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Nancy B. Beck, PhD
Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency

Recommendations from AIHA on EPA's Proposed Rule on D4 Under the Toxic Substances Control Act (TSCA)

Agency/Docket Numbers: EPA-HQ-OPPT-2018-0443

Dear Principal Deputy Assistant Administrator Beck:

The American Industrial Hygiene Association, AIHA, is an association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety. We appreciate the opportunity to provide feedback on EPA's draft risk evaluation for D4 (octamethylcyclotetrasiloxane) under TSCA. We hope you find our feedback useful and are happy to answer any questions you may have.

In our recent comments on EPA's proposed rule to amend regulations regarding Procedures for Chemical Substance Risk Evaluations (40 CFR 702 Part B), AIHA recommended that when EPA establishes a hazard benchmark as part of the risk evaluation for a chemical substance for the purpose of determining whether that substance presents an unreasonable risk of injury to health or the environment we encouraged EPA meet the statutory requirement to "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health..." [15 U.S.C. § 2605 (b)(2)(F)(i)]. AIHA believes that such information includes published regulatory/public health agency occupational exposure limits (OELs) such in the United States National Institute of Occupational Safety and Health (NIOSH) Recommended Exposure Limits (RELs), American Conference of Governmental Industrial Hygienist (ACGIH) Threshold Limit Values (TLVs) and Workplace Environmental Exposure Limits (WEELs). Outside the United States, there are a number of authoritative sources for OEL development such as MAK values (Germany), recommendations of the European Commission Scientific Committee on Occupational Exposure Limit Values and recommendations from the Japan Society for Occupational Health.

In 2017, a WEEL for D4 was published.¹ The development and maintenance of WEELs now falls under the AIHA Guideline Foundation and its OEL Committee. AIHA has been engaged in the development and maintenance of high-quality occupational exposure limits (OELs) for worker health protection for over 45 years and can serve as a partner to EPA to share critical knowledge, experience and expertise regarding

¹ Octamethylcyclotetrasiloxane (D4). WEEL. *Toxicology and Industrial Health*. 2016;33(1):2-15.
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the setting of health protective OELs. The AIHA OEL Committee was formed to establish and publish health-based OELs and has the overall mission of protecting workers and communities from occupational and environmental hazards through the application of scientific knowledge. The AIHA OEL Committee is an independent organization that is composed of health science experts that are experienced in setting OELs, using a rigorous science-based approach. Committee members cover a span of public health sciences including occupational hygiene, toxicology, epidemiology, medicine, and risk assessment science. The committee uses the same rigorous scientific approaches used by other health-based exposure limit groups. The committee's methodologies, technical approaches, and administrative procedures are available for review, and the latest occupational risk assessment methods are applied to ensure the use of the best available science in committee deliberations. The committee also provides an opportunity for engagement with interested stakeholders and is committed to transparency and open access to the science behind its work products. Thus, AIHA is well positioned to engage with and assist EPA regarding best practices in OEL applying existing OELs for risk assessment and risk management for D4 and other high priority chemicals.

The recommended WEEL value for D4 is 10 ppm as an 8-hour time-weighted average (TWA). The WEEL documentation is attached to this submission and referenced below. We note that the WEEL and EPA's draft risk evaluation appear to use the same high-quality study to establish a point of departure (POD), that is WIL Research 2001. However, the inhalation exposure concentration that EPA derived as a threshold for determining unreasonable risk of injury to human health is far different from the WEEL. AIHA believes the risk evaluation would benefit from a description of why that difference exists. Moreover, AIHA believes that EPA should apply the policies it proposed in the amendments to the regulations regarding Procedures for Chemical Substance Risk Evaluations, specifically those risk-related factors included in the risk evaluation to determine whether unreasonable risk is presented 40 CFR 702.39(f)(3):

- (i) The severity of the hazard (e.g., the nature of the hazard and irreversibility of the hazard);
- (ii) Exposure-related considerations (e.g., likely duration, intensity, and frequency of exposure);
- (iii) The population exposed (including any potentially exposed or susceptible subpopulations (PESS)); and
- (iv) The confidence in the information used to inform the hazard and exposure values, including an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization.

Conclusion

If you have any questions about AIHA's comments on this proposed rulemaking or other matters, please contact me at mtwilley@aiha.org or (703) 846-0745. Thank you for your time and consideration.

Sincerely,

AIHA



Michele Twilley, DrPH, CIH
Chief Science Officer

About AIHA

AIHA is the association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety in the workplace and community. Founded in 1939, we support our

members with our expertise, networks, comprehensive education programs, and other products and services that help them maintain the highest professional and competency standards. More than half of AIHA's nearly 8,500 members are Certified Industrial Hygienists, and many hold other professional designations. AIHA serves as a resource for those employed across the public and private sectors as well as to the communities in which they work. For more information, please visit www.aiha.org.

References

Workplace Environmental Exposure Level (WEEL). 2017. Octamethylcyclotetrasiloxane (D4). *Toxicology and Industrial Health*. Vol. 33(1) 2–15.