacking, review of existing data may also suggest that a lower reference value might result if additional data were available. Consequently, in deciding to apply this factor to account for deficiencies in the available data set and in identifying its magnitude, the assessor should consider both the data lacking and the data available for particular organ systems as well as life stages."

The size of this UF can vary between 3 and 10. EPA guidance advises that "the size of the database factor to be applied will depend on other information in the database and on how much impact the missing data may have on determining the toxicity of a chemical and, consequently, the POD."<sup>79</sup>

The IRIS assessment applied a UF of 3 for database inadequacy based on the lack of "an adequate multigeneration study of reproductive function by any route of exposure."<sup>80</sup> The draft risk evaluation identifies developmental toxicity as another endpoint with limited data,<sup>81</sup> and there is also no neurodevelopmental toxicity study on CTC, an area of potential concern given its serious neurotoxic effects. No endocrine effects data are available either. Given the extent of these data gaps, we believe a UF of 10 is warranted.

The paucity of any toxicology data on CTC's effects by the dermal route of exposure, combined with the lack of dermal absorption studies, create a high level of uncertainty in EPA's assessment of dermal risks. EPA should add a UF of 10 to its current benchmark MOEs for dermal exposure of 100 (acute) and 30 (chronic).

## **VI. EPA's Unreasonable Risk Determinations for Workers Should Not Assume They Will be Protected by PPE**

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<sup>76</sup> EPA, Consideration of the FQPA Safety Factor and Other Uncertainty Factors In Cumulative Risk Assessment of Chemicals Sharing a Common Mechanism of Toxicity, February 28, 2002, available at <https://www.epa.gov/sites/production/files/2015-07/documents/apps-10x-sf-for-cra.pdf>; U.S. EPA. Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. U.S. Environmental Protection Agency, Washington, DC, EPA/630/R-03/003F, 2005.

<sup>77</sup> While EPA applies an intraspecies UF of 10 for CTC's chronic effects, it uses a UF of 3 for interspecies variability, apparently based on application of its human PBPK model to convert the results of animal studies to human dose levels. CTC Evaluation, at 131. It is not clear why the PBPK model reduces uncertainty in animal to human extrapolation sufficiently to justify this reduction in the UF.

<sup>78</sup> RD and RC Review at 4-44

<sup>79</sup> Id. at 4-45.

<sup>80</sup> IRIS, Toxicological Review of Carbon Tetrachloride (CAS No. 56-23-5), at 206-207, [https://cfpub.epa.gov/ncea/iris/iris\\_documents/documents/toxreviews/0020tr.pdf](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0020tr.pdf).

<sup>81</sup> CTC Evaluation at 170.

As in previous risk evaluations, EPA proposes to determine that CTC's risks to workers are not unreasonable where the "expected" use of respirators and gloves would reduce exposures to levels that provide "acceptable" MOEs and cancer risk levels as compared to EPA's benchmarks. The impact of this approach on EPA's risk determinations is far-reaching. Whereas numerous groups of workers have risk levels exceeding EPA's benchmarks in the absence of PPE, none would experience unreasonable risks if use of respirators and gloves is assumed and, therefore, EPA would place no restrictions on CTC under TSCA to protect workers.<sup>82</sup> However, as the SACC has repeatedly underscored and EPA's draft evaluations recognize, this "expectation" of universal PPE use is not grounded in data, departs from established workplace protection policy, and is contrary to the realities of worker exposure to unsafe chemicals.

#### **A. The SACC Has Repeatedly Raised Serious Concerns About EPA's Undue Reliance on PPE to Determine the Absence of Unreasonable Risk**

In each of its reviews of draft evaluations, the SACC has repeatedly raised concerns about EPA's undue over-reliance on PPE for determinations of unreasonable risk. In its report on the PV29 draft, the SACC noted that "the analysis in the Evaluation does not discuss or account for the fact that downstream commercial users may be oblivious to chemical risks and lack even rudimentary industrial hygiene measures."<sup>83</sup> Similarly, in reviewing the 1,4-dioxane evaluation, the SACC concluded that the "consensus of the Committee believes that PPE may not be consistently and properly worn, as EPA assumed"<sup>84</sup> and noted that "[g]love use should not always be assumed to be protective" and, if worn improperly, gloves "could actually lead to higher exposures."<sup>85</sup> As it concluded, "8-hour use of PPE should not be used in the risk characterization of inhaled 1,4-Dioxane. Risk estimates should be presented without the use of PPE as reasonable worst case."<sup>86</sup>

