Possible Conditions of Use (COU) Table for Octamethylcyclotetra- siloxane

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Chemical Data Reporting (CDR) Results

Section 6(b) of the Toxic Substances Control Act requires that the US Environmental Protection Agency (EPA, or "the Agency") conduct risk evaluations on existing chemicals and identifies the minimum components EPA must include in all chemical substance risk evaluations. 15 U.S.C. 2605(b). TSCA section 6(b) also allows manufacturers of a chemical to request an EPA conducted risk evaluation on the chemical. TSCA required EPA to develop the form and manner under which these requests must be made, and the criteria for which EPA will determine whether to grant a request. These requirements and criteria are set out in 40 CFR 702.37. Under 40 CFR 702.37(e)(3), EPA is required to assess whether the circumstances identified in a manufacturer request for a risk evaluation constitute COUs (as defined under TSCA section (3)(4) and implementing regulations (40 CFR 702.33)), and whether those COUs warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA must also assess what, if any, additional conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will conduct these assessments based on the same considerations applied in the same manner as it would for a risk evaluation for a high-priority substance.

The COUs in this document are a compilation of those identified by EPA from a review of recent data submitted to EPA under the Chemical Data Reporting (CDR) rule in 2016, of (material) safety data sheets (M)SDS using internet searches, and of COUs identified in the manufacturer request for risk evaluation. These constitute possible additional COUs that may warrant inclusion in the scope of a risk evaluation. For a list of uses of interest to the manufacturer, refer to the manufacturer request for a risk evaluation of octamethylcyclotetra- siloxane in Docket ID No. EPA-HQ-OPPT-2018-0443. This list does not constitute all the uses that may be evaluated in a risk evaluation for octamethylcyclotetra- siloxane.

As defined under the TSCA, COUs are "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). EPA defines the approach it will use to identify the COUs in the Procedures for Chemical Substance Risk Evaluation (40 CFR 702). While EPA interprets the circumstances that constitute conditions of use as largely factual—i.e., EPA is to determine whether a chemical substance is actually intended, known, or reasonably foreseen to be used in one or more of the activities listed in the definition—considerations of the COUs will inevitably involve the exercise of some discretion. As EPA interprets the statute, the Agency will exercise that discretion consistent with the objective of conducting a technically sound, manageable risk evaluation to determine whether a chemical substance – not just individual uses or activities – presents an unreasonable risk to health or the environment. EPA will be guided by its best understanding, informed by legislative text and history, of the circumstances of manufacture, processing, distribution in commerce, use and disposal as Congress intended EPA to consider in conducting risk evaluations.

The statute grants some discretion to determine the circumstances that are appropriately considered to be the chemical's COUs. In exercising that discretion, for example, EPA would not generally consider that a single unsubstantiated or anecdotal statement (or even a few isolated statements) on the internet that a chemical can be used for a particular purpose would necessitate concluding that this represented part of the chemical substance's COUs.

As a further example, although the definition could be read literally to include all intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in some circumstances, EPA interprets the risk evaluation process of TSCA section 6(b) as a focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. In 2019, the Ninth Circuit Court of Appeals ruled that EPA cannot categorically exclude "legacy use" and "associated disposal" from the definition of "conditions of use" (Safer Chemicals, Healthy Families v. U.S. Envtl. Prot. Agency, 943 F.3d 397, 425 (9th Cir. 2019)). As a result of the court's opinion, EPA will no longer exclude legacy use or associated disposal from the definition of conditions of use for chemical risk evaluations. Rather, when these activities are intended, known, or reasonably foreseen, they will be considered uses and disposal, respectively, within the definition of conditions of use. EPA will use the statutory definition and EPA's approach described above to assess whether the circumstances identified in the manufacturer request for a risk evaluation of octamethylcyclotetra- siloxane constitute COUs under 40 CFR 702.33, and whether those COUs warrant inclusion within the scope of a risk evaluation for the chemical substance, octamethylcyclotetra- siloxane. Subject to further analysis and public comment, EPA anticipates including activities identified in the request as COUs in the risk evaluation of this chemical substance.

