Possible Conditions of Use (COU) Tables for Di-isodecyl Phthalate (DIDP)

CAS Numbers: 26761-40-0 and 68515-49-1 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 and 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 DIDP in Docket ID No. EPA-HQ-OPPT-2018-0435. This list does not constitute all the uses that may be evaluated in a risk evaluation for DIDP.

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. EPA believes the statute is better interpreted to focus on the prospective flow of the chemical substance, and therefore does not consider legacy uses, or associated disposal as a COU. 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 DIDP constitute COUs under 40 CFR 702.33, and whether those COUs warrant inclusion within the scope of a risk evaluation for the chemical substance, DIDP. 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.

CAS Number: 26761-40-0

Category	Subcategory of Use	Source
Manufacturing		U.S. EPA (2016)
Importing		U.S. EPA (2016)
Incorporation into	Adhesives and	U.S. EPA (2016)
formulation, mixture, or	Sealants	
reaction product	Petroleum lubricating oil and grease manufacturing	U.S. EPA (2016)
	Paint and coating manufacturing	U.S. EPA (2016)
Repackaging	Wholesale and retail trade	U.S. EPA (2016)
Distribution in Commerce		U.S. EPA (2016)
Adhesives and sealant chemicals	Adhesives and sealants	U.S. EPA (2016)
	Paints and coatings	U.S. EPA (2016)
Lubricants and lubricant additives	Lubricants and greases	U.S. EPA (2016)
Plasticizers	Paints and coatings	U.S. EPA (2016)
	Importing Incorporation into formulation, mixture, or reaction product Repackaging Distribution in Commerce Adhesives and sealant chemicals Lubricants and lubricant additives	Importing Incorporation into formulation, mixture, or reaction product Repackaging Adhesives and sealant chemicals Lubricants and lubricant additives Importing Adhesives and Sealants Petroleum lubricating oil and grease manufacturing Paint and coating manufacturing Wholesale and retail trade Adhesives and sealant sealants Paints and coatings Lubricants and greases

^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.

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Manufacturing Importing	Manufacturing Importing		U.S. EPA (2016)
	Importing		
	i iiiborung		U.S. EPA (2016)
Processing	Incorporation into	Adhesives	U.S. EPA (2016)
Trocoming	formulation, mixture, or	manufacturing	
	reaction product	Plastics product	U.S. EPA (2016)
	_	manufacturing	
		Plastic material and	U.S. EPA (2016)
		resin manufacturing	
		Oil and gas drilling,	U.S. EPA (2016)
		extraction, and	
		support activities	
		Paint and coating	U.S. EPA (2016)
		manufacturing	
	Incorporation into article	Plastics product	U.S. EPA (2016)
		manufacturing	
		Electrical equipment,	U.S. EPA (2016)
		appliance, and	
		component	
		manufacturing	
		Rubber product	U.S. EPA (2016)
		manufacturing	
		Transportation	U.S. EPA (2016)
		equipment	
	District of	manufacturing	THE EDITION
Distribution in Commerce ^{a b}	Distribution in Commerce		U.S. EPA (2016)
Industrial uses			
Commercial uses	Plasticizers	Adhesives and sealants	U.S. EPA (2016)
Consumer uses	Plasticizers	Adhesives and sealants	U.S. EPA (2016)
Disposal ^a			

^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.

Reference

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