TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-17-0239

Number: P-17-0239
TSCA Section 5(a)(3) Determination: The chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic: Substituted carboxylic acid, polymer with 2,4-diisocyanato-1-methylbenzene, hexanedioic acid, alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2- ethanediyl)], 1,1'-methylenebis[4-isocyanatobenzene], 2,2'-oxybis[ethanol], 1,1'-oxybis[2-propanol] and 1,2-propanediol.

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (generic): Manufacture (including import) for use as an adhesive for open non-descriptive use, consistent with the manufacturing, processing, use, distribution, and disposal information described in the PMN.
Known conditions of use: Applying such factors as described in footnote 1, EPA evaluated whether there are known conditions of use and found none.
Reasonably foreseen conditions of use: Applying such factors as described in footnote 1, EPA has identified, based on changes made to the conditions of use in the initial PMN and information about other products marketed under the same trade name, the following conditions of use: manufacture, processing, or use in a manner that results in releases to water and use involving spray application and consumer use.

Summary: The chemical substance is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, based on the risk assessment presented below and

[1] Under TSCA § 3(4), the term "conditions of use" means "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." In general, EPA considers the intended conditions of use of a new chemical substance to be those identified in the section 5(a) notification. Known conditions of use include activities within the United States that result from manufacture that is exempt from PMN submission requirements. Reasonably foreseen conditions of use are future circumstances, distinct from known or intended conditions of use, under which the Administrator expects the chemical substance to be manufactured, processed, distributed, used, or disposed of. The identification of "reasonably foreseen" conditions of use will necessarily be a case-by-case determination and will be highly fact-specific. Reasonably foreseen conditions of use will not be based on hypotheticals or conjecture. EPA's identification of conditions of use includes the expectation of compliance with federal and state laws, such as worker protection standards or disposal restrictions, unless case-specific facts indicate otherwise. Accordingly, EPA will apply its professional judgment, experience, and discretion when considering such factors as evidence of current use of the new chemical substance outside the United States, evidence that the PMN substance is sufficiently likely to be used for the same purposes as existing chemical substances that are structurally analogous to the new chemical substance, and conditions of use identified in an initial PMN submission that the submitter omits in a revised PMN. The sources EPA uses to identify reasonably foreseen conditions of use include searches of internal confidential EPA PMN databases (containing use information on analogue chemicals), other U.S. government public sources, the National Library of Medicine's Hazardous Substances Data Bank (HSDB), the Chemical Abstract Service STN Platform, REACH Dossiers, technical encyclopedias (e.g., Kirk-Othmer and Ullmann), and Internet searches.

the terms of the proposed Significant New Use Rule (SNUR) signed by EPA.[2] Although EPA estimates that the new chemical substance's hydrolysis products could be very persistent, the new chemical substance and its hydrolysis products have low potential for bioaccumulation, such that repeated exposures are not expected to be cumulative. Based on test data on analogous chemical substances, EPA estimates that the chemical substance has high environmental hazard and potential for the following human health hazards based on EPA's TSCA New Chemicals Program Chemical Category for Diisocyanates: dermal and respiratory sensitization and irritation to all tissues. The PMN describes conditions of use that mitigate both ecological and human health risks. Therefore, EPA concludes that the new chemical substance is not likely to present unreasonable risk to human health or the environment under the intended conditions of use.

As set forth below, the information available to EPA is sufficient to permit the Agency to conduct a reasoned evaluation of the health and environmental effects of the chemical substances under the conditions of use that are not subject to the proposed SNUR, in order to determine that the chemical substances are not likely to present an unreasonable risk under those conditions of use. As such, EPA does not need to impose test requirements to conduct this evaluation. Whether testing is needed to evaluate the effects of the intended, known, or reasonably foreseen conditions of use of a chemical substance subject to a PMN is determined on a case-by-case basis. To the extent that testing may be necessary to conduct a reasoned evaluation of the health or environmental effects of the reasonably foreseen conditions of use that are subject to the proposed SNUR, EPA will make the appropriate determination if a SNUN is submitted following finalization of the SNUR.

