

**STATE OF MICHIGAN
Rick Snyder, Governor**



DEPARTMENT OF ENVIRONMENTAL QUALITY

AIR QUALITY DIVISION

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September 5, 2017

**Response to Public Comments for
Diethylene Glycol (CAS # 111-46-6)**

Summary:

Based on public comments, the Michigan Department of Environmental Quality (MDEQ), Air Quality Division (AQD), has reviewed the Initial Threshold Screening Level (ITSL) for diethylene glycol (DEG). As a result, the AQD agrees with the commenter that the ITSL basis was not the most appropriate. Therefore, the ITSL is changed from 21,000 $\mu\text{g}/\text{m}^3$ (24-hour averaging time) to 1,600 $\mu\text{g}/\text{m}^3$ (annual averaging time).

Background:

Revisions to the Air Pollution Control Rules¹ were promulgated December 22, 2016. Subsequently, the 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.

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:

Comment:

The AQD received comments from one party regarding the ITSL for DEG. The commenter stated that the Ethylene Glycols Panel of the American Chemistry Council (“the Panel”) recently completed a manuscript providing a toxicology literature review for DEG with a recommended Reference Dose (RfD). The commenter stated that the Panel supports the development of a scientifically robust and high quality ITSL that includes clear and transparent data evaluation criteria, and recognizes the importance of incorporating up-to-date scientific knowledge. The commenter also provided several additional references for DEG toxicity studies published since 1996.

Response:

The AQD obtained the recommended paper, which has been published since the time the comment was submitted (Snellings et al., 2017). This paper was found to provide an excellent toxicology review and risk assessment for DEG. The paper concluded that the most appropriate key study for RfD development is an unpublished research report not previously available to the AQD (Gaunt et al., 1976). The AQD agrees that this key study and the review by Snellings et al. (2017) provide a more appropriate ITSL basis than the previous ITSL derivation by the AQD in 1996. As summarized by the commenter, Snellings et al. (2017) utilized Gaunt et al. (1976) with a critical effect of renal hydropic degeneration in male rats treated with DEG in the diet for 14 weeks (with another experiment that extended to 32 weeks). The AQD agrees with the approach of Snellings et al. (2017) to derive an RfD, with one exception. The AQD will use the lower confidence limit of the benchmark dose for a 10% response (BMDL₁₀, as provided by the authors) as the Point of Departure for the risk assessment, rather than the No Observed Adverse Effect Level from the key study as chosen by the authors. This choice by the AQD is less conservative; however, the use of the BMDL₁₀ is preferred because it better accounts for the dose-response information. The AQD then applied a standard conversion of (70 kg body weight / 20 m³/day ventilation rate) to convert the RfD (in units of mg/kg/day) to an ITSL (in units of µg/m³) (as per Rule 232(1)(b)). These and further details have been described in an updated ITSL justification document for DEG that will soon be posted to the AQD’s screening levels website.

Summary and Conclusions:

Based on public comments, the AQD has reviewed the ITSL for diethylene glycol. As a result of that review, the AQD agrees with the commenter that the ITSL basis was not the most appropriate. Therefore, the ITSL is changed from 21,000 µg/m³ (24-hour averaging time) to 1,600 µg/m³ (annual averaging time). This change is fairly consistent with the recommendations of the commenter, the findings of a key toxicology review (Snellings et al., 2017) and a previously unavailable toxicology study (Gaunt et al., 1976).

The primary AQD reviewer for these comments was Robert Sills, AQD Toxics Unit Supervisor. The secondary (peer) reviewer was Mike Depa, AQD Senior Toxicologist.

References:

Gaunt, I.F., et al. 1976. Studies of the toxicity of diethylene glycol in rats. Final report. Research report no. 5/1976. The British Industrial Biological Research Association, Carshalton, Surrey, United Kingdom.

Snellings, W.M. et al. 2017. Human health assessment for long-term oral ingestion of diethylene glycol. Reg Tox Pharm 87: S1-S20.