

**STATE OF MICHIGAN**  
**Rick Snyder, Governor**



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October 6, 2017

**Response to Public Comments for**  
**Dipropylene Glycol (CAS No. 25265-71-8)**

**Summary:**

Research studies identified because of an updated literature review provided two inhalation studies on dipropylene glycol indicating low inhalation toxicity. Additionally, oral toxicity studies show that dipropylene glycol has a low order of toxicity by this route. Based on this information, the Air Quality Division (AQD) has rescinded the Initial Threshold Screening Level (ITSL) of 242  $\mu\text{g}/\text{m}^3$  with annual averaging time for dipropylene glycol. AQD will not be establishing a new ITSL. Dipropylene glycol is expected to be a liquid aerosol particle in the ambient atmosphere; therefore, in lieu of setting a screening level for dipropylene glycol, the primary National Ambient Air Quality Standards (NAAQS) for particulate matter (PM<sub>2.5</sub>, PM<sub>10</sub>) are reasonable and appropriate concentration limits for the protection of public health.

**Background:**

Revisions to the Air Pollution Control Rules<sup>1</sup> were promulgated December 22, 2016. Subsequently, the Michigan Department of Environmental Quality (MDEQ), Air Quality Division (AQD) published toxic air contaminant screening levels and their basis as required by Rule 230(1). Pursuant to Rule 230(2), the AQD solicited and received public comments on these screening levels for 60 days: February 14 through April 14, 2017. The AQD must respond to these comments within 180 days; the latest date for response is October 11, 2017.

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<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:

**Comment:** The Initial Threshold Screening Level (ITSL) for dipropylene glycol is based on the 1996 AQD assessment of dipropylene glycol which is outdated and should be updated. A list of study reports and publications available since 1996 is provided. Summaries of unpublished toxicity reports were prepared for the EU REACH registration of dipropylene glycol and are available online. A recently published review article by Dr. Jefferson Fowles summarized recent toxicity information for dipropylene glycol. The toxicology database for dipropylene glycol supports the conclusion that exposure to dipropylene glycol is a low concern for human and environmental health.

**Response:** A review of the dipropylene glycol toxicological database found that it has low oral toxicity in both acute and chronic exposure studies. The European Union (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH, 2017) registration file for dipropylene glycol identified an acute inhalation study: a lethal concentration 50% (LC50) of greater than 2.34 mg/L (2340 mg/m<sup>3</sup>). Another LC50 was identified as “Not lethal: 6000-8000 mg/m<sup>3</sup> (aerosol, nominal concentration)”. It was not deemed appropriate to derive an ITSL from these lethal concentration studies since there were no deaths in either of two studies identified. In a 2-year drinking water study in mice and rats, a no-observed-adverse-effect-level (NOAEL) of 470 mg/kg/day was identified. A reference dose (RfD) could be derived<sup>2</sup> from this study, however, using an oral-to-inhalation route extrapolation would yield<sup>3</sup> an ITSL greater than 15,000 µg/m<sup>3</sup>, annual averaging time. Dipropylene glycol has a melting point lower than -39 °C, a boiling point of 230.5 °C, and has a vapor pressure of 1.3 Pa (0.01 mmHg) at 25 °C (REACH, 2017). Given the low vapor pressure and melting point, dipropylene glycol is presumed to exist as a liquid aerosol particle in ambient air. Since the lethal dose studies were deemed inappropriate to use to develop a health based screening level and the oral studies would result in an excessively high particle exposure, it was reasonable to assume that inhalation health effects from exposures to dipropylene glycol would be negligible, or at worst cause irritation. Therefore, in lieu of setting a screening level for dipropylene glycol the AQD deemed it appropriate to use the U.S. Environmental Protection Agency (EPA) National Ambient Air Quality Standard (NAAQS) for particulate matter (PM). Presently, EPA has designated NAAQS for two size fractions for PM. For PM with aerodynamic diameter less than 2.5 micrometers (µm) (PM<sub>2.5</sub>) there is a long-term NAAQS of 12 µg/m<sup>3</sup> with annual averaging, and a short-term NAAQS of 35 µg/m<sup>3</sup> with a 24-hr averaging time. The NAAQS for PM less than 10 µm of aerodynamic diameter (PM<sub>10</sub>) is 150 µg/m<sup>3</sup> with 24-hr averaging time. The NAAQS for PM for both size fractions of particles (PM<sub>2.5</sub> and PM<sub>10</sub>) will be used to assess the acceptability of dipropylene glycol exposure concentrations for compliance with Rule 225(1).

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<sup>2</sup> RfD = NOAEL/(UF1 x UF2), where NOAEL = 470 mg/kg, UF1 = uncertainty factor of 10 for animal-to-human extrapolation, and UF2 = 10 for sensitive individuals. RfD = 470/100 = 4.7mg/kg.

<sup>3</sup> Pursuant to Rule 232(1)(b): ITSL = RfD x (70kg/20m<sup>3</sup>) = 4.7mg/kg x 3.5kg/m<sup>3</sup> = 16.45 mg/m<sup>3</sup>; unit adjustment of 1000µg/mg yields ITSL of 16,000 µg/m<sup>3</sup> (rounded to two significant figures).

The following footnote will apply to Rule 225 evaluations of dipropylene glycol:

*This toxic air contaminant (TAC) is reasonably anticipated to exist as a particle in the ambient air. A toxicological review has determined that, in lieu of setting a screening level, the primary NAAQS for particulate matter (PM<sub>2.5</sub>, PM<sub>10</sub>) are reasonable and appropriate health protective levels for the particulate. The combined ambient impact of all particulate TAC emissions from the process must be below the applicable PM primary NAAQS (PM<sub>2.5</sub>, PM<sub>10</sub>). The PM primary NAAQS for particulate matter may be used in permit to install exemption determinations for this TAC under Rule 290(a)(iii)(C).*

### **Summary and Conclusion**

An updated review of the toxicity database for dipropylene glycol did not provide new inhalation data relevant to setting an ITSL. The inhalation health effects of dipropylene glycol are expected to be negligible, or at worst cause irritation. It was deemed appropriate to use the NAAQS for PM to assess emissions of dipropylene glycol for complying with Rule 225.

The primary AQD reviewer for these comments was Mike Depa, AQD Toxics Unit Toxicologist. The secondary (peer) reviewer was Keisha Williams, AQD Toxics Unit Toxicologist.

### **References**

REACH. 2017. Oxydipropanol Registration Dossier. EC number: 246-770-3. CAS number: 25265-71-8. Accessed 2017-September-28.  
<https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/16016>