

TSCA Section 5(a)(3) Determination for Significant New Use Notices (SNUNs) SN-24-0005-0006

Number: SN-24-0005/ SN-24-0006

TSCA Section 5(a)(3) Determination: The significant new uses are not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:

Generic: Dicarboxylic acids, polymers with alkanolic acid, alkanediol, substituted-alkylalkanoic acid, substituted alkyl carbonyl, alkanedioic acid and alkanediol, alkanolamine blocked, compds with alkanolamine

Significant New Use: The SNUNs were submitted for the specific new use of the substances containing a proportion of amine counterions greater than 4% by weight. The significant new use rule (SNUR) at 40 CFR 721.11304 for these chemical substances requires notification to EPA for manufacture, processing, or use of the PMN substances such that the proportion of amine counterions is greater than 4% by weight; the average molecular weight is smaller than the molecular weight specified in the PMNs or the proportion of the low molecular weight species is greater than the values specified in the PMNs for the 500 and 1000 Dalton species; the proportion of the acid group is greater than 20% by weight substance; or free isocyanate residuals are present at greater than 0.1% by weight.

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

Intended conditions of use (generic): Import for use in, and use in, paints, consistent with the use, distribution, and disposal information described in the SNUN.

Known conditions of use: Applying such factors as described in footnote 1, EPA evaluated whether there are known conditions of use and found, based on previous TSCA submissions: use in [contains CBI].

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 any condition of use of a chemical substance that EPA believes is ongoing in the United States at the time of submission of the notification, as well as 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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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 domestic manufacture, use as an additive in coatings, and use in a consumer products based on analogue uses as reasonably foreseen.

Summary: The significant new uses are 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 the SNUR for the chemical substances. Although EPA estimated that the chemical substances could be very persistent (anions), the substances have a low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms. Based on EPA's TSCA New Chemicals Program Chemical Category for Polyanionic Polymers², their estimated physical/chemical properties, and by comparing them to structurally analogous chemical substances for which there is information on human health hazard, EPA estimates that the chemical substances have low environmental hazard and low human health hazard. EPA concludes that the significant new uses are 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 significant new use of a chemical may present an unreasonable risk. EPA estimated physical/chemical and fate properties of the anions using data for analogues (polymers) and of the cations using data for the cations and EPI (Estimation Program Interface) Suite™ (<http://www.epa.gov/tsca-screening-tools/epi-suite-estimation-program-interface>). In wastewater treatment, the anions are expected to be removed with an efficiency of 0% to 50% due to possible sorption and the cations are expected to be removed with an efficiency of 90% due to biodegradation. Removal of the anions by biodegradation is negligible and removal of the cations by biodegradation is high. Sorption of the anions to sludge, soil, and sediment is expected to be low to moderate and sorption of the cations to sludge, soil, and sediment is expected to be low. Migration of the anions to groundwater is expected to be moderate to rapid due to low to moderate sorption to soil and sediment and migration of the cations to groundwater is expected to be negligible due to biodegradation. Due to low estimated vapor pressure and Henry's law constant, the anions and the cations are expected to undergo negligible volatilization to air in wastewater treatment. Overall, these estimates indicate that the anions have low potential to volatilize to air in wastewater treatment and have moderate to high potential to migrate to groundwater; and that the cations have low potential to volatilize to air in wastewater treatment or migrate to groundwater.

² TSCA New Chemicals Program (NCP) Chemical Categories. <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemical-categories-used-review-new>.

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Persistence³: Persistence is relevant to whether a significant new use of a 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 anions using data for analogues (polymers) and of the cations using data for the cations and EPI Suite™. EPA estimated that the anions' aerobic and anaerobic biodegradation half-lives are > 6 months; and that the cations' aerobic and anaerobic biodegradation half-lives are < 2 months. These estimates indicate that the anions may be very persistent in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment). Further, these estimates indicate that the cations may have limited persistence in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment).

Bioaccumulation⁴: Bioaccumulation is relevant to whether a significant new use of a 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 anions to bioaccumulate using data for analogues (polymers) and of the cations to bioaccumulate using EPI Suite™. EPA estimated that the anions have low bioaccumulation potential based on large predicted molecular volume, which limits bioavailability, and the cations have low bioaccumulation potential based on BCFBAF model result < 1000 (cations bioconcentration factor = 3 (estimated by linear regression from log Kow) and bioaccumulation factor = 1 (estimated by the Arnot-Gobas method (2003)))⁵. Although EPA estimated that the anions could be very persistent, the substances have low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms. EPA estimated that the cations could have limited persistence and low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms.

Human Health Hazard⁶: Human health hazard is relevant to whether a significant new use of a

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 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)

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 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 if 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)

⁵ 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.

⁶ 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

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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 the chemical substances based on their estimated physical/chemical properties and available test data on the neutral forms of their cations. Absorption of the parent polymers (>1000 Da) and low molecular weight (LMW) fractions <1000 Da ([contains CBI]%) is predicted to be nil to poor through the skin when neat, poor through the skin when in solution, and nil through the lungs and gastrointestinal tract based on physical/chemical properties. Absorption of the LMW fractions <500 Da ([contains CBI]%) is predicted to be nil to poor through the skin when neat, poor to moderate through the skin when in solution, and moderate through the lungs and gastrointestinal tract based on physical/chemical properties. For the chemical substances, EPA did not identify any hazards. No test data were submitted for the chemical substances. EPA did not identify a point of departure based on no hazard concerns identified.

Environmental Hazard⁷: Environmental hazard is relevant to whether a significant new use of a 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. EPA estimated environmental hazard for the chemical substances based on SAR predictions for Polyanionic Polymers (special class within ECOSAR v.2.2). These substances fall within the TSCA New Chemicals Category of Polyanionic Polymers. Acute toxicity values estimated for fish, aquatic invertebrates, and algae are all >100 mg/L, respectively. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are all >10 mg/L, respectively. The chemical substances are 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.

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.

⁷ 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>).

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Exposure: The exposure to a chemical substance is potentially relevant to whether a significant new use of a 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 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 risk assessment, EPA did not assess worker exposures via the dermal or inhalation routes because no human health hazards were identified. Exposures to the general population were not assessed because no human health hazards were identified. Consumer exposures were not assessed because consumer uses were not identified as intended conditions of use.

Risk Characterization: Due to low hazard, EPA believes that the significant new uses would be not likely to present an unreasonable risk even if potential exposures were high. Therefore, EPA concludes that the significant new uses are not likely to present unreasonable risk under the conditions of use.

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Date: _____

/s/

Shari Z. Barash, Director
New Chemicals Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency