

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-21-0020

Number: P-21-0020

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

Chemical Name:

Generic: Alkanedioic acid, dialkyl ester, polymer with dialkyl-alkanediol, alkyl (substituted alkyl)-alkanediol and heteropolycycle

Conditions of Use (intended, known, or reasonably foreseen)¹:

Intended conditions of use (specific): Import for processing and use as, and use as a modifier for hardness development in paint formulations for metal applications, 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 evaluated whether there are reasonably foreseen conditions of use and identified use in a resin as reasonably foreseen based on prior TSCA submissions for analogous substances, and identified use in consumer products as reasonably foreseen based on an internet search.

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. Although EPA estimated that the new chemical substance could be very persistent, the substance has low potential for bioaccumulation, such that repeated exposures are not expected to cause

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.

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food-chain effects via accumulation in exposed organisms. Based on test data on analogous chemical substances and physical/chemical properties of the new chemical substance, EPA estimates that the chemical substance has low environmental hazard and potential for the following human health hazards: skin and eye irritation. EPA concludes that the new chemical substance is not likely to present an unreasonable risk under the conditions of use.

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 the new chemical substance using data for analogue(s) (polymers). In wastewater treatment, the new chemical substance is expected to be removed with an efficiency of 90% due to sorption. Removal of the new chemical substance by biodegradation is negligible. Sorption of the new chemical substance to sludge is expected to be strong and to soil and sediment is expected to be very strong. Migration of the new chemical substance to groundwater is expected to be negligible due to very strong sorption to soil and sediment. Due to low estimated vapor pressure and Henry's law constant, the new chemical substance is expected to undergo negligible volatilization to air. Overall, these estimates indicate that the new chemical substance has low potential to volatilize to air or migrate to groundwater.

Persistence²: 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. EPA estimated degradation half-lives of the new chemical substance using data submitted for analogue(s) (polymers). EPA estimated that the new chemical substance's aerobic and anaerobic biodegradation half-lives are > 6 months. These estimates indicate that the new chemical substance may be very persistent in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment).

Bioaccumulation³: 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. EPA estimated the potential for the new chemical substance to bioaccumulate using data for analogue(s) (polymers). EPA estimated that the new chemical substance has low

² 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 if 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 if there are equivalent or analogous data. (64 FR 60194; November 4, 1999)

³ 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 if 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 if there are equivalent or analogous data. (64 FR 60194; November 4 1999)

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bioaccumulation potential based on large predicted molecular volume, which limits bioavailability. Although EPA estimated that the new chemical substance could be very persistent, the substance has low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms.

Human Health Hazard⁴: 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, test data on residuals and potential hydrolysis products, and other structural information. Absorption of the new chemical substance and the LMW fraction < 1000 Dalton (Da) is expected to be poor to moderate through skin when neat, moderate through skin when in solution, and nil through the lungs and gastrointestinal (GI) tract based on physical/chemical properties. Absorption of the LMW fraction < 500 Da is expected to be poor to moderate through the skin when neat, moderate to good through the skin when in solution, poor through the lungs, and good through the GI tract based on physical/chemical properties. For the new chemical substance, EPA identified skin irritation based on test data for hydrolysis products [claimed CBI] and [claimed CBI]; and eye irritation based on test data for a feedstock residual, [claimed CBI], and a hydrolysis product, [claimed CBI], as well as the information provided in the Safety Data Sheet (SDS). No systemic effects were identified as hazards; therefore, no quantitative POD was identified for the new chemical substance. EPA qualitatively evaluated irritation effects.

Environmental Hazard⁵: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risk because the significance of the risk is dependent

⁴ 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](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.

⁵ 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

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upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated environmental hazard using predictions based on the negligible water solubility of the new chemical substance. Acute and chronic toxicity values estimated for fish, aquatic invertebrates, and algae are all no effects at saturation. These toxicity values indicate that the new chemical substance is expected to have low environmental hazard. Because hazards are not expected up to the water solubility limit, acute and chronic concentrations of concern are not identified.

