TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-20-0161

Number: P-20-0161
TSCA Section 5(a)(3) Determination: The chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Specific: Propanedioic acid, 2-methylene-, 1,3-diethyl ester, polymer with 1,4-butanediol

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (specific): Manufacture and process for use as and use as a film former or crosslinker additive used in coatings and adhesives, and as a crosslinker additive used in waterborne emulsions consistent with the manufacturing, processing, use, distribution, and disposal information described in the PMN.
Known conditions of use: EPA evaluated whether there are known conditions of use and found none.
Reasonably foreseen conditions of use: EPA evaluated whether there are reasonably foreseen conditions of use and found none.

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 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 polymerization product 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

[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.

organisms. Based on EPA's TSCA New Chemicals Program Chemical Category for Acrylates/Methacrylates[2] and test data on analogous chemical substances, EPA estimates that the chemical substance has low environmental hazard and potential for the following human health hazards: acute toxicity, skin irritation, serious eye damage, and skin sensitization. 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 analogues (rapidly polymerizable compounds) and of the polymerization product using data for analogues (polymers). In wastewater treatment, the new chemical substance is expected to be removed with an efficiency of 90% to 99% due to rapid polymerization and the polymerization product is expected to be removed with an efficiency of 90% due to sorption. Removal of the polymerization product by biodegradation is negligible. Sorption of the polymerization product 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 rapid polymerization and migration of the polymerization product 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 and the polymerization product are expected to undergo negligible volatilization to air. Overall, these estimates indicate that the new chemical substance and the polymerization product have low potential to volatilize to air and low potential to migrate to groundwater.

Persistence[3]: 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 analogues (rapidly polymerizable compounds) and of the polymerization product using data for analogues (polymers). EPA estimated that the new chemical substance's polymerization half-life is minutes to hours, and that the polymerization product's aerobic and anaerobic biodegradation half-lives are > 6 months. These estimates indicate that the new chemical substance may have limited persistence in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediments) due to polymerization. Further, these estimates indicate that the polymerization

[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.

[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)

product may be very persistent in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment).

Bioaccumulation[4]: 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 analogues (rapidly polymerizable compounds) and of the polymerization product to bioaccumulate using data for analogues (polymers). EPA estimated that the new chemical substance has low bioaccumulation potential based on rapid polymerization of the parent compound and the polymerization product has low bioaccumulation potential based on large predicted molecular volume, which limits bioavailability. EPA estimated that the new chemical substance 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 polymerization product 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, by comparing it to structurally analogous chemical substances for which there are information on human health hazard. The new chemical substance is expected to react with water to polymerize within minutes to hours; the polymerization

[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 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] 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.

product will be a highly crosslinked, high molecular weight polymer. Absorption of the parent polymer is expected to poor via the skin based on the MW <1000 and nil via the GI and lungs; rapid polymerization is expected when exposure to water. Absorption of the low molecular weight (LMW) fractions (15.42% < 500 Daltons, 44.23% < 1000 Daltons) is expected to be good through the skin, moderate through the GI tract, and poor through the lungs based on physical/chemical properties; however, the LMW fractions are also expected to undergo rapid polymerization when exposed to water. EPA identified hazards for the new chemical substance based on its expected reactivity and based on test data for analogues of the LMW fractions. EPA identified skin, respiratory tract, and eye irritation, and skin sensitization based on submitted data on analogues to the LMW fractions. EPA also identified local stomach effects based on analogue data and acute inhalation toxicity based on reactivity if the new chemicals substances are ingested or inhaled, respectively. Submitted tests on analogues to the LMW fractions indicate that the substances are skin sensitizers (OECD 422D and OECD 429), increased aberrations in a chromosomal aberration test (OECD 473), are not corrosive *in vitro* (OECD 431), and have low oral acute toxicity (OECD 420). No POD was identified to quantify hazards. EPA qualitatively evaluated acute inhalation toxicity, skin, eye, respiratory tract irritation, and skin sensitization.

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 environmental hazard for this new chemical substance based on SAR predictions for nonionic polymers (special class within ECOSAR V2.0).This substance falls within the TSCA New Chemicals Category of Acrylates/Methacrylates. 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-

[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).

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 and inhalation exposures. Releases to air, and landfill were estimated. Exposure to the general population was assessed via fugitive air inhalation. Exposures to the general population were not assessed via drinking water and fish ingestion because releases to surface water are not expected or via groundwater impacted by landfill leachate and stack air inhalation because exposures were expected to be negligible (below modeling thresholds). Consumer exposures were not assessed because consumer uses were not identified as conditions of use.

Risk Characterization: EPA assesses risks to workers considering engineering controls described in the PMN but on 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).

Risks to human health for the new chemical substance were evaluated qualitatively. EPA identified skin, eye, respiratory tract irritation, skin sensitization, and acute inhalation toxicity hazards to worker based on data for analogues of the LMW fractions of the new chemical substances and reactivity in water. Risks for these endpoints were not quantified due to a lack of dose-response information for these hazards. However, exposures can be mitigated by the use of appropriate personal protective equipment (i.e., impervious gloves, eye protection, and respiratory protection) consistent with the Safety Data Sheet (SDS) prepared by the PMN submitter, in a manner adequate to protect them.

Risks were not evaluated for the general population via drinking water or fish ingestion because releases to surface water are not expected or via groundwater impacted by landfill leachate and stack air inhalation because exposures were expected to be negligible. Corrosion and sensitization hazards to the general population are not expected via fugitive air releases due to dilution and/or rapid polymerization of the chemical substance in the media. Risks to consumers were not evaluated because consumer uses were not identified as conditions of use.

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

Because worker exposures can be controlled by PPE, no unreasonable risks to 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.

11/14/2020
Date:

/s/
Madison H. Le, Director
New Chemicals Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency