

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-22-0164

Number: P-22-0164

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

Chemical Name:

Specific: Fatty acids, C18-unsatd., dimers, polymers with 1,4:3,6-dianhydro-D-glucitol, 1,3-propanediol and succinic acid; CASRN: 2651284-66-9

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

Intended conditions of use (generic): Manufacture and process for use as and use as a reactive intermediate polyester polyol and polyester polyol diluent, 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 identified 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 without worker PPE and hazard communication and release to a different receiving body of water based on submitter provided NPDES #.

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

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 chemical substance may be manufactured, processed, distributed, used, or disposed of. EPA expects that the identification of “reasonably foreseen” conditions of use will be made on a fact-specific, case-by-case basis. EPA will apply its professional judgment and experience when considering factors such as evidence of current use of the new chemical substance outside the United States, information about known or intended uses of 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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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) and EPI (Estimation Program Interface) Suite™ (<http://www.epa.gov/tsca-screening-tools/epi-suite™-estimation-program-interface>). In wastewater treatment, the new chemical substance is expected to be removed with an efficiency of 90% due to biodegradation and possible sorption. Removal of the new chemical substance by biodegradation is moderate to high. Sorption of the new chemical substance to sludge is expected to be low to strong and to soil and sediment is expected to be low to very strong. Migration of the new chemical substance to groundwater is expected to be negligible due to very strong sorption to soil and sediment or biodegradation. 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 for analogue(s) (polymers) and EPI Suite™. EPA estimated that the new chemical substance's aerobic and anaerobic biodegradation half-lives range from < 2 months to 6 months. These estimates indicate that the new chemical substance may be 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) and EPI Suite™. EPA estimated that the new chemical substance has low bioaccumulation potential based on large predicted molecular volume, which limits bioavailability (high MW fraction), and BCFBAF model results <1,000 (low MW fraction) (bioconcentration factor = 3 (estimated by linear regression from log Kow) and bioaccumulation

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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factor = 1 (estimated by the Arnot-Gobas method (2003)⁴). Although EPA estimated that the new chemical substance could be 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 Hazard⁵: 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, by comparing it to structurally analogous chemical substances for which there are information on human health hazard, and test data for metabolites. Absorption of the new chemical substance as the parent polymer is expected to be poor through the skin and nil through the lungs and gastrointestinal (GI) tract based on physical/chemical properties. Absorption of the low molecular weight (LMW) fractions < 500 Da (16%) and < 1,000 Da (31.78%) is expected to be poor through the skin, good through the lungs, and poor through the GI tract based on physical/chemical properties. For the new chemical substance, EPA identified hazards for skin and eye irritation based on test data for a potential metabolite. There are no measured data on the new chemical substance. EPA qualitatively evaluated irritation effects.

Environmental Hazard⁶: 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 Arnot JA, Gobas FAPC. 2003. A generic QSAR for assessing the bioaccumulation potential of organic chemicals in aquatic food webs. *QSAR and Combinatorial Science* 22: 337-345.

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](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

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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 of this new chemical substance using the Ecological Structure Activity Relationships (ECOSAR) Predictive Model (<https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model>); specifically the QSAR for Esters. This substance falls within the TSCA New Chemicals Category of Esters. Acute toxicity values estimated for fish, aquatic invertebrates, and algae are > 100 mg/L, > 100 mg/L, and > 100 mg/L, respectively. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are > 10 mg/L, > 10 mg/L, and > 10 mg/L, respectively. These toxicity values indicate that the new chemical substance is expected to have low environmental hazard. Application of assessment factors of 5 and 10 to acute and chronic toxicity values, respectively, results in acute and chronic concentrations of concern of 20 mg/L (20,000 ppb) and 1 mg/L (1,000 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 worker exposure via dermal exposure. Inhalation exposures to workers is not expected. Releases to water, landfill, and air were estimated. Exposure to the general population was assessed via drinking water, fish ingestion, and inhalation of stack air. Exposure to the general population was not assessed via groundwater impacted by landfill leachate because migration to groundwater is expected to be negligible. Exposure to the general population was not assessed via fugitive air inhalation because releases are not expected. Consumer exposures were not assessed because consumer uses were not identified as intended conditions of use.

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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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).

Skin and eye irritation hazards to workers were identified based on test data for a potential metabolite. 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 via dermal contact; therefore, risks were not calculated.

Dermal and eye irritation hazards to the general population are not expected via drinking water ingestion, fish ingestion, or stack air releases due to dilution of the chemical substance in the media. No relevant systemic hazards were identified for the new chemical via drinking water, fish ingestion, or inhalation of stack air; therefore, risks were not calculated. Risks were not evaluated for the general population via groundwater impacted by landfill leachate because migration to groundwater is expected to be negligible. Risks were not evaluated for the general population via fugitive air inhalation because releases to fugitive air are not expected. Risks to consumers were not evaluated because consumer uses were not identified as conditions of use.

Risks to the environment were not identified because the new chemical substance is expected to have low environmental hazard. The reasonably foreseen condition of use of release to a different receiving body of water is not expected to result in unreasonable risk because there is low environmental hazard.

Because no unreasonable risks to workers, the general population or environment were identified, and there are no expected consumer exposures, 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.

8/17/2023
Date:

/s/
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