In the case of HBCD, the SACC noted that "it was unreasonable to assume workers would wear PPE for entire 8-hour shifts due to underlying medical conditions, facial hair, discomfort, and other issues" and added that:<sup>87</sup>

"[M]any members of the Committee believed EPA should place more emphasis on the limited likelihood that respiratory protection will be adopted without specific occupational exposure guidelines for HBCD . . . Dust exposures in the construction trades (especially residential construction) continue to represent an occupational health concern because of the many small-to-medium size operators and the use of temporary (and, not infrequently, undocumented) workers. Workers in these small-to-medium enterprises may not be likely to adopt personal protective equipment (PPE) controls, so EPA's characterization of reasonable risk relying on use of PPE is not sufficiently supported by the practical realities of many workplaces."

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<sup>82</sup> The only exception would be for ONUs, who are predicted to have unreasonable risks since EPA assumes they will not use PPE.

<sup>83</sup> SACC Report on PV29 at 37.

<sup>84</sup> These "heightened exposures" could occur as a result of "contamination of the interior of the glove" (if workers were not properly trained in glove use and replacement) or by "acting as a reservoir" for contaminants (if the gloves were not impermeable). Such occlusion (greater penetration of the skin where contaminants build up inside the glove because it is permeable) would result in *greater* dermal exposure than in the "no glove" scenario.

<sup>85</sup> SACC Report on 1,4-dioxane and HBCD, at 55.

<sup>86</sup> *Id.* at 53.

<sup>87</sup> *Id.* at 118.

The SACC report on 1-BP provides further amplification of these concerns:<sup>88</sup>

“One member noted that the Committee has now received public testimony from two former highly distinguished Occupational Safety and Health Administration (OSHA) administrators expressing concerns regarding EPA’s reliance upon non-regulatory guidance and PPE to reduce risks to reasonable levels. Persons familiar with PPE use realize that nominal protection factors may not be achieved in actual practice. The most recent of these comments also noted that compounds with high vapor pressures (such as 1-BP) may “breakthrough” cartridge type respirators in time frames much shorter than a work shift. Since respirators do not have real-time indicators of remaining capacity, respiratory protection failure is more likely for high vapor pressure compounds. 1-Bromopropane also is known to penetrate many glove types. This increases the likelihood of failure to select an appropriate glove.”

The SACC concluded that EPA “[a]ssumptions about PPE use are likely unrealistic for many of the scenarios and so the determination of whether a condition of use results in an acceptable or unacceptable risk should be based on no PPE use, with the possible exception of in a manufacturing facility.”<sup>89</sup>

#### **B. The CTC Risk Evaluation Itself Casts Serious Doubt on Whether PPE Consistently and Reliably Protects Workers from Unsafe Exposure**

The CTC risk evaluation provides a detailed discussion of the role of PPE in workplace protection strategies, which demonstrates that PPE are not a substitute for more effective controls on workplace exposure and that there is considerable uncertainty about whether PPE is consistently used even where legally required.

EPA describes the well-established “hierarchy of controls” as follows:<sup>90</sup>

“OSHA and NIOSH recommend employers utilize the hierarchy of controls to address hazardous exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, the use of elimination, substitution, engineering controls, administrative controls, and lastly PPE. . . . The respirators do not replace engineering controls and they are implemented in addition to feasible engineering controls (29 CFR § 1910.134(a)(1)). The PPE (e.g., respirators, gloves) could be used as the last means of control, when the other control measures cannot reduce workplace exposure to an acceptable level.”

Thus, to rely entirely on PPE without first requiring engineering controls and other protections – as EPA effectively does in the CTC risk evaluation – is contrary to accepted principles of worker protection.

