TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-23-0170

Number: P-23-0170
TSCA Section 5(a)(3) Determination: The chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic: Ethanaminium, 2-[3-(2,5-dioxo-1-heteromonocyclic) propoxy]-N,N,N-trimethyl-, monopolyisobutylene derivs., Me ethanedioate

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (generic): Import and process for use as and use as a fuel additive, 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 the following reasonably foreseen conditions of use: domestic manufacture, use as a pigment dispersant, use that results in inhalation exposures, and use at a higher production volume based on analogues.

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.

EPA estimated that the anion 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. Although EPA estimated that the cation 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. Based on test data on the new chemical substance, data on analogous chemical substances and estimated

[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.

physical/chemical properties, EPA estimates that the chemical substance has low environmental hazard and no human health hazards were identified. 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 anion using EPI (Estimation Program Interface) Suite™ (http://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface) and of the cation using data for analogue(s) (polymers). In wastewater treatment, the anion is expected to be removed with an efficiency of 90% due to biodegradation, and the cation is expected to be removed with an efficiency of 90% due to sorption. Removal of the anion by biodegradation is high, and removal of the cation by biodegradation is negligible. Sorption of the anion to sludge, soil, and sediment is expected to be low, and sorption of the cation to sludge, soil, and sediment is expected to be very strong. Migration of the anion to groundwater is expected to be negligible due to biodegradation, and migration of the cation 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 anion and the cation are expected to undergo negligible volatilization to air. Overall, these estimates indicate that the anion and the cation have low potential to volatilize to air and low potential to migrate to groundwater.

Persistence[2]: 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 anion using EPI Suite™ and of the cation using data for analogue(s) (polymers). EPA estimated that the anion's aerobic and anaerobic biodegradation half-lives are < 2 months; and that the cation's aerobic and anaerobic biodegradation half-lives are > 6 months. These estimates indicate that the anion may have limited persistence in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment). Further, these estimates indicate that the cation may be very persistent in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment).

Bioaccumulation[3]: 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 5,000 or there are equivalent or analogous data. A chemical substance is considered to be very

species pose the potential for elevated exposures to humans and other organisms via food chains. EPA estimated the potential for the anion to bioaccumulate using EPI Suite™ and of the cation to bioaccumulate using data for analogue(s) (polymers). EPA estimated that the anion has low bioaccumulation potential based on BCFBAF model result < 1000 and the cation has low bioaccumulation potential based on large predicted molecular volume, which limits bioavailability (anion 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 anion 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. Although EPA estimated that the cation 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 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, available data on the new chemical substance and a hydrolysis product, and by comparing it to structurally analogous chemical substances for which there is information on human health hazard. Absorption of the new chemical substance as the parent polymer and the low molecular weight (LMW) fraction < 1000 Da ([claimed CBI]%) is predicted to be nil to poor through the skin, and nil through the lungs and gastrointestinal (GI) tract based on physical/chemical properties. Absorption of the LMW fraction < 500 Da ([claimed CBI]%) is predicted to be poor to moderate through the skin, poor through the lungs, and moderate through the GI tract based on physical/chemical properties. For the new chemical substance, EPA did not identify any hazards. Submitted tests of the new chemical substance

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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)), structure-activity relationships, and/or structural alerts to support characterizing human health hazards.

reported the test substance as not acutely toxic by the oral or dermal routes (OECD 423, OECD 402), slightly irritating to skin (OECD 404), minimally irritating to eyes (OECD 405), not sensitizing to skin (OECD 406), not genotoxic (OECD 471, OECD 473, OECD 490), and causing no adverse effects in repeat dose oral studies (OECD 407, OECD 408) and no maternal or developmental toxicity in developmental studies (OECD 414, non-guideline).

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. EPA determined the environmental hazard for this new chemical substance based on acute and chronic toxicity data submitted and physical chemical properties of the new chemical substance. This substance falls within the TSCA New Chemicals Category of cationic surfactants. Acute and chronic toxicity values for fish, aquatic invertebrates, and algae are all no effects at saturation. 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 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.

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

[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).

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Date:

/s/
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