

Response to Public Comments for Digycol amine (CAS No. 929-06-6)

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 for non-cancer risks
- Initial Risk Screening Levels for potential carcinogenic risks
- Secondary Risk Screening Levels for potential carcinogenic risks

SUMMARY:

After a review of the public comments on the Initial Threshold Screening Level (ITSL) for diglycol amine, we have determined that the current ITSL of 9 micrograms per cubic meter (μ g/m³) (8-hour averaging time) is appropriate and defensible. In addition, we will adopt the chronic ITSL of 0.2 μ g/m³ (annual averaging time) and regulate diglycol amine together with diethanolamine (CAS No. 111-42-2).

BACKGROUND:

Pursuant to the Air Pollution Control Rule¹ 230(2), we solicited comments on the derivation of the ITSL for diglycol amine from April 15 to May 15, 2024.

¹ 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:

Diglycol amine, used in various industrial applications, can pose health risks if inhaled over long periods. Given its usage and the possible exposure in both occupational and residential environments, it is crucial to ensure that the screening level is set at a point that is protective of all individuals, including vulnerable populations such as children and those with pre-existing health conditions. It would be helpful if the justification provided by the AQD includes detailed research and analysis on the potential chronic effects of exposure to this chemical at different concentrations. I urge the Air Quality Division to provide detailed research and analysis to justify this screening level, and focus on the chronic effects of exposure and the protection of vulnerable groups.

Response:

There are limited research studies into the health impacts of long-term inhalation exposure to diglycol amine. This lack of information makes it difficult to know the health risks of inhalation over long periods. However, structurally similar chemicals like diethanolamine are expected to have similar toxicological effects. We have considered the chronic ITSL for diethanolamine, and have determined that it is appropriate and defensible to adopt the chronic ITSL for diethanolamine. This is to help protect against health effects from long-term exposure to diglycol amine.

Both the acute and chronic ITSLs for diglycol amine are meant to protect the public, including vulnerable groups. This is done using research studies and safety factors to estimate a concentration that is not expected to cause health effects, and this information is provided in the justification for diglycol amine (EGLE, 2024).

For the chronic ITSL, we use the United States Environmental Protection Agency (USEPA) Provisional Peer-Reviewed Toxicity Value (PPRTV) for chronic exposure (EPA, 2012; EGLE, 2022). The PPRTV was developed from an approximately 90-day inhalation exposure study in rats (Gamer et al., 2008). At 3 milligrams per cubic meter (mg/m³), the most sensitive health effect observed in the study was increased squamous metaplasia in the upper respiratory tract, specifically in the epiglottis and in the larynx. Benchmark Dose Software and safety factors were used to estimate a concentration that is not expected to cause the most sensitive health effect. The safety factors accounted for animal-to-human differences, vulnerable human groups, uncertainty from lack of reproductive/developmental studies, and uncertainty from using a 90-day study instead of a longer-term one.

A chronic ITSL derived from a diglycol amine study was considered (EGLE, 2024), as it could be helpful to have a screening level derived from a chemical-specific study. However, this chronic screening level would be based on a 48-day study, which is not typically used to derive a screening level that protects against local effects from long-term exposure that are not reproductive nor developmental-toxicity related (EPA, 2022). Deriving an acute screening level that protects against the local, acute effects observed in this diglycol amine study is sounder and has fewer measures of uncertainty than the extrapolation needed to derive a chronic screening level from the same information. Furthermore, deriving a chronic screening level from the same study and the same critical effect used to derive the acute screening level is not defensible. The acute ITSL derived for diglycol amine is based on an occupational exposure limit that was derived to protect workers from a similar upper respiratory effect as the most sensitive effect observed in the diethanolamine inhalation study. The basis for the occupational exposure limit is a rat inhalation study, where rats were exposed to 0, 4, 16, or 40 mg/m³ for 6 hours/day for up to 48 days. The study found no effects at 4 mg/m³. A lowest observable adverse effect level was 16 mg/m³ with laryngeal metaplasia and inflammation. The occupational exposure limit is 0.87 mg/m³ for an 8-hour exposure period. Safety factors were used to further account for sensitive groups in the general public as well as different exposure durations. As a result, the acute ITSL is based on the occupational exposure limit divided by a safety factor of 100.

2. Comment:

When it comes to the dangers of diglycol amine, someone like me that already suffers from seasonal allergies and bad asthma attacks in the spring needs to never encounter this. Diglycol amine can irritate both your skin and your lungs.

I would like to see rules and guidelines put in place to make sure that communities are aware of these dangerous chemicals.

Response:

Our Air Toxics Program uses the air toxics rules (<u>Rules 224-233, Part 2 of the Michigan Air</u> <u>Pollution Control Rules</u>) to develop health-based screening levels to protect against risks of adverse health effects from exposure to toxic air contaminants from sources included in our regulatory authority. The acute ITSL for diglycol amine is set at a level where irritation is not expected to occur, including for sensitive groups. A chronic ITSL is being adopted based on a similar chemical to protect against irritation effects that may occur from chronic exposure.

To help the public get information about chemicals we regulate and have screening levels for, we:

- Hold public comment periods for new or updated screening levels;
- Post all screening levels online; and
- Update our <u>Toxics webpage</u> with additional information the public may find helpful.

3. Comment:

We urge EGLE to consider the cumulative impact of the air toxics being emitted throughout metropolitan Detroit. As it stands, the impacts that these air toxics have in tandem with not only one another, but in combination with the total emissions throughout the city, is a major public health concern that is being overlooked. This should be a prominent point of focus, as R 336.1228 from the AQD allows the department to establish a maximum allowable emission rate that provides adequate protection of human health or the environment.

Response:

Michigan Air Pollution Control Rule 225 requires predicted air concentrations from new or modified emission units to not exceed applicable screening levels established to prevent non-cancer effects and to protect against cancer risks.

Rule 228 allows the AQD to lower the maximum allowable emission rate for a TAC on a caseby-case basis if adequate protection of human health or the environment is not expected to be provided by rules like Rule 225. This determination must be based on scientific information about the TACs and their expected impacts. The evaluation for whether a lower maximum allowable emission rate is needed has been based on the technical review, specific source types, and public comments. Outside of the context of a review for a specific permit application, Rule 228 cannot be applied.

However, based on further review of similar toxic air contaminants to diglycol amine, both the chronic ITSL from diethanolamine is being adopted and the combined impacts of these two pollutants will be evaluated when they are expected to be emitted from the same process.

REFERENCES:

EGLE. 2022. *Memo from Doreen Lehner to File for Diethanolamine (CAS# 111-42-2). Subject: Screening Level for Diethanolamine (CAS# 111-42-2).* December 5, 2022. AQD, EGLE.

EGLE. 2024. *Memo from Keisha Williams to File for* diglycol amine (CAS# 929-06-6). *Subject: Screening level derivation for diglycol amine (CAS#* 929-06-6). July 15, 2024. AQD, EGLE.

EPA. 2012. Provisional Peer-Reviewed Toxicity Values for Diethanolamine (CASRN 111-42-2). EPA/690/R-12/012F. Superfund Health Risk Technical Support Center, National Center for Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency, Cincinnati, OH 45268. 12-03-2012. Available online at: Diethanolamine | Provisional Peer-Reviewed Toxicity Values (PPRTV) | US EPA.

EPA. 2022. U.S. EPA. Ord Staff Handbook for Developing IRIS Assessments. U.S. EPA Office of Research and Development, Washington, DC, EPA/600/R-22/268, 2022.

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