EPA also emphasizes that “implementation of a full respiratory protection program requires employers to provide training, appropriate selection, fit testing, cleaning, and change-out schedules in order to have confidence in the efficacy of the respiratory protection.” However, as the draft evaluation describes, NIOSH has found that respirator programs often provide inadequate protection even where respirator use is legally

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<sup>88</sup> SACC Report on 1-BP, at 30-31.

<sup>89</sup> Id at 66.

<sup>90</sup> CTC Evaluation at 54.

required. As cited in the draft risk evaluation,<sup>91</sup> a NIOSH survey found that found that establishments subject to respirator requirements had the following program deficiencies:<sup>92</sup>

- 59% provided training to workers on respirator use;
- 34% had a written respiratory protection program;
- 47% performed an assessment of the employees' medical fitness to wear respirators;
- 24% included air sampling to determine respirator selection.

With these omissions, there is serious doubt whether respirator use at many facilities is consistent, reliable and protective. Moreover, to the extent that employers provide respirators, they need only provide sufficient protection to attain the OSHA PEL of 10 ppm (eight-hour time weighted average). However, the PEL is years out of date and EPA identified unreasonable risk at exposures far below the PEL.<sup>93</sup> There is no basis for EPA to assume that employers will voluntarily exceed the OSHA standard and provide additional respiratory protection to eliminate the risks below the PEL.

The draft evaluation also indicates that “[g]loves, if proven impervious to the hazardous chemical, and if worn on clean hands and replaced when contaminated or compromised, could provide employees with protection from hazardous substances.”<sup>94</sup> However, the extent to which the preconditions for effective glove use are in fact followed in workplaces is highly uncertain. As the draft evaluation explains:<sup>95</sup>

“Most nitrile gloves have a breakthrough time of only a few minutes and thus offer little protection when exposed to carbon tetrachloride. For operations involving the use of larger amounts of carbon tetrachloride, when transferring carbon tetrachloride from one container to another or for other potentially extended contact, the only gloves recommended are Viton. The gloves should not be assumed to provide full protection. Regarding glove use, data about the frequency of effective glove use – that is, the proper use of effective gloves – is very limited in industrial settings. Initial literature review suggests that there is unlikely to be sufficient data to justify a specific probability distribution for effective glove use for a chemical or industry.”

For CTC, EPA adds “workers are exposed to carbon tetrachloride-based product that may penetrate the gloves, such as seepage through the cuff from improper donning of the gloves, and if the gloves occlude the evaporation of carbon tetrachloride from the skin.”<sup>96</sup>

Overall, EPA concedes that it “does not know the actual frequency, type, and effectiveness of glove use in specific workplaces of the occupational exposure scenarios.”<sup>97</sup> Given this admission, there is simply no basis for EPA’s “expectation” that CTC manufacturers and processors will use “appropriate PPE consistent with the applicable SDSs in a manner adequate to protect employees.”<sup>98</sup>

The SACC should recommend that EPA revise the CTC risk evaluation so that its unreasonable risk determinations for workers are based on workplace exposure levels in the absence of PPE. Where

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<sup>91</sup> Id at 63

<sup>92</sup> NIOSH, Respirator Usage in Private Sector Firms, 2001, <https://www.cdc.gov/niosh/docs/respsurv/>

<sup>93</sup> CTC Evaluation at 130.

<sup>94</sup> CTC Evaluation at 64.

<sup>95</sup> Id. at 60

<sup>96</sup> Id.

<sup>97</sup> Id. at 168

<sup>98</sup> Id at 176.

unreasonable risk is demonstrated, PPE along with other worker protection measures should be considered in determining how best to eliminate the unreasonable risk.

### **Conclusion**

We appreciate this opportunity to comment to the SACC on the draft CTC risk evaluation.

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## Consumer Appendix

### Consumer Products Containing Carbon Tetrachloride

**Introduction.** Below is a list of products sold on retail websites, and thus available for purchase by consumers, that have been verified to contain carbon tetrachloride (CTC) (CASRN 56-23-5) from Material Safety Data Sheets (MSDSs) or Safety Data Sheets (SDSs).

