# Response to Public Comments for Diethyl methyl benzenediamine (CAS No. 68479-98-1)

## **PURPOSE:**

The purpose of this response to comments document is to discuss comments received from the public during comment periods and the subsequent re-evaluation of specific health-based screening levels developed by toxicologists from the Michigan Department of Environment, Great Lakes, and Energy (EGLE), Air Quality Division (AQD). Screening levels are used during air permitting to evaluate potential releases of toxic air contaminants (TAC) and to ensure these are protective of public health and the environment. A TAC is any air contaminant for which there is no national ambient air quality standard and is not exempt from the TAC definition in the air rules as defined in <u>Part 1 Rule 120(f)</u>.

During air permitting, permit engineers and toxicologists work together to ensure releases of TACs meet any screening levels that apply. There are three types of screening levels that may be developed depending on the TAC in question. A TAC may have one or all three of these levels.

These levels are called:

- Initial Threshold Screening Levels (ITSL) for non-cancer risks
- Initial Risk Screening Levels (IRSL) for potential carcinogenic risks
- Secondary Risk Screening Levels (SRSL) for potential carcinogenic risks

### SUMMARY:

After a review of the public comments received on the screening levels for diethyl methyl benzenediamine, we have determined that the current screening levels are appropriate, defensible, and will be retained. The screening levels are:

- Acute ITSL is 80 micrograms per cubic meter (µg/m<sup>3</sup>) (24-hour averaging time) based on Rule 336.1233.
- IRSL is 0.2 µg/m<sup>3</sup> (annual averaging time) based on Rule 336.1231 (3).
- SRSL is 2.0 µg/m<sup>3</sup> (annual averaging time) based on Rule 336.1231 (3).

# BACKGROUND:

Pursuant to the Air Pollution Control Rule<sup>1</sup> 230(2), the AQD solicited comments on the derivation of the screening levels for diethyl methyl benzenediamine from April 15 to May 15, 2024.

<sup>&</sup>lt;sup>1</sup> Air Pollution Control Rules in Michigan Administrative Code promulgated pursuant to Article II Pollution Control, Part 55 (Sections 324.5501-324.5542), Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994, PA 451, as amended (NREPA).

# **COMMENTS AND RESPONSES:**

#### 1. Comment:

Dimethyl methyl benzenediamine, while useful in various industrial applications, can be harmful if not handled with caution. The permissible exposure limit of 9  $\mu$ g/m<sup>3</sup> for 8 hours highlights the need for regulatory oversight to protect both workers and the general public.

I already have a hard time enjoying the summer air and having fun with my family and friends outside. Without putting rules in place to make sure healthy people and individuals with chronic diseases like asthma aren't suffering additionally, air toxins like this could ruin more than just summer fun.

I believe it is essential for regulatory agencies like yours to prioritize environmental sustainability and public health, especially in communities like Flint. We deserve equitable access to clean air and environmental justice.

Therefore, I urge you to consider stricter regulations and proactive measures to mitigate the risks associated with chemicals like dimethyl methyl benzenediamine. By working together, we can ensure a healthier future for all residents of Michigan, regardless of their age or background.

#### **Response:**

We agree that it is important to have regulatory oversight to protect public health, especially for vulnerable groups. We agree that communities deserve access to clean air and environmental justice. The health-based screening levels for diethyl methyl benzenediamine were developed to be protective of public health, including sensitive groups, using the best available information. These screening levels are used in Michigan's air permitting process, which is a proactive measure to lessen the risks of inhaling toxic air contaminants from outdoor air.

The Michigan Occupational Health and Safety Administration has oversight of workers in settings where they may be exposed to diethyl methyl benzenediamine and other TACs. Exposure levels for workers are developed and considered differently than the way we develop screening levels for industrial sources of emissions to the outdoor air and the public.

#### 2. Comment

In Flint, where we have faced environmental challenges, including past water crises, the introduction of additional pollutants into the air raises significant concerns. Reports, like The American Lung Association's State of the Air Report of 2024, emphasize the ongoing air quality issues in our county.

#### **Response:**

The health-based screening levels for diethyl methyl benzenediamine and other TACs are used in Michigan's air permitting process to protect public health. Our air toxics rules (<u>Rules 224-233</u>, <u>Part 2 of the Michigan Air Pollution Control Rules</u>) and screening levels are applied when a permit applicant wants to install a new source or modify an existing source of these chemicals. By regulating these sources of TACs through air permitting, the risk of adverse health effects from inhaling this chemical by the public is reduced through a legally binding action and the emissions are not expected to be a health concern.

The <u>American Lung Association's (ALA's) State of the Air Report of 2024</u> focuses on two pollutants that can be major health risk drivers across the nation. The report focuses on particulate matter (size fraction of 2.5 microns and smaller also called PM2.5) and ozone for a given three-year time period. The ALA's scoring method uses the United States Environmental Protection Agency's Air Quality Index to calculate a factor that results in a letter grade.

We review this report's data table for Michigan and may provide feedback, sometimes at the request of the ALA. We have concerns with the grading method. Most notably, the grading method can contradict the methods used to determine if an area meets the health-based National Ambient Air Quality Standards (NAAQS) for PM2.5 and ozone. At the same time, the Air Quality Index results that the ALA uses, are based on near-real, local-time air monitoring and can help people understand how to protect themselves on bad air quality days. As a result, the report may have helpful information about air quality issues.

The 2024 report uses Air Quality Index results from 2020-2022. For Genesee County, there were a reported six days when the Air Quality Index was at the orange level for ozone, which is the level when air quality may be unhealthy for sensitive groups. We agree that this level is a health concern for sensitive groups like people who have asthma. It is important for people to be aware of these levels when they occur so they can protect themselves.