EPA found no known conditions of use, assessed the intended conditions of use, and addressed reasonably foreseen conditions of use by proposing a SNUR. Therefore, EPA determines the new chemical substance is not likely to present an unreasonable risk to human health or the environment.

Fate: Environmental fate is the determination of which environmental compartment(s) a chemical moves to, the expected residence time in the environmental compartment(s) and removal and degradation processes. Environmental fate is an important factor in determining exposure and thus in determining whether a chemical may present an unreasonable risk. EPA estimated physical/chemical and fate properties of this new chemical substance using data for

[2] Reasonably foreseen conditions of use subject to a proposed SNUR are not likely to present an unreasonable risk of injury to health or the environment. Based on EPA's experience, it is the Agency's judgment that a new use would not commence during the pendency of a proposed SNUR because web posting of a proposed SNUR serves as the cut-off date for a significant new use. Therefore, manufacturers and processors would not commence a prohibited new use that would be legally required to cease upon the finalization of the SNUR. Once a SNUR is final and effective, no manufacturer or processor – including the PMN submitter – may undertake the conditions of use identified as a significant new use of the PMN substance in the SNUR. EPA must first evaluate the new use in accordance with the requirements of TSCA Section 5 and (a) either conclude that the new use is not likely to present an unreasonable risk under the conditions of use; or (b) take appropriate action under section 5(e) or 5(f). If EPA were not to finalize the proposed SNUR, then that decision would be based on information and data provided to the Agency during the comment period demonstrating that the reasonably foreseen conditions of use subject to the proposed SNUR are not likely to present an unreasonable risk. Under either scenario, the reasonably foreseen condition of use is not likely present an unreasonable risk.

analogous chemical substances. The chemical substance is estimated to be removed during wastewater treatment with an efficiency of 90% via sorption and 90-99% via hydrolysis. The hydrolysis products are also estimated to be removed during wastewater treatment with an efficiency of 90% based on sorption. For both the hydrolysis products, removal by biodegradation is estimated to be negligible. Sorption to sludge is estimated to be strong, and sorption to soil and sediment is estimated to be very strong, resulting in negligible migration to groundwater for both the new chemical substance and its hydrolysis products. Volatilization to air is estimated to be negligible because of the high molecular volume. Overall, these estimates are indicative of low potential for this chemical substance and its hydrolysis products to volatilize into the air and to migrate into groundwater.

Persistence[3]: Persistence is relevant to whether a new chemical substance is likely to present an unreasonable risk because chemicals that are not degraded in the environment at rates that prevent substantial buildup in the environment, and thus increase potential for exposure, may present a risk if the substance presents a hazard to human health or the environment. Based on data for analogous chemical substances, EPA estimated the hydrolysis half-life of the new chemical substance to be minutes to hours. The anaerobic and aerobic biodegradation half-lives for the hydrolysis products are estimated to be greater than six months. These estimates for biodegradation indicate that the new chemical substance will not be persistent in aerobic environments (e.g., surface water) or anaerobic environments (e.g., sediment) and that the hydrolysis products may be very persistent in aerobic and anaerobic environments.

Bioaccumulation[4]: Bioaccumulation is relevant to whether a new chemical substance is likely to present an unreasonable risk because substances that bioaccumulate in aquatic and/or terrestrial species pose the potential for elevated exposures to humans and other organisms via food chains. The new chemical substance and its hydrolysis products have low bioaccumulation potential based on the rapid hydrolysis half-life of the new chemical substance and the large predicted molecular volume of the both the new chemical substance and its hydrolysis products, which limit bioavailability and bioaccumulation. Although EPA estimates that the hydrolysis products could be very persistent, the hydrolysis products have low potential for bioaccumulation, such that repeated exposures are not expected to cause food chain effects via accumulation in exposed organisms

[3] Persistence: A chemical substance is considered to have limited persistence if it has a half-life in water, soil or sediment of less than 2 months or there are equivalent or analogous data. A chemical substance is considered to be persistent if it has a half-life in water, soil or sediments of greater than 2 months but less than or equal to 6 months or if there are equivalent or analogous data. A chemical substance is considered to be very persistent if it has a half-life in water, soil or sediments of greater than 6 months or there are equivalent or analogous data. (64 FR 60194; November 4, 1999)

