

TSCA Section 5(a)(3) Determination for Premanufacture Notices (PMNs) P-20-0148-0149-0150-0151

Number: P-20-0148-0149-0150-0151

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

Chemical Name:

Generic: Hydroxyalkanoic acid, salt, oxidized

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

Intended conditions of use (generic): Manufacture and process for use as and use as an additive for consumer, industrial, and commercial uses, 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 found use as chemical intermediates as reasonably foreseen based on prior TSCA submissions for analogous chemical substances, and found use at a higher percentage in formulation in consumer products as reasonably foreseen based on an amendment to the submission.

Summary: The chemical substances 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. The new chemical substances are ionic compounds, or salts, that are comprised of both an anion and cation. EPA estimated that the anions 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. Estimations of physical/chemical and fate properties are not applicable for the cations; the cations are elements (alkali metals) and are unlikely to impact the overall persistence and bioaccumulation of the new chemical substance. Based on estimated physical/chemical properties and by comparing them to structurally analogous chemical substances, EPA estimates that the chemical substances have moderate environmental hazard 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 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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potential for the following human health hazards: skin irritation and eye irritation. EPA concludes that the new chemical substances 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 chemical may present an unreasonable risk. EPA estimated physical/chemical and fate properties of the anions of the new chemical substances using data for analogous substances and EPI (Estimation Program Interface) Suite™ (<http://www.epa.gov/tsca-screening-tools/epi-suite-estimation-program-interface>). Estimations of physical/chemical and fate properties are not applicable to the cations because the cations of the new chemical substances are elements (alkali metals) and are unlikely to impact the overall persistence and bioaccumulation of the new chemical substances. The cations are not expected to drive the human health and eco hazard assessments. The cations are also not expected to be a concern for food chain effects and were not evaluated for persistence and bioaccumulation. In wastewater treatment, the anions are expected to be removed with an efficiency of 90% to 95% due to biodegradation. Removal of the anions by biodegradation is high and destruction (mineralization) of the anions by biodegradation is complete. Sorption of the anions to sludge, soil, and sediment is expected to be low. Migration of the anions to groundwater is expected to be negligible due to biodegradation. Due to low estimated vapor pressure and Henry's law constant, the anions are expected to undergo negligible volatilization to air. Overall, these estimates indicate that the anions have 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 anions of the new chemical substances using data for analogous substances. EPA estimated that the anions' aerobic and anaerobic biodegradation half-lives are < 2 months. These estimates indicate that the anions may have limited persistence 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

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

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species pose the potential for elevated exposures to humans and other organisms via food chains. EPA estimated the potential for the new chemical substances to bioaccumulate using EPI Suite™. EPA estimated that the anions of the new chemical substances have low bioaccumulation potential based on BCFBAF model result < 1000 (bioconcentration factor = 3 (estimated by linear regression from log Kow) and bioaccumulation factor = 1 (estimated by the Arnot-Gobas method (2003)⁴). EPA estimated that the anions 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 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 the new chemical substances based on their estimated physical/chemical properties and by comparing them to structurally analogous chemical substances for which there is information on human health hazard. Absorption of the new chemical substances is expected to be poor to moderate through the skin when neat and moderate when in solution, nil through the gastrointestinal tract, and good through the lungs based on physical/chemical properties. For the new chemical substances, EPA identified irritation to skin, eyes, and respiratory tract based on pH and the acid groups as hazards. No data were submitted on the new chemical substances. 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

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)

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

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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 these new chemical substances using hazard data for analogous chemicals. These substances fall within the TSCA New Chemicals Category of Polyanionic Polymers (& Monomers)⁷. Acute toxicity values estimated for fish, aquatic invertebrates, and algae are >100 mg/L, > 100 mg/L, and 95.2 mg/L, respectively. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are >10 mg/L (acute-to-chronic ratio (ACR) 10), > 10 mg/L (ACR 10), and 8.19 mg/L, respectively. These toxicity values indicate that the new chemical substances are expected to have moderate 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 20 mg/L (20,000 ppb; default highest acute COC; rounded down from 23,796 ppb) and 0.819 mg/L (819 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 the dermal and inhalation routes. Releases to water, air, and landfill were estimated. Exposure to the general population was assessed via drinking water and fugitive air inhalation. Exposure to the general population was not assessed via fish ingestion because the bioaccumulation potential was evaluated to be low or via groundwater impacted by landfill leachate or stack air inhalation because releases to

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>).

⁷ 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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landfill and air were expected to be negligible (below modeling thresholds). Exposure to the general population resulting from down-the-drain consumer uses was assessed via drinking water and exposure to consumers was assessed via dermal contact, oral ingestion, and inhalation.

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).

For this new chemical assessment, risks to human health for the new chemical substances were qualitatively evaluated. Based on the hazard determination and available qualitative risk information, EPA did not identify risks for the new chemical substances. Irritation hazards to workers via inhalation and dermal contact were identified based on pH (3-5 at 60% in water). 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 substances; therefore, risks were not calculated. Based on no identified relevant systemic hazards, risks are not expected. EPA expects that employers will provide and workers will use appropriate PPE (i.e., impervious gloves, eye protection, and respiratory protection), consistent with the safety data sheet prepared by the PMN submitter, in a manner adequate to protect workers from irritation via dermal and inhalation exposures under the intended and reasonably foreseen conditions of use.

Irritation hazards to the general population are not expected via drinking water ingestion or fugitive air releases due to dilution of the chemical substances in the media. No relevant systemic hazards were identified for the new chemical substances; therefore, risks were not calculated. Based on no identified hazards, risks are not expected.

EPA assumes that skin, eye, and respiratory tract irritation is possible from exposure to the new chemical substances in a consumer product based on the chemical structure and/or properties of the new chemical substances and their irritating properties are assumed to persist even in the presence of other unknown components. EPA does not consider irritation to consumers to be unreasonable risk. No relevant systemic hazards were identified for the new chemical substances; therefore, risks were not calculated. Based on no identified relevant systemic hazards, risks are not expected.

Risks to the environment were evaluated by comparing estimated surface water concentrations with the acute and chronic concentrations of concern. Risks from acute exposure to the environment were not identified due to releases to water that did not exceed the acute COC. Risks from chronic exposure to the environment were not identified since the chronic COC is exceeded less than 20 days per year⁸. EPA expects releases from the reasonably foreseen conditions of use (i.e., use as a chemical intermediate) to be lower than from the intended use and therefore not likely to present unreasonable risk.

⁸ The 20-day criterion for concluding chronic risk is not likely is based on partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration.

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Because no unreasonable risks to workers, the general population, consumers, or the environment were identified, EPA has determined that the new chemical substances are not likely to present unreasonable risk to human health or the environment under the conditions of use.

8/30/2021
Date:

/s/
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