Genessee County had no days when the Air Quality Index reached the orange level for PM2.5. The report listed the county as one of the "Cleanest Counties for Short-Term Particle Pollution" in the nation.

PM2.5 and ozone pollution are major health risk drivers across the nation, and we use the Air Quality Index and the NAAQS to address air quality issues related to these and the other pollutants with national standards. The Michigan-specific health-based screening levels for dimethyl methyl benzenediamine are used during air permitting to prevent proposed outdoor air emissions from being a health concern.

#### 3. Comment:

For dimethyl methyl benzenediamine, the proposed levels are 80 micrograms per cubic meter for a 24-hour period and 0.2 micrograms per cubic meter annually. This chemical, found in some manufacturing processes, can be particularly concerning due to its potentially toxic effects. Exposure to similar chemicals has been linked to serious health issues such as organ damage, respiratory problems, and other chronic conditions. The substantial difference between the short-term and long-term exposure limits raises questions about the cumulative effects of daily exposure over the course of a year and how these were evaluated. Transparency in how these figures were determined, and the scientific evidence supporting them, would greatly enhance public trust and understanding.

#### **Response:**

The health-based screening levels for dimethyl methyl benzenediamine are based on the exposure concentrations used in research studies and set at levels where health effects are not expected to occur, even in vulnerable populations. Since research studies use different concentrations to address different questions, there may be significant differences between the concentrations used between studies. Short-term (or acute) exposures tend to cause effects at higher concentrations while lower concentrations can cause effects if experienced over a longer time.

For dimethyl methyl benzenediamine, we developed an acute initial threshold screening level (ITSL) and an initial risk screening level (IRSL). The secondary risk screening level is 10 times the IRSL.

- The acute ITSL is based on an oral reproductive and developmental study in rats. In this study, the most sensitive effect, which is the effect seen at the lowest dose given in the study, was decreased body weight and changes in the pancreas (Chemview; ECHA, 2020; and Dow, 1992). The pregnant rats were given 0, 2.63, 7.83, or 20.45 milligrams of diethyl methyl benzenediamine per kilogram of body weight<sup>2</sup> per day during the rats' pregnancies. The dose where no effects were observed was 2.63 mg/kg per day. Safety factors were used to account for animal-to-human differences and sensitive groups of people (EGLE, 2023). A 24-hour averaging time was used because the most sensitive effects were observed within the first three days of dosing.
- The IRSL is based on a 24-month rat dietary study (Ethyl Corp, 1992), where male and female rats were given diethyl methyl benzenediamine at 0.4, 1.4, and 3.2 mg/kg for male rats and 0.5, 1.8, and 3.8 mg/kg for female rats. Statistically significant increases in tumors, most notably liver tumors, were observed in male rats fed the highest dose. Statistically significant increases in liver tumors were also observed in female rats fed the highest dose. Statistically significant increases in other tumors called fibroadenomas were observed in female rats at the mid-level and high dose groups. A computer program called Benchmark Dose (BMD) was used to determine which tumor should be the initial risk screening level's basis for the most sensitive endpoint (EGLE, 2023).

Trends for increased tumors were sometimes observed even when statistical analysis did not show statistically significant increases. Since there were trends for increased tumors at lower doses in the study, BMD modeling was performed across the full range of dose groups when statistically significant increases in specific tumor types were observed. This was not done for fibroadenomas in female rats where both the study control animals and control animals from other studies showed a relatively high incidence rate of these types of tumors. It was determined that the most sensitive endpoint was liver tumors in male rats. Safety and adjustment factors were used to account for the potential risk of developing cancer with any level of exposure, animal-to-human differences, and oral-to-inhalation differences.

### **REFERENCES:**

Dow. 1992. Unpublished data, Diethyltoluene diamine: Acute Toxicological Properties in Male Rats (Final Report). Dow Chem Co.

ECHA. 2020. Registration Dossier for diethylmethylbenzenediamine (CAS No. 68479-98-15). Published in accordance with the Registration, Evaluation, Authorisation and Restriction of Chemicals (i.e., REACH) legislation. Accessed August 11, 2022. Retrieved from <a href="https://echa.europa.eu/registration-dossier/-/registered-dossier/13306">https://echa.europa.eu/registration-dossier/-/registered-dossier/13306</a>

EPA. 2022. *Chemview* [database]. Chemical Test Rule Data: Mutagenicity/Genetic toxicity. Retrieved from <u>https://chemview.epa.gov/chemview</u>.

<sup>&</sup>lt;sup>2</sup> Note milligrams of a chemical per kilogram of body weight is often abbreviated as "mg/kg."

EPA. 2023. *Chemview* [database]. 2015 CDR Data and Chemical Test Rule Data. Retrieved from <u>https://chemview.epa.gov/chemview</u>.

EGLE. 2023. Memo from Keisha Williams to File for diethyl methyl benzenediamine (CAS# 68479-98-1). Subject: Screening Level for diethyl methyl benzenediamine (CAS# 68479-98-1). November 8, 2023. AQD, EGLE.

Ethyl Corp. 1992. Unpublished data, Oncogenicity Study-Rat 24 Month Study: PH 474-ET-001-88 Diethyl Toluene Diamine, Lot# 6581-14. Ethyl Corporation.

### **PREPARED BY:**

Dr. Keisha Williams, Toxicologist Toxics Unit, Air Quality Division <u>WilliamsK29@MIchigan.gov</u> 517-582-3721