

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-21-0087

Number: P-21-0087

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

Chemical Name:

Generic: Syrups, hydrolyzed starch, dehydrated, polymers with methacrylic acid and alkenenylbenzene

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

Intended conditions of use (generic): Import and process for use as and use as a detergent 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 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 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 biodegradation 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. Based on EPA's TSCA New Chemicals Program Chemical Category for polyanionic polymers², test data on PMN substance, and analogous chemical substances, EPA estimates that the chemical substance has moderate environmental hazard and low human health hazard. 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.

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>.

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-21-0087

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) (starches) and data submitted for the new chemical substance and of the biodegradation product using data for analogue(s) [claimed CBI]. In wastewater treatment, the new chemical substance is expected to be removed with an efficiency of 90% due to sorption and biodegradation and the biodegradation product is expected to be removed with an efficiency of 90% due to sorption. Removal of the new chemical substance by biodegradation is moderate to high, destruction (mineralization) of the new chemical substance by biodegradation is partial, and removal of the biodegradation product by biodegradation is negligible. Sorption of the new chemical substance to sludge, soil, and sediment is expected to be moderate to strong and sorption of the biodegradation 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 biodegradation and migration of the biodegradation 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 biodegradation product are expected to undergo negligible volatilization to air. Overall, these estimates indicate that the new chemical substance and the biodegradation product have low potential to volatilize to air and low potential to migrate to groundwater.

Persistence³: 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) (starches) and data submitted for the new chemical substance and of the biodegradation product using data for analogue(s) [claimed CBI]. EPA estimated that the new chemical substance's aerobic and anaerobic biodegradation half-lives are < 2 months, and that the biodegradation 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., sediment). Further, these estimates indicate that the biodegradation product may be very persistent in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment).

Bioaccumulation⁴: 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

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

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-21-0087

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) (starches) and of the biodegradation product to bioaccumulate using data for analogue(s) [claimed CBI]. EPA estimated that the new chemical substance and the biodegradation product have 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 biodegradation 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.⁵

Human Health Hazard⁶: 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 and available data on the new chemical substance. Absorption of the new chemical substance as the parent polymer is expected to be nil to poor through the skin, and nil through the gastrointestinal (GI) tract and lungs, based on physical/chemical properties. Absorption of the low molecular weight fraction of the new chemical substance is expected to be nil to poor through the skin when neat, poor through the skin in solution, and nil through the GI tract and lungs based on physical/chemical properties. For the new chemical substance, EPA did not identify any significant hazard concerns. Submitted tests on the new chemical substance reported the test substance as not acutely toxic in rats (OECD 423), non-corrosive and non-irritating to skin *in vitro* (OECD 431 and 439, respectively), non-irritating to eyes *in vitro* (OECD 492), non-sensitizing to skin in

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 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 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.

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-21-0087

mice (OECD 429), and non-mutagenic in a bacterial reverse mutation assay (OECD 471). No quantitative POD was selected as there were no hazard concerns identified.

Environmental Hazard⁷: 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 toxicity data submitted for the new chemical substance and hazard data for an analogous chemical. This substance falls within the TSCA New Chemicals Category of Polyanionic polymers (& monomers). Acute toxicity values estimated for fish, aquatic invertebrates, and algae are > 100 mg/L, > 120 mg/L, and 25.1mg/L, respectively. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are > 10 mg/L, > 10 mg/L, and 3.1 mg/L, respectively. These toxicity values indicate that the new chemical substance is 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 6.275 mg/L (6,275ppb) and 0.31 mg/L (310 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

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>).

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-21-0087

basis of greater exposure potential compared to the general population who do not use specific products.

For this new chemical assessment, EPA assessed worker inhalation exposure. Releases to water were estimated. No releases to air or landfill were expected. Exposure to the general population was assessed via drinking water. Exposure to the general population via landfill or inhalation was not assessed because releases to groundwater from landfill and air were expected to be negligible. Exposure to the general population via fish ingestion was not assessed because bioaccumulation potential was evaluated to be low. Exposure to consumers was assessed via drinking water and dermal contact.

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).

Risks to human health were not evaluated because no significant hazards were identified.

Risks to the environment were evaluated by comparing estimated surface water concentrations with the acute and chronic concentrations of concern (COCs). To evaluate risks from chronic exposures, the number of days the estimated surface water concentration (SWC) was predicted to exceed the COC was also considered. Risks from acute exposures to the environment were not identified because the estimated SWC did not exceed the acute COC. Risks from chronic exposures to the environment were not identified because the estimated SWC did not exceed the chronic COC.

Because no significant human health hazards or unreasonable risks to the environment were identified, 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.

09/07/2021
Date:

/s/

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