Life Cycle Stage	Category	Subcategory of Use	Source
Manufacturing	Manufacturing		U.S. EPA (2016)
	Importing		U.S. EPA (2016)
Processing	Processing as a reactant	Adhesives and sealant chemicals	U.S. EPA (2016)
		All other basic inorganic chemical manufacturing	U.S. EPA (2016)
		All other basic organic chemical manufacturing	U.S. EPA (2016)
		All other chemical product and preparation manufacturing	U.S. EPA (2016)
		Plastic material and resin manufacturing	Dow Silicones Corporation et al. 2020
		Synthetic rubber manufacturing	Dow Silicones Corporation et al. 2020
	Incorporation into formulation, mixture, or reaction product	All other basic inorganic chemical manufacturing	U.S. EPA (2016)
		All other chemical product and preparation manufacturing	U.S. EPA (2016)
		Asphalt paving, roofing, and coating materials manufacturing	U.S. EPA (2016)
		Computer and electronic product manufacturing	U.S. EPA (2016)
		Cyclic crude and intermediate manufacturing	U.S. EPA (2016)
		Electrical equipment, appliance, and component manufacturing	U.S. EPA (2016)
		Miscellaneous manufacturing	Dow Silicones Corporation et al. 2020
		Personal care product manufacturing	U.S. EPA (2016)
		Paint and coating manufacturing	Dow Silicones Corporation et al. 2020
		Rubber product manufacturing	U.S. EPA (2016)
		Synthetic rubber manufacturing	U.S. EPA (2016)
	Processing – Repackaging	All other basic inorganic chemical manufacturing	U.S. EPA (2016)
		All other chemical product and preparation manufacturing	U.S. EPA (2016)
		Personal care product manufacturing	U.S. EPA (2016)
Distribution in commerce [a b]	Distribution in commerce		
Commercial uses	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2016)
	Automotive care products	Automotive care products	U.S. EPA (2016)
	Cleaning and furnishing care products	Cleaning and furnishing care products	U.S. EPA (2016)
	Ink, Toner, and Colorant Products	Ink, Toner, and Colorant Products	3M (2018) 3M (2019) Orafol (2019)
	Laboratory chemicals	Laboratory chemicals	Dow Silicones Corporation et al. 2020
	Paints and coatings	Paints and coatings	U.S. EPA (2016)
	Personal care products	Personal care products	U.S. EPA (2016)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S. EPA (2016)

Consumer uses	Adhesives and sealants	Adhesives and sealants	Dow Silicones Corporation et al. 2020
	Automotive care products	Automotive care products	Dow Silicones Corporation et al. 2020
	Laundry and dishwashing products	Laundry and dishwashing products	Dow Silicones Corporation et al. 2020
	Paints and coatings	Paints and coatings	U.S. EPA (2016)
	Personal care products	Personal care products	Dow Silicones Corporation et al. 2020
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S. EPA (2016)
Disposal [a]	Disposal		

[a] CDR includes information on the manufacturing, processing, and use of chemicals. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal).
[b] EPA is particularly interested in information from the public on distribution in commerce.

References

3M Company. (2018). *Safety Data Sheet: 3M™ Flow Additive 892*. Version number 6.00. Issue Date: 5/21/2018.

3M Company. (2019). *Safety Data Sheet: 3M™ Screen Printing UV Ink 9864 Transparent Green (BS)*. Version number 7.02. Issue Date 5/22/2019.

Dow Silicones Corporation, E. S. U. Corporation, et al. (2020). Request for Risk Evaluation under the Toxic Substances Control Act; Octamethylcyclotetrasiloxane (D4; CASRN: 556-67-2).

Orafol Europe GmbH. (2019). *Safety Data Sheet: ORALITE® 5019i yellow (020)*. Revision Date: 5/27/2019.

U.S. EPA (U.S. Environmental Protection Agency). (2016). Non-confidential 2016 Chemical Data Reporting (CDR) Database. http://www.epa.gov/cdr/.