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 worker exposure via dermal contact. Inhalation hazards are not identified; therefore inhalation exposures to workers were not assessed. Releases to air and landfill were estimated. EPA did not assess releases to water because health hazards via ingestion were not identified and ecological hazards were assessed to be low. Exposure to the general population was not assessed via drinking water, fish ingestion, or groundwater impacted by landfill leachate because oral hazards were not identified. Exposure to the general population was not assessed via stack air or fugitive air because inhalation hazards were not identified. Exposure to consumers was assessed via dermal contact.

Risk Characterization: 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).

ChVs is less than 0.1 mg/L (Sustainable Futures <https://www.epa.gov/sustainable-futures/sustainable-futures-p2-framework-manual>).

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Based on the hazard determination and available qualitative risk information, EPA did not identify risks for the new chemical substance. Irritation hazards to workers via dermal contact were identified based on test data for the expected hydrolysis products and feedstocks. Risks for these endpoints were not quantified due to a lack of dose-response for these hazards. No relevant systemic hazards were identified for the new chemical substance; therefore, dermal risks were not quantified. Based on no relevant systemic hazards, dermal risks are not expected. Inhalation hazards are not identified, therefore inhalation exposures were not assessed. Risks will be mitigated if exposures are controlled by the use of appropriate PPE, including impervious gloves and eye protection, for the intended use and the reasonably foreseen resin use. EPA expects that employers will provide and workers will use appropriate PPE (i.e., impervious gloves and eye protection), consistent with the SDS prepared by the PMN submitter, in a manner adequate to protect workers from irritation via dermal exposure.

Risks to the general population were not evaluated because health hazards via the ingestion and inhalation routes were not identified.

EPA identified consumer use of the new chemical substance as reasonably foreseen. No relevant systemic hazards were identified for the new chemical substance; therefore, dermal risks to consumers were not quantified. Based on no relevant systemic hazards, dermal risks are not expected. EPA assumes that skin and eye irritation is possible from exposure to the new chemical substance in a consumer product based on its intended use at levels $\geq 3\%$, and its irritating properties are assumed to persist even in the presence of other unknown components⁶. However, for this chemical substance and use, EPA does not consider dermal irritation to consumers to lead to unreasonable risks.

Risks from acute and chronic exposures to the environment are not expected at any concentration of the new chemical substance soluble in the water (i.e., no effects at saturation).

Because worker exposures can be controlled by PPE, and no unreasonable risks to the general population, consumers, or the environment were identified, EPA has determined that the new chemical substance is not likely to present unreasonable risk to human health or the environment under the conditions of use.

⁶ EPA is using the *Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Eighth Revised Edition* (UN, New York, <https://doi.org/10.18356/f8fbb7cb-en>, Chapters 3.2 and 3.3), to establish the cut-off value for the new chemical substance's skin and eye irritation effects in consumer products. EPA will consider a new chemical substance in a mixture to be irritating to the skin or eye when intended to be used at $\geq 3\%$ in the mixture. When selecting the cut-off value, EPA assumes that a mixture containing irritant ingredients cannot be evaluated based on the additivity approach. The theory of additivity assumes that each ingredient contributes to the overall irritant properties of the mixture in proportion to its potency and concentration. However, there are types of chemicals that the theory of additivity might not apply, for instance where an ingredient contributes to the overall irritation properties of the mixture to a greater extent than its proportion would suggest (e.g., synergy). Annex 5 of the GHS document states “[e]stimates of possible exposures and risk to consumers should be based on conservative, protective assumptions to minimize the possibility of underestimating exposure or risks [Section A5.2.1(c)].” Thus, EPA selected the more health-protective cut-off value ($\geq 3\%$) under the assumption that the additivity approach does not apply for the new chemical substance in relation to the other ingredients in the consumer product.

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