UNDERSTANDING RISK: WHAT'S BEHIND THE NUMBERS

1,4-DIOXANE

What is 1,4-Dioxane?

1,4-Dioxane is a clear liquid chemical that easily dissolves in water. It is used primarily as a solvent when making other chemicals and as a laboratory reagent.

1,4-Dioxane is a trace contaminant of some chemicals used in cosmetics, detergents, and shampoos.

However, now manufacturers remove as much 1,4-Dioxane from these chemicals as they can before they are made into consumer products.

CDC ATSDR ToxFAQs, http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=954&tid=199, accessed April 7, 2016.

Several organizations throughout the government work to ensure that public health is protected when it comes to toxic chemicals.

The Occupational Safety and Health Administration (OSHA) and Center for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) are charged with ensuring the protection of our nation's workers from toxic chemicals. Occupational screening levels for toxic chemicals are often higher than public health levels because they assume workers are only being exposed to the chemical for a short amount of time (their work day) and then they go home away from the exposure, whereas residential exposure is likely more consistent and long-term.

The CDC's Agency for Toxic Substances and Disease Registry (ATSDR) and the U.S. Environmental Protection Agency (EPA) develop public health screening levels to protect the general population. Locally, the Michigan Department of Environmental Quality (MDEQ) is charged with developing and implementing criteria that protect the general population in Michigan.

The calculations for these screening levels and criteria may take into account the:

- multiple ways people can be exposed to the chemical,
- time periods of exposure to the chemical, and
- age at time of exposure to the chemical.

The assumptions that they use are determined by:

- the population they are meant to protect,
- the amount of time they need protection,
- considering the life stage / age of population that needs protection, and the
- negative health outcomes they are meant to protect against - whether it's cancer or another health problem (aka *non-cancer risk*).

However, there is no way to determine if health effects - cancer or not - will occur in any individual if they are exposed to harmful chemicals. These numbers are meant to be protective of the population as a whole based on what we know about the population and the known health effects of the chemical.

The following is an introductory overview of the many exposure factors considered when determining screening levels and criteria for 1,4-Dioxane and the general assumptions that go into the calculations.

EPA Exposure Factors Handbook

Since it is impossible for scientists to develop custom exposure assumptions for each of us individually, it is necessary for them to make certain assumptions about exposure pathways and lifestyles in general when calculating public health risk. The assumptions used by most toxicologists come from the *EPA Exposure Factors Handbook*. This handbook is available at http://1.usa.gov/1Zx5wI2. These assumptions are developed through careful review of numerous scientific studies from a variety of sources.

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Definitions & Assumptions

Assumption #1: Amount of Drinking Water Consumed Per Day

ATSDR Screening Levels

For these calculations, it is assumed that an average 154 pound adult drinks 2 liters of water per day.

It is assumed that an average 22 pound child drinks 1 liter of water per day.

EPA Drinking Water Concentrations for protection at 1 in 100,000 Risk Level

For these calculations, it is assumed that an average 154 pound adult drinks 2 liters of water per day.

EPA Regional Screening Levels (RSLs)

For these calculations, it is assumed that an average 176 pound adult drinks 2.5 liters of water per day.

For the EPA RSL calculations, it is assumed that an average 33 pound child drinks 0.78 liters of water per day.

MDEQ Drinking Water Criterion (current)

For these calculations, it is assumed that an average 154 pound adult drinks 2 liters of water per day.

MDEQ Drinking Water Criterion (proposed)

For these calculations, it is assumed that an average 176 pound adult drinks 2.5 liters of water per day.

It is assumed that an average 33 pound child drinks 0.78 liters of water per day.

Assumption #2: Lifetime of Exposure

When calculating risk, scientists need to take into account the length of time people may be exposed. These assumptions are based on population mobility information from the *US EPA Exposure Factors Handbook*.

Public health risk screening numbers are lower because they assume longer term exposures. In public health calculations, a lifetime is 70 to 78 years, depending on the information source. The following are assumptions used to calculate public health risk.

ATSDR Screening Levels

ATSDR Screening Levels are calculated to be protective for daily exposure for a child for

- one year using the Intermediate Oral Minimal Risk Level (MRL), or
- a lifetime using the Integrated Risk Information System Reference Dose.

EPA Drinking Water Concentration for 1 in 100,000 Risk Level

EPA Drinking Water Concentration for 1 in 100,000 risk level values are calculated to be protective for a lifetime, but they assume 70 years of exposure for an adult from drinking water only.

EPA Regional Screening Levels (RSLs)

RSLs are calculated to be protective for a lifetime, building in assumptions for both child and adult drinking water exposures, as well as incidental exposures when bathing/showering (for both dermal contact and respiratory pathways). They also assume only 30 years of exposure due to typical residential habits, and they also subtract two weeks per year of exposure to account for vacations and other periods away from the home exposure.

