DEPARTMENT OF HEALTH

Water Gremlin

HEALTH ASSESSMENT SERIES I TRANS-1,2-DICHLOROETHYLENE IN AIR AND HEALTH

At a Glance

- A general overview of the published toxicity studies indicates that t-DCE displays relatively low toxicity. However, information regarding possible health effects from breathing t-DCE over long periods is lacking and no studies have been conducted to assess possible cancer risk.
- In January 2019, MDH developed chronic Risk Assessment Advice (RAA) specifically for t-DCE air permitting applications at the Water Gremlin facility. The RAA, which is defined as an amount that is safe to breathe daily for a lifetime, was 70 µg/m3 (micrograms per cubic meter).
- The Minnesota Pollution Control Agency (MPCA) used air modeling to determine that Water Gremlin could emit 92 tons of t-DCE per year without exceeding an annual average concentration of 70 µg/m3 in air outside of the Water Gremlin property boundary.
- Water Gremlin used t-DCE during March 2019-August 2019, then again from January 2020 to the present. Sixty tons of t-DCE was used from March 2019 to March 2020.
- Air monitoring around the Water Gremlin facility began on March 1, 2019, and is on-going. Monitoring results are highly variable, reflecting variations in weather (mainly wind speed and direction) and the rate of t-DCE use at the facility.
- In April 2020, MDH revised the t-DCE chronic RAA to 20 µg/m3, and developed a subchronic RAA value of 200 µg/m3 for exposures greater than 30 days up to 8 years.
- MDH does not expect health effects to occur in the community from Water Gremlin's past or current emissions of t-DCE.

Purpose

This document describes

- how MDH uses t-DCE toxicology studies and risk assessment to develop air guidance values,
- how MDH Risk Assessment Advice developed in January 2019 was used to set limits for Water Gremlin t-DCE emissions,
- the results of the t-DCE air monitoring data from monitors on Water Gremlin's property,
- the new MDH Risk Assessment Advice for t-DCE developed in April 2020, and
- Water Gremlin's t-DCE emissions and MDH conclusions about health risk.

What is *trans*-1,2-Dichloroethylene (t-DCE)?

t-DCE is a clear liquid that is highly flammable and evaporates easily (part of a chemical class called volatile organic compounds or VOCs). It is used as a solvent for cleaning and degreasing, as well as a propellant and blowing agent (U.S. EPA, 2019). It has recently been used as an alternative to trichloroethylene (TCE). Exposure occurs mainly by breathing it in at workplaces where t-DCE is made or used.

After Water Gremlin was forced to stop TCE use in January 2019, they expressed interest in resuming coating operations with a product called FluoSolv WS (NuGenTec, 2019). FluoSolv is composed primarily of t-DCE, and its use in coating would result in air emissions of t-DCE.

What Happens to t-DCE in the Air?

When t-DCE gas is continuously released into the air there can be localized elevated air concentrations. Farther away from the source t-DCE mixes into the atmosphere by spreading out in all directions and becomes increasingly diluted. t-DCE is also broken down in the atmosphere. It takes about five days for an amount of t-DCE in air to reduce by half by breaking down (U.S. EPA, 2010). t-DCE is not expected to settle on soil or surface water, and any that does would evaporate back into the air quickly.

What Happens to t-DCE in the Body?

t-DCE is a volatile, fat-soluble compound that is quickly taken up through the lungs and gastrointestinal tract (ATSDR 1996). While t-DCE is fat-soluble, there is no solid data indicating accumulation in the liver, brain, kidney, or other fat tissue following exposure. t-DCE can be metabolized in the liver, as shown by rodent studies. It is likely broken down into more water-soluble metabolites which are quickly removed by the kidneys (ATSDR 1996; U.S. EPA 2010). Some studies show the body can eliminate t-DCE by exhaling it (U.S. EPA 2010).

MDH Risk Assessment Advice – January 2019

In January 2019, MPCA requested that MDH develop a site-specific air guidance value that could be used to determine a safe amount of t-DCE that Water Gremlin could release into the air.

MDH derived a *chronic* inhalation value of 70 µg/m^3 (micrograms per cubic meter) as Risk Assessment Advice (RAA), or an amount that is safe to breathe daily for a lifetime. The RAA was developed to be protective against immune system effects that were shown in a study of mice exposed to t-DCE in drinking water. Exposures to t-DCE in amounts greater than 70 µg/m^3 does not mean health effects are likely, especially if they only occur episodically and for less-than-lifetime durations. However, the risk of health effects generally increases as the amount and duration of chemical exposures increase.

MDH's RAA was unable to take into account the minor constituents of FluoSolv WS, hydrofluoroethers, because toxicological data are unavailable. Hydrofluoroethers are very persistent chemicals that are added to make the FluoSolv mixture non-flammable.

A description of how air guidance values are developed using toxicology studies and risk assessment is below.

Toxicology Studies and Risk Assessment

Risk assessment is a science-based tool used to evaluate the potential effects of a chemical on human health. Risk assessment uses the best available scientific information, as well as professional judgment and policy, to estimate risks in a standardized way to help make informed decisions about managing or reducing risks.

To determine a safe level of exposure to contaminants, scientists frequently rely on animal studies. In these studies, animals in a laboratory (often rodents) are exposed to large amounts of a chemical of

interest at different doses and durations; acute (hours), subchronic (often 90 days), and chronic (often 1-2 years). Because it is unclear how well short-term, high exposure tests on animals predict how people may respond to low level exposures over a longer period of time, scientists err on the side of caution when determining safe exposure amounts for people. This is generally done by dividing the amounts shown to cause an effect in study animals by uncertainty factors of 10 to 3,000 to arrive at an amount expected to be safe for all members of the population. Greater reductions are used when there is less certainty in the scientific data available. Using such margins of safety increases confidence that health effects would be extremely unlikely at the calculated safe amount, even among sensitive individuals such as children and pregnant women.

The U.S. Environmental Protection Agency (EPA) completed a review of t-DCE in 2010 (U.S. EPA, 2010). EPA states that a general overview of the toxicity studies conducted indicates t-DCE displays low toxicity. However, there is a lack of information regarding the possible health effects from breathing t-DCE over long periods. EPA concluded that there was insufficient inhalation data to support deriving a safe air value for long-term (chronic) exposures. EPA also states that there is "inadequate information to assess the carcinogenic potential" of t-DCE based on the absence of human or animal cancer studies.

Although there are no chronic studies of t-DCE, there are several subchronic animal studies (U.S. EPA, 2010). Five studies exposed rodents to t-DCE by drinking water or food, and two studies exposed rodents by inhalation (one unpublished). Changes in liver and kidney weight were the main effects observed (EPA, 2010).

The results of the two inhalation studies were inconsistent. A limitation to both was that exposures occurred intermittently (six and eight hours/day) rather than continuously. With intermittent dosing, exposure concentrations should be adjusted to reflect a continuous exposure to use for calculating health risk values. The earliest study (Fruendt et al., 1977) showed an effect of fat accumulation in the liver and liver cells in rodents exposed to t-DCE at 794,000 µg/m^3 [equivalent to 200 parts per million (ppm)]. The Agency for Toxic Substances and Disease Registry (ATSDR) used this study's results to develop *acute* and *subchronic* air values of 790 µg/m^3 (dividing the effect level by an uncertainty factor of 1,000) based on fat accumulation in liver cells (ATSDR, 1996).