**Methodology.** Safer Chemicals, Healthy Families staff searched via Google for MSDSs and SDSs referring to "56-23-5," including key words for relevant product types, and then confirmed the products are sold on websites such as [www.amazon.com](http://www.amazon.com) or [www.walmart.com](http://www.walmart.com). Additionally, we reviewed the lists of products in EPA's February 2017 "Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal" for CTC to determine which products are sold on retail websites. An asterisk means the product is on EPA's February 2017 list.

**Notes.** The product descriptions quoted below are from the seller's website, unless otherwise noted. Safer Chemicals, Healthy Families has not verified the accuracy of the product descriptions.



## ADHESIVES

### ➤ *Devcon Zip Patch\**



#### Product Description:

“... cures at room temperature and makes permanent, waterproof field repairs to pipes, tanks and containers. High technology, adhesive-impregnated patching system is easy-to-use ...”

Sold At: <https://www.amazon.com/Devcon-11500-Brown-Adhesive-Coverage/dp/B001RSTPYQ> & <https://www.walmart.com/ip/Devcon-Zip-Patch-zip-patch-kit-old-72250must-ship-m/19296470>

Contains 0.1-1% CTC by weight, according to the 2015 SDS: [http://www.devcon.com/profiles/pdfs/sku\\_msds\\_66.pdf](http://www.devcon.com/profiles/pdfs/sku_msds_66.pdf)

### ➤ *Loctite Epoxy Plastic Bonder\**



#### Product Description:

“... is an acrylic formula that is specially formulated to bond and repair plastic surfaces.”

Sold At: <https://www.amazon.com/Loctite-Plastic-0-85-Fluid-Syringe-1363118/dp/B0044FBB8C/>

Contains 0.1-1% CTC, according to the SDS for Part A available here:

<http://www.loctiteproducts.com/techdata-msds.shtml#>

➤ **Permatex MotoSeal Ultimate Gasket Maker Grey\***



**Product Description:**

“... forms a tough flexible bond that is highly effective on irregular and uneven joint surfaces. Ideal for use on frequently disassembled engines and two and four cycle engines.”

Sold At: <https://www.amazon.com/Permatex-29132-MotoSeal-Ultimate-Gasket/dp/B000HBGHKE>

Contains 0.1-1% CTC by weight, according to the SDS:  
[https://www.permatex.com/wp-content/uploads/tech\\_docs/sds/01\\_USA-English/29132.pdf](https://www.permatex.com/wp-content/uploads/tech_docs/sds/01_USA-English/29132.pdf)

➤ **SEM Patch Panel Adhesive**



**Product Description from SEM:**

“... a two-component adhesive for quickly bonding metal panels without the use of an external primer.”

Sold At: <https://www.walmart.com/ip/SEM-PRODUCTS-39897-PATCH-PANEL-ADHESIVE/108856532>

Contains ≤1% CTC by weight, according to the SDS available here: <https://www.semproducts.com/oem-recommended-panel-bonding-adhesives/dual-mixtm-patch-panel-adhesive>

➤ **SEM Weld Bond Adhesive\***



**About This Item:**

“a non-sag, two-component methacrylate adhesive system formulated to bond metal surfaces without the use of an external primer”

Sold At: <https://www.walmart.com/ip/SEM-PRODUCTS-39537-WELD-BOND-ADHESIVE/112064302>

Contains ≤1% CTC by weight, according to the SDS:

<https://www.semproducts.com/manage/html/public/conte>

## MISCELLANEOUS

➤ **Dollhouse Miniature Glass Bottle of “Vintage Carbon Tetrachloride Poison”**



**Product Description:**

“Glass Bottle of ‘Vintage Carbon Tetrachloride Poison’ made of real glass with a faux vintage label.”

Sold At: <https://www.amazon.com/Dollhouse-Miniature-Bottle-Vintage-Tetrachloride/dp/B00TIS61K8>

No MSDS available. EPA should verify whether this product contains any real carbon tetrachloride poison.