MDEQ Drinking Water Criterion (current)

The current MDEQ Drinking Water Criterion for 1 in 100,000 cancer risk level values was calculated to be protective for a lifetime (formerly 70 years), but they assumed 30 years of exposure for adults from drinking water only. They made this assumption because on average, people generally live in one location for a maximum of 30 years.

MDEQ Drinking Water Criterion (proposed)

The proposed draft criterion are age-adjusted for 32 years of exposure - 6 years as a child and 26 years as an adult with an assumed lifetime of 78 years.

Assumption #3: Cancer v. Non-Cancer Risk

The MDEQ uses a cancer risk factor of 1 in 100,000 as an acceptable risk for development of the criterion.

A cancer risk factor of 1 in 100,000 means that when a population is exposed to a chemical for a certain length of time, there is a risk of only one extra person in every 100,000 people acquiring cancer from this exposure.

While surely no one wants to be that one case, this is a very, very low risk.

Non-Cancer health effects include all other health issues, like kidney or liver damage, for example.

When choosing a criterion to protect public health, MDEQ will choose the lower (more protective) number between the cancer and non-cancer effects.

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Definitions & Assumptions

What are the health effects?

1,4-Dioxane is classified by the EPA as "likely to be carcinogenic to humans" by all routes of exposure.

Short-term exposure to high levels of 1,4-Dioxane in the air may cause eye, nose and throat irritation.

Non-Cancer Health Effects
Long-term exposure through ingestion may cause non-cancer health effects such as kidney and liver damage.

Potential Cancer Risk
1,4-Dioxane can also cause cancers if exposure is sufficient.

Screening values and criteria are meant to be protective of the population as a whole - to the end that no more than 1 extra person in 100,000 exposed could potentially develop cancer.

However, individual health factors and genetics determine your actual personal risk. Exposure at any level does not guarantee that you will experience adverse health effects.

How are these values established?

To learn about the various assumptions and calculation methods that are used to develop these numbers, please see page 2.

It's important to note, that as the screening levels and criteria get smaller, the margin of error for lab analysis stays the same.

Because of variability in the lab analysis, differences between numbers that are very similar and small (such as 3.5, 4.6, and 7.2 ppb) may not be as certain as differences between larger numbers - 85 ppb and 7.2 ppb, for example.

18,000 parts per billion (ppb)
- Agency for Toxic Substances and Disease Registry (ATSDR) Screening Level
- Based on ATSDR Oral Intermediate Minimal Risk Level (MRL)
- Protective for adults only
- Protective for up to one year of exposure
- Only considers drinking water ingestion pathway
- Protects only for non-cancer health effects*

5,000 ppb
- ATSDR Screening Level
- Based on ATSDR Oral Intermediate MRL
- Protective for children and adults
- Protective for up to one year of exposure
- Only considers drinking water ingestion pathway
- Protects against non-cancer health effects*

1,100 ppb
- ATSDR Screening Level
- Based on EPA Integrated Risk Information System (IRIS) Reference Dose (2010)
- Protective for adults
- Protective for lifetime of exposure
- Only considers drinking water ingestion pathway
- Protects against non-cancer health effects*

300 ppb
- ATSDR Screening Level
- Based on the EPA IRIS Reference Dose (2010)
- Protective for children and adults
- Protective for lifetime of exposure
- Only considers drinking water ingestion pathway
- Protects against non-cancer health effects*

85 ppb
- MDEQ Drinking Water Criterion
- Based on review of 1978 National Cancer Institute study and a MDEQ Cancer Slope Factor (2000)
- Protective for adults
- Protective for 30 years of adult exposure
- Only considers drinking water ingestion pathway
- Protects against potential cancer risk* (1 in 100,000)

7.2 ppb
- MDEQ Drinking Water Criterion (Draft 2016)
- Based on updated EPA Cancer Slope Factor (2013)
- Protective for children and adults
- Protective for 32 years of exposure, age-adjusted
- Only considers drinking water ingestion pathway
- Protects against potential cancer risk* (1 in 100,000)

4.6 ppb
- EPA Risk Based Screening Level (2015)
- Based on updated EPA Cancer Slope Factor (2013)
- Protective for children and adults
- Protective for 30 years of exposure, age-adjusted
- Considers ingestion, dermal, and inhalation pathways
- Protects against potential cancer risk* (1 in 100,000)

3.5 ppb
- EPA Drinking Water Concentration for 1 in 100,000 Risk Level (2012)
- Based on EPA Cancer Slope Factor (2013)
- Protective for adults
- Protective for 70 years, assumes continuous adult exposure
- Only considers drinking water ingestion pathway
- Protects against potential cancer risk* (1 in 100,000)