In 2006, EPA used the same study results to derive a "provisional" *chronic* air value of 60 µg/m^3 by adjusting the 794,000 µg/m^3 dose to a continuous exposure and dividing by an uncertainty factor of 3,000 (U.S. EPA, 2014). EPA did not derive a *subchronic* value at that time. However, when EPA did a more thorough toxicological review of t-DCE in 2010, they declined to calculate an air value based on this study's data because of its limitations and a lack of corroboration with other studies (U.S. EPA, 2014). A later unpublished subchronic rodent inhalation study (DuPont, 1998) did not show any effects even at doses of 15,800,000 µg/m^3.

In their 2010 toxicological review, EPA determined there was enough information to derive a safe amount for oral exposure to t-DCE. A subchronic drinking water study showing rodent immune suppression (Shopp et al., 1985) was used to derive a safe amount of t-DCE that could be consumed by people over a lifetime (0.02 milligram/kilogram-day). EPA applied an uncertainty factor of 3,000 to account for differences between animals and humans, variability among humans, use of a subchronic study, and a lack of additional studies. In January, 2019, MDH used this oral dose to derive a *chronic* air guidance value, by converting the oral exposure to an air exposure to arrive at the 70 µg/m^3 site-specific RAA for t-DCE use at Water Gremlin.

MPCA Air Modeling

Air quality dispersion modeling uses computer simulation to predict pollutant concentrations at different locations and distances from a source. MPCA uses the AERMOD dispersion model, developed and recommended by the U.S. EPA, to estimate the levels of air pollutants emitted from sources. MPCA conducted air modeling of proposed Water Gremlin t-DCE emissions to back-calculate an annual emission rate that would not result in long-term exceedances of the t-DCE inhalation RAA that MDH developed in January 2019. According to the MPCA's modeling, 92 tons of t-DCE could be emitted in a year without exceeding an annual average concentration of 70 µg/m^3 in air outside of the property.

Restart of Coating Operations – March 2019

Water Gremlin resumed coating operations using t-DCE in place of TCE, on March 1, 2019, after MPCA and Water Gremlin signed a settlement agreement to resolve the company's air quality violations. The agreement limited Water Gremlin's total VOC emissions to 90 tons per year, as a 12 month rolling sum, using a mass balance calculation that assumes all of the t-DCE used in operations is emitted to air, except any that is accounted for as leaving the facility as liquid waste. Based on the air modeling described above, this 90-ton-per-year limit prevents the annual average t-DCE levels from exceeding the RAA of 70 µg/m^3 in locations where people live.

On August 22, 2019, MPCA ordered Water Gremlin to suspend the operation of the coating lines because t-DCE was found in the soil vapor beneath the building. See Water Gremlin Health Assessment Series: Soil Vapor and Health (https://www.health.state.mn.us/communities/environment/hazardous/docs/sites/ramsey/wgsoilvapor.pdf) for more information. Because of this suspension, t-DCE use lasted for slightly under six months in 2019. The coating lines remained shut down until January 21, 2020. Use of the coating lines was phased in slowly, and some lines transitioned to a water-based coating. As a result, less t-DCE was used in 2020 each month (through March) compared to monthly active coating operations in 2019. The one year period of t-DCE use (from March 2019- March 2020) totaled 60 tons. The 12 month rolling sum is currently decreasing due to the reduced use of t-DCE. For additional information and a chart of the t-DCE emissions as a rolling sum, see the MPCA Water Gremlin air monitoring webpage (https://www.pca.state.mn.us/air/water-gremlin-air-monitoring).

Air Monitoring for t-DCE – Data from March 2019 to March 2020

The 2019 settlement agreement required Water Gremlin to conduct ambient air monitoring. Five air monitors were placed on the Water Gremlin property near the property boundaries. Beginning on March 1, 2019, 24-hour samples were collected every three days, and analyzed for a standard list of VOCs. Monitoring results are highly variable; reflecting variation in weather (mainly wind speed and direction) and the rate of t-DCE use at the facility.