[4] Bioaccumulation: A chemical substance is considered to have a low potential for bioaccumulation if there are bioconcentration factors (BCF) or bioaccumulation factors (BAF) of less than 1,000 or there are equivalent or analogous data. A chemical substance is considered to be bioaccumulative if there are BCFs or BAFs of 1,000 or greater and less than or equal to 5,000 or there are equivalent or analogous data. A chemical substance is considered to be very bioaccumulative if there are BCFs or BAFs of 5,000 or greater or there are equivalent or analogous data. (64 FR 60194; November 4 1999)

Human Health Hazard[5]: Human health hazard is relevant to whether a new chemical substance is likely to present an unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties and by comparing it to structurally analogous chemical substances for which there is information on human health hazard, as well as information in EPA's TSCA New Chemicals Program Chemical Category for Diisocyanates. EPA identified skin and lung sensitization and irritation as hazards based on the terminal isocyanate moieties. In addition, the new chemical substance contains approximately [claimed CBI] diisocyanate residuals. EPA qualitatively assessed the irritation and sensitization because dose-response information is not available for these endpoints.

Environmental Hazard[6]: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. The new chemical substance (nonionic polymer MW [claimed CBI] with [claimed CBI]% <500, [claimed CBI]% <1000) reacts with water (hydrolysis half-life of minutes to hours). Therefore, EPA estimated environmental hazard of this new chemical substance using the Ecological Structure Activity Relationships (ECOSAR) Predictive Model (https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-releationships-ecosar-predictive-model); specifically the QSAR for carbamate esters based on the low molecular weight (LMW) components (MW [claimed CBI]) of the hydrolyzed product. Acute toxicity

[5] A chemical substance is considered to have low human health hazard if effects are observed in animal studies with a No Observed Adverse Effect Level (NOAEL) equal to or greater than 1,000 mg/kg/day or if there are equivalent data on analogous chemical substances; a chemical substance is considered to have moderate human health hazard if effects are observed in animal studies with a NOAEL less than 1,000 mg/kg/day or if there are equivalent data on analogous chemical substances; a chemical substance is considered to have high human health hazard if there is evidence of adverse effects in humans or conclusive evidence of severe effects in animal studies with a NOAEL of less than or equal to 10 mg/kg/day or if there are equivalent data on analogous chemical substances. EPA may also use Benchmark Dose Levels (BMDL) derived from benchmark dose (BMD) modeling as points of departure for toxic effects. See https://www.epa.gov/bmds/what-benchmark-dose-software-bmds. Using this approach, a BMDL is associated with a benchmark response, for example a 5 or 10 % incidence of effect. The aforementioned characterizations of hazard (low, medium, high) would also apply to BMDLs. In the absence of animal data on a chemical or analogous chemical substance, EPA may use other data or information such as from in vitro assays, chemical categories (e.g., Organization for Economic Co-operation and Development, 2014 Guidance on Grouping of Chemicals, Second Edition. ENV/JM/MONO(2014)4. Series on Testing & Assessment No. 194. Environment Directorate, Organization for Economic Co-operation and Development, Paris, France. (http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)4&doclanguage=en)), structure-activity relationships, and/or structural alerts to support characterizing human health hazards.

[6] A chemical substance is considered to have low ecotoxicity hazard if the Fish, Daphnid and Algae LC50 values are greater than 100 mg/L, or if the Fish and Daphnid chronic values (ChVs) are greater than 10.0 mg/L, or there are not effects at saturation (occurs when water solubility of a chemical substance is lower than an effect concentration), or the log Kow value exceeds QSAR cut-offs. A chemical substance is considered to have moderate ecotoxicity hazard if the lowest of the Fish, Daphnid or Algae LC50s is greater than 1 mg/L and less than 100 mg/L, or where the Fish or Daphnid ChVs are greater than 0.1 mg/L and less than 10.0 mg/L. A chemical substance is considered to have high ecotoxicity hazard, or if either the Fish, Daphnid or Algae LC50s are less than 1 mg/L, or any Fish or Daphnid ChVs is less than 0.1 mg/L (Sustainable Futures https://www.epa.gov/sustainable-futures/sustainable-futures-p2-framework-manual).

