

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0370 and -371

Numbers: P-18-0370 and -371

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

Chemical Names:

P-18-0370:

Generic: Salt of a maleic anhydride and substituted alkene copolymer

P-18-0371:

Generic: Salt of a maleic anhydride - substituted alkene copolymer

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

Intended conditions of use (generic): Import for use as and use as processing aids, consistent with the 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 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 salts that are comprised of an anion and cations. 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. Estimations of physical/chemical and fate properties are not applicable for the cations ([claimed CBI]); the cations ([claimed CBI]) are [claimed CBI] and are

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.

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0370 and -371

unlikely to impact the overall persistence and bioaccumulation of the new chemical substance. The other cation ([claimed CBI]) will enter the environment and become part of [claimed CBI]. Based on estimated physical/chemical properties and test data on analogous chemical substances, EPA estimates that the chemical substances have moderate environmental hazard and potential for the following human health hazards: none identified. 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 using data for analogues (polyanionic polymers). The cations ([claimed CBI]) are not expected to drive the human health and eco hazard assessments. The cations ([claimed CBI]) are also not expected to be a concern for food chain effects and were not evaluated for persistence and bioaccumulation. The other cation ([claimed CBI]) was also not evaluated for persistence and bioaccumulation. In wastewater treatment, the anions are expected to be removed with an efficiency of 50% to 90% due to sorption. Removal of the anions by biodegradation is negligible. Sorption of the anions to sludge is expected to be moderate to strong and to soil and sediment is expected to be strong. Migration of the anions to groundwater is expected to be slow due to strong sorption to soil and sediment. 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 and have low potential to 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 using data for analogues (polyanionic polymers). EPA estimated that the anions' aerobic and anaerobic biodegradation half-lives are > 6 months. These estimates indicate that the anions may be very persistent 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 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)

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0370 and -371

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 (polyanionic polymers). EPA estimated that the anions have low bioaccumulation potential based on large predicted molecular volume, which limits bioavailability. 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.

Human Health Hazard⁴: 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 these chemical substances based on their estimated physical/chemical properties, by comparing them to structurally analogous chemical substances for which there are information on human health hazard, and other structural information. Absorption is expected to be nil through the skin, lung and gastrointestinal (GI) tract based on physical/chemical properties. Absorption of the low molecular weight components could not be estimated. Hazards were expected to be low based on analogue data and pH of 4-7. EPA qualitatively evaluated corrosion effects.

Environmental Hazard⁵: 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

⁴ 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.

⁵ 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-18-0370 and -371

substance. EPA estimated environmental hazard of these new chemical substances using hazard data on an analogous chemical ([claimed CBI]). Acute toxicity values estimated for fish, aquatic invertebrates and algae are > 100 mg/L, 90 mg/L, and 17 mg/L, respectively. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are > 10 mg/L (acute to chronic ratio of 10), 9.0 mg/L (acute to chronic ratio of 10), and 6.9 mg/L for fish, aquatic invertebrates, and algae, 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 4.25 mg/L (4250 ppb) and 0.69 mg/L (690 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 assessment, EPA assessed worker exposure via dermal exposure and inhalation exposures were not expected. Releases to water, landfill, and air were estimated. Exposures to the general population were assessed via drinking water. Exposure to the general population was not assessed via fish ingestion because bioaccumulation potential was expected to be low or via ingestion of groundwater from landfill leachate or via 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 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).

Hazards were determined to be low for the new chemical substances to workers; therefore, risks were not calculated. Based on the low hazard, risks are not expected.

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0370 and -371

Hazards were determined to be low for the new chemical substances to general population; therefore, risks were not calculated. Based on the low hazard, risks are not expected via drinking water ingestion. Risks to consumers were not evaluated because consumer uses were not identified as conditions of use.

Risks to the environment were evaluated by comparing estimated surface water concentrations with the acute and chronic concentrations of concern. Risks to the environment were not identified due to releases to water (0.42 ppb) that did not exceed the acute COC and exceeded the chronic COC of 690 ppb for less than 20 days/year (0 days/year during use of the PMN substance).⁶

Because no unreasonable risks to workers, the general population, or environment were identified, and there are no expected consumer exposures, 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.

8/19/2020
Date:

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

⁶ 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.