During the period from March 1 to August 22, 2019 when FluoSolv was used, t-DCE results ranged from not detected (shown by a < symbol and a number which is the lowest level detectable) to 648 µg/m^3 as summarized in the table below.

t-DCE Air Monitoring Results on Water Gremlin Property from 3/1/19 to 8/22/19 (µg/m^3)

Monitor location	Minimum	Maximum	Median*	Average
East	<1.1	205	11	29
North	<1	208	5	33
Northwest	<1.1	149	5	21
South	<1.1	104	4	15
West	<1.1	648	21	86

* A median is the middle value of the results (approximately half the results are less than and half the results are greater than the median). When the monitors did not detect any t-DCE, MDH used the detection limit (rather than zero) when calculating the median and average results.

Air monitoring at the five monitors on the Water Gremlin property continued during the time the coating lines were shut down. Out of a total of 237 individual samples analyzed from 48 sampling days during the shutdown period, low levels of t-DCE were detected in only 16 samples, ranging from 1.2 to 5.6 µg/m^3.

Use of t-DCE resumed on January 21, 2020, at lower quantities than in 2019. At the end of April 2020, monitoring results reflected this decline in use of t-DCE in 2020 for coating (see below; ranging from not detected to 97 µg/m^3).

t-DCE Air Monitoring Results on the Water Gremlin Property from 1/21/20 to 4/30/20 (µg/m^3)

Monitor location	Minimum	Maximum	Median	Average
East	<1	52	1.7	7.1
North	<1	60	1.2	6.6
Northwest	<1	47	1.2	4.6
South	<1.1	51	3.3	8.3
West	<1	97	1.2	10

MPCA installed additional VOC monitors at Birch Lake Elementary School (north of Water Gremlin) and Columbia Park (northwest of Water Gremlin) to provide air monitoring results in the community. Only two 24-hour samples (see below) were collected at these monitors before the t-DCE coating shut down on August 22, 2019. MPCA reported that a majority of the subsequent sampling results at these locations have not detected t-DCE. This additional data will be provided on the MPCA website this summer.

t-DCE Air Monitoring Results at Birch Lake Elementary and Columbia Park (µg/m^3)

Monitor location	8/13/19	8/19/19
Birch Lake Elementary	0.79	16 (estimated)
Columbia Park	1.3	3.9

More information about air monitoring at and near the Water Gremlin facility and all of the results can be found on the MPCA Water Gremlin air monitoring webpage (https://www.pca.state.mn.us/air/water-gremlin-air-monitoring)

MDH Risk Assessment Advice – April 2020

In 2020, MDH conducted a re-evaluation of t-DCE toxicity studies that could be used to develop an air guidance value. No new studies were identified. However, an improvement in the modeling of the data in the study used to derive the 2019 RAA was discovered (California EPA, 2018). MDH, in consultation with the U.S. EPA, decided to use the improved study model data. Using these data, MDH updated its *chronic* inhalation RAA for t-DCE to 20 µg/m^3. MDH also developed a *subchronic* inhalation value for t-DCE of 200 µg/m^3. A *subchronic* duration is defined as a repeated exposure for greater than 30 days and up to 10% of an average human lifespan (eight years).

MDH Risk Assessment Advice (RAA) for *trans*-1,2-Dichloroethylene

Duration	2019 RAA (µg/m^3)	2020 RAA (µg/m^3)	Health Endpoint
Acute (up to 24 hours)	ND	ND	
Short-term (> 24 hours to 30 days)	ND	ND	
Subchronic (> 30 days to 10% of a lifetime)	ND	**200**	Immune System
Chronic (> 10% of a lifetime to a lifetime)	70	**20**	Immune System
Cancer (lifetime)	ND	ND	

ND = Not derived

The 2020 RAA values are based on the amount of t-DCE (approximately 50,000 µg/m^3) where an immune system effect was observed in a subchronic animal study. Therefore, it is expected that a small risk of immune system effects may exist for people exposed to t-DCE repeatedly at 50,000 µg/m^3. The RAA is much lower than this to reflect uncertainties in the data and the desire to develop a safe exposure level for the population, including vulnerable subgroups.