values estimated for fish and aquatic invertebrates are no effects at saturation, and algae is 0.42 mg/L. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are 0.33 mg/L, 0.46 mg/L, and < 0.42 mg/L, respectively. These toxicity values indicate that the new chemical substance is expected to have high environmental hazard. Application of assessment factors of 4 and 10 to acute and chronic toxicity values, respectively, results in acute and chronic concentrations of concern of 0.105 mg/L (105 ppb) and 0.033 mg/L (33 ppb), respectively.

Exposure: The exposure to a new chemical substance is potentially relevant to whether a new chemical substance is likely to present unreasonable risks because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance.

EPA estimates occupational exposure and environmental release of the new chemical substance under the intended conditions of use described in the PMN using ChemSTEER (Chemical Screening Tool for Exposures and Environmental Releases https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases). EPA uses EFAST (the Exposure and Fate Assessment Screening Tool; https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014) to estimate general population, consumer, and environmental exposures.

EPA considers workers to be a potentially exposed or susceptible subpopulation (PESS) on the basis of greater exposure potential compared to the general population. EPA also considers PESS in conducting general population drinking water exposures by evaluating risks associated with water intake rates for multiple age groups, ranging from infants to adults. EPA considers consumers of specific products to be a potentially exposed or susceptible subpopulation on the basis of greater exposure potential compared to the general population who do not use specific products.

For this new chemical assessment, EPA assessed exposure to workers via the dermal and inhalation routes. Exposure to the general population via drinking water, fish ingestion, or inhalation was not assessed because releases to water and air are not expected. Exposures to consumers were not assessed because consumer uses were not identified as an intended condition of use.

Risk Characterization: EPA characterizes risks to human health and the environment by comparing the potential hazards and exposures for the chemical substance, estimated as described above. EPA assesses risks to workers considering engineering controls described in the PMN but in the absence of personal protective equipment (PPE) such as gloves and respirators. If risks are preliminarily identified, EPA then considers whether the risks would be mitigated by the use of PPE (e.g., impervious gloves, respirator).

Risks to human health for the new chemical were evaluated qualitatively. Irritation and sensitization hazards to workers were identified for dermal and inhalation exposures. Risks will be mitigated if exposures can be controlled by the use of appropriate PPE, including impervious gloves, eye protection, and a respirator. EPA expects that employers will require and workers will use appropriate personal protective equipment (i.e., impervious gloves, NIOSH certified

respirator APF 50), consistent with the Safety Data Sheet prepared by the PMN submitter, in a manner adequate to protect them.

For the intended conditions of use of the chemical substance, risks were not evaluated for the general population via inhalation or ingestion because there are no expected releases to water, based on information provided by the submitter, and releases to air are expected to be negligible (i.e., below modeling thresholds). Risks to consumers were not evaluated because consumer use was not identified as an intended condition of use.

Risks to the environment are not expected because no releases to water are associated with the intended conditions of use.

It is reasonably foreseen, based on extensive examples of LOCTITE products sold for consumer use with some with spray application, that this new chemical substance could be used by consumers and spray applied. It is also reasonably foreseen that manufacture, processing, or use could result in releases to water based on the information provided in the original PMN submission prior to amendment, which showed releases to water resulting in surface water concentrations above the COC. The SNUR that has been proposed for this chemical substance defines certain conditions of use as significant new uses. The proposed significant new uses are: use in consumer products, any use involving spray application that results in inhalation exposures, and any predictable or purposeful release into the waters of the United States that exceeds 33 ppb. Conditions of use that fall under the restrictions of the proposed SNUR are not likely to present unreasonable risk of injury to health or the environment because (1) those conditions of use are not likely to be commenced during the pendency of the proposed SNUR, and (2) upon finalization of the SNUR, those conditions of use would be prohibited unless and until EPA makes an affirmative determination that the significant new use is not likely to present an unreasonable risk or takes appropriate action under section 5(e) or 5(f).

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Date:

/s/
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