

**STATE OF MICHIGAN
Rick Snyder, Governor**



DEPARTMENT OF ENVIRONMENTAL QUALITY

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October 10, 2017

**Response to Public Comments for
N-Methyl Pyrrolidone (CAS # 872-50-4)**

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 N-methyl pyrrolidone (NMP). As a result, the AQD agrees with the commenter that the ITSL basis was not the most appropriate. Therefore, the ITSL is changed from 700 $\mu\text{g}/\text{m}^3$ (annual averaging time) to 5,600 $\mu\text{g}/\text{m}^3$ (24 hour 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 Poet et al. (2016) study supports the application of physiologically-based pharmacokinetic (PBPK) modeling and benchmark dose methods to derive occupational exposure limits (OELs) for NMP and may provide a more appropriate basis for deriving an ITSL. Also, AQD should review the NMP toxicology assessment by OECD (2007).

Response:

The AQD obtained and reviewed the recommended paper (Poet et al, 2016) and the recommended review (OECD, 2007). Also very helpful was an extensive literature review and assessment of NMP developmental toxicity by EPA OPPT (2015). The AQD agrees with the commenter that PBPK and benchmark dose modeling focused on the critical reproductive/developmental effects would be a more appropriate basis for ITSL derivation. As a result of this review, the ITSL is being changed from 700 ug/m³ (annual averaging time) to 5,600 ug/m³ (24 hour averaging time). This ITSL is somewhat more restrictive than the Poet et al. (2016) proposed OELs for healthy adult workers, as it is instead intended for protection of the general population from repeated or continuous ambient air exposures from air emission sources. This ITSL is fairly consistent with the EPA (2015) risk assessment utilizing PBPK and benchmark dose modeling.

Summary and Conclusions:

Based on public comments, the AQD has reviewed the ITSL for N-methyl pyrrolidone (NMP). 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 700 µg/m³ (annual averaging time) to 5,600 µg/m³ (annual averaging time). This change is fairly consistent with the recommendations of the commenter and the findings of key toxicology reviews (Poet et al, 2016; EPA, 2015).

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:

EPA. 2015. TSCA Workplan Chemical Risk Assessment. N-Methylpyrrolidone: Paint Stripper Use. CASRN: 872-50-4. Office of Pollution Prevention and Toxics (OPPT). #740-R1-5002. March 2015.

OECD. 2007. SIDS Initial Assessment Profile. 1-Methyl-2-pyrrolidone. 872-50-4.

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Poet et al. 2016. Using physiologically based pharmacokinetic modeling and benchmark dose methods to derive an occupational exposure limit for N-methylpyrrolidone. *Reg Tox Pharm* 76: 102-112.