Other t-DCE Air Values

Occupational Values

While occupational limits can provide context for ambient air concentrations, MDH believes that these values are sometimes not protective of worker health over the long-term, and certainly are not adequate to protect the general population. The Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), and the American Conference of Governmental Industrial Hygienists all have adopted occupational criteria for 1,2-DCE (note this is a mixture of t-DCE and *cis*-1,2-DCE) over a work day of 200 parts per million in air-- equivalent to 790,000 µg/m^3. NIOSH lists symptoms of occupational exposure as irritation of the eyes and respiratory system, as well as a central nervous system depression. These values are intended to allow workers to be able to do their work safely and may not be protective for long-term exposure.

Other State Values

While there is wide agreement that toxicity data needed to derive a chronic air value for t-DCE is lacking, it is arguably helpful to have some value that limits air emissions, or provides some assessment of health risk, rather than no value at all. Some states use or have developed chronic t-DCE air values (ranging from 60–80 µg/m^3) based on the ATSDR and EPA values discussed above for use in soil and groundwater cleanup programs. The Michigan Department of Environmental Quality's Air Quality Division took a slightly different approach and developed a chronic t-DCE air value of 200 µg/m^3 (MDEQ, 2016) for air quality permitting purposes based on the same study MDH used for the RAA. States often use different uncertainty factors or other parameters in their risk assessment calculations resulting in a range of values that reflect differences in policies, changes in application over time, and even varying scientific opinions. MDH's professional judgment about developing an inhalation values for t-DCE appears to generally be in line with decisions other states have made to address this chemical, although the 2020 chronic RAA may now be the most protective value in the country.

Water Gremlin t-DCE Emissions in Air and Health

The outdoor air surrounding Water Gremlin is affected by use of t-DCE at the facility. Air concentrations from the five monitors on the Water Gremlin property are highly variable, based largely on weather and facility use. The t-DCE from Water Gremlin is expected to spread out in air surrounding the facility similar to past TCE emissions, although current use of t-DCE is significantly lower than past use of TCE.

In 2020, MDH developed safe inhalation values for t-DCE for two different exposure durations – *chronic*, for up to a lifetime of exposure, and *subchronic*, defined as repeated exposure for greater than 30 days, up to 10% of an average lifetime (8 years). The subchronic value was developed in response to community member's requests to help understand shorter duration health risks.

While recent exposure to t-DCE from Water Gremlin is a subchronic duration, the more appropriate objective of controlling ongoing facility emissions is to remain at or below the chronic air guidance of 20 µg/m^3. This is particularly true in a community where past emissions of TCE were excessive.

MDH does not expect health effects in the community from Water Gremlin's past or current emissions of t-DCE. Given the available air monitoring data on the Water Gremlin property, and what can be estimated from modeling, there were times when air concentrations were over the current chronic RAA value (20 µg/m^3) beyond Water Gremlin's property boundary, and very limited times when air

concentrations were over the subchronic RAA value (200 µg/m^3) for a short duration. However, neither the chronic nor subchronic RAA were exceeded for a length of time that poses a health concern. The air monitoring results on the Water Gremlin property are also higher than actual exposures to t-DCE (how much t-DCE enters the body through breathing) experienced by people in the community.

Are Some People at Greater Risk?

As a general rule, MDH considers women who are pregnant or may become pregnant, infants and children, the elderly, and people living with chronic disease or a compromised immune system to be more sensitive to exposure to chemicals. MDH's air guidance values are developed to be protective of people who may be more susceptible.

There is no information available regarding t-DCE exposure and effects to a developing human fetus or small children. Based on the results of only one animal study, t-DCE is not currently expected to cause developmental effects in people, but the information is too limited to draw this conclusion (U.S. EPA, 2010).

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