

Possible Conditions of Use (COU) Tables for Octahydro-Tetramethyl-Naphthalenyl-Ethanone Chemical Category (“OTNE”)

Chemical Abstracts Service Registry Numbers (CASRN): 54464-59-4, 54464-57-2, 68155-67-9, and 68155-66-8

Chemical Data Reporting (CDR) Results

Section 6(b) of the Toxic Substances Control Act (TSCA) requires the U.S. Environmental Protection Agency (EPA, or “the Agency”) to conduct risk evaluations on existing chemical substances¹, under the conditions of use (COUs), 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. 15 U.S.C. § 2605(b)(4)(C)(ii). TSCA requires EPA to develop the form and manner under which these requests must be made, and the criteria EPA will use to 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 which, if any, additional COUs 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 TSCA 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 using internet searches, and of COUs identified in the manufacturer request for risk evaluation. These constitute possible COUs that may warrant inclusion in the scope of a risk evaluation. For a list of COUs of interest to the manufacturer, refer to the manufacturer request for a risk evaluation of octahydro-tetramethyl-naphthalenyl-ethanone chemical category in Docket ID No. EPA-HQ-OPPT-2020-0738. This list does not constitute all the COUs that may be evaluated in a risk evaluation for OTNE.

As defined under 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 (82 Fed. Reg. 33726 (July 20, 2017)). While EPA interprets the circumstances that constitute COUs as largely factual (i.e., EPA is to determine whether a chemical substance, or category of chemical substances, 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, or category of chemical substances, presents an unreasonable risk to health or the environment under each identified COU.

¹ TSCA section 26(c) provides for EPA to take action on a category of chemical substances whenever authorized or required by TSCA to take action on a chemical substance. EPA is treating the four CASRNs (54464-59-4, 54464-57-2, 68155-67-9, and 68155-66-8) as a category of chemical substances for purposes of this manufacturer-requested risk evaluation.

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 COUs for a chemical substance or a category of chemical substances. 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 does not generally intend to include such activities in a risk evaluation for a chemical substance or category of chemical substances. Without these exclusions, the concept of "conditions of use" would likely result in no meaningful limitation on EPA risk evaluations, and risk evaluations could present unmanageable challenges--an outcome that EPA does not expect Congress intended.

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. Evtl. 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 COUs 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 COUs.

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 octahydro-tetramethyl-naphthalenyl-ethanone constitute COUs under 40 CFR 702.33, and whether those COUs warrant inclusion within the scope of a risk evaluation for octahydro-tetramethyl-naphthalenyl-ethanone. Subject to further analysis and public comment, EPA anticipates including activities identified in the request as COUs in the risk evaluation of this category of chemical substances.

Ethanone, 1-(1,2,3,4,5,6,7,8 octahydro-2,3,5,5-tetramethyl-2-naphthalenyl) (CASRN: 54464-59-4)

Life Cycle Stage	Category	Subcategory of Use	Source
Manufacturing	Manufacturing		OTNE Consortium (2020)
	Importing		U.S. EPA (2016)
Processing	Incorporation into formulation, mixture, or reaction product	Used in manufacturing of fragrance formulations (compounds)	U.S. EPA (2016)
Distribution in commerce ^{a b}	Distribution in commerce		
Commercial uses	Laundry and dishwashing products	Laundry and dishwashing products	U.S. EPA (2016)
	Personal care products	Personal care products	U.S. EPA (2016)
	Air care products	Air care products	U.S. EPA (2016)
Consumer uses	Laundry and dishwashing products	Laundry and dishwashing products	U.S. EPA (2016)
	Personal care products	Personal care products	U.S. EPA (2016)
	Air care products	Air care products	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 lifecycle 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.

Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8 tetramethyl-2-naphthalenyl) (CASRN: 54464-57-2)

Life Cycle Stage	Category	Subcategory of Use	Source
Manufacturing	Manufacturing		U.S. EPA (2016)
	Importing		U.S. EPA (2016)
Processing	Incorporation into formulation, mixture, or reaction product	Air Care	U.S. EPA (2016)
		All other chemical product and preparation manufacturing	U.S. EPA (2016)
		Fragrance	U.S. EPA (2016)
		Soap, cleaning compound, and toilet preparation manufacturing	U.S. EPA (2016)
		Used in manufacturing of fragrance formulations (compounds)	U.S. EPA (2016)
	Incorporation into article	Plastic material and resin manufacturing	U.S. EPA (2016)
	Repackaging	All other chemical product and preparation manufacturing	U.S. EPA (2016)
		Miscellaneous manufacturing	U.S. EPA (2016)
Distribution in commerce ^{a b}	Distribution in commerce		
Commercial uses	Air care products	Air care products	U.S. EPA (2016)
	Cleaning and furnishing care products	Cleaning and furnishing care products	U.S. EPA (2016)
	Laundry and dishwashing products	Laundry and dishwashing products	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	Air care products	Air care products	U.S. EPA (2016)
	Cleaning and furnishing care products	Cleaning and furnishing care products	U.S. EPA (2016)
	Laundry and dishwashing products	Laundry and dishwashing products	U.S. EPA (2016)
	Paper products	Paper products	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)
Disposal ^a	Disposal		

^a CDR includes information on the manufacturing, processing, and use of chemicals. CDR may not provide information on other lifecycle 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.

Ethanone, 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2 naphthalenyl) (CASRN: 68155-67-9)

Life Cycle Stage	Category	Subcategory of Use	Source
Manufacturing	Manufacturing		U.S. EPA (2016)
	Importing		U.S. EPA (2016)
Processing	Incorporation into formulation, mixture, or reaction product	All other chemical product and preparation manufacturing	U.S. EPA (2016)
		Soap, cleaning compound, and toilet preparation manufacturing	U.S. EPA (2016)
		Used in manufacturing of fragrance formulations (compounds)	U.S. EPA (2016)
	Incorporation into article	Plastic material and resin manufacturing	U.S. EPA (2016)
	Repackaging	All other chemical product and preparation manufacturing	U.S. EPA (2016)
Distribution in commerce ^{a b}	Distribution in commerce		
Commercial uses	Air care products	Air care products	U.S. EPA (2016)
	Cleaning and furnishing care products	Cleaning and furnishing care products	U.S. EPA (2016)
	Laundry and dishwashing products	Laundry and dishwashing products	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	Air care products	Air care products	U.S. EPA (2016)
	Cleaning and furnishing care products	Cleaning and furnishing care products	U.S. EPA (2016)
	Laundry and dishwashing products	Laundry and dishwashing products	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)
Disposal ^a	Disposal		

^a CDR includes information on the manufacturing, processing, and use of chemicals. CDR may not provide information on other lifecycle 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.

Ethanone, 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl) (CASRN: 68155-66-8)

Life Cycle Stage	Category	Subcategory of Use	Source
Manufacturing	Manufacturing		U.S. EPA (2016)
	Importing		U.S. EPA (2016)
Processing	Incorporation into formulation, mixture, or reaction product	All other chemical product and preparation manufacturing	U.S. EPA (2016)
		Soap, cleaning compound, and toilet preparation manufacturing	U.S. EPA (2016)
		Used in manufacturing of fragrance formulations (compounds)	U.S. EPA (2016)
	Incorporation into article	Plastic material and resin manufacturing	U.S. EPA (2016)
	Repackaging	All other chemical product and preparation manufacturing	U.S. EPA (2016)
Distribution in commerce ^{a b}	Distribution in commerce		
Commercial uses	Air care products	Air care products	U.S. EPA (2016)
	Cleaning and furnishing care products	Cleaning and furnishing care products	U.S. EPA (2016)
	Laundry and dishwashing products	Laundry and dishwashing products	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	Air care products	Air care products	U.S. EPA (2016)
	Cleaning and furnishing care products	Cleaning and furnishing care products	U.S. EPA (2016)
	Laundry and dishwashing products	Laundry and dishwashing products	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)
Disposal ^a	Disposal		

^a CDR includes information on the manufacturing, processing, and use of chemicals. CDR may not provide information on other lifecycle 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

OTNE Consortium. (2020). Request for Risk Evaluation under the Toxic Substances Control Act; Octahydro-Tetramethyl-Naphthalenyl-Ethanone Chemical Category.

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