

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0142

Number: P-18-0142

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

Chemical Name:

Generic: Alkanoic acid, alkyl-, alkyl ester, polymer with substituted alkenoates, alkenoic acid, alkyl peroxyoate-initiated; polymer exemption flag.

Polymer exemption flag: The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).

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

Intended use(s) (specific): Import the PMN substance in solution at a maximum yearly production volume of [claimed CBI], with a lowest number average molecular weight of approximately 8200 g/mol and acid content less than 20% (i.e., [claimed CBI] by weight of the polymer, for use as a binder for topcoat coating.

Known conditions of use: None.

Reasonably foreseen use(s): 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. The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard when manufactured to meet the polymer exemption criteria and with an acid content less than 20% by weight of the polymer. The PMN describes conditions of use consistent with these criteria. Although EPA estimated that the new chemical substance would be very persistent, this did not indicate a likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health hazard, and low environmental hazard.

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. 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.

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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 a number of physical-chemical and fate properties of this new chemical substance using data for analogous chemicals. Based on these estimates, the chemical substance is expected to be removed with an efficiency of 90% during wastewater treatment due to strong sorption to sludge and biodegradation. Additionally, the chemical substance is expected to have very strong sorption to soil and sediments, resulting in negligible migration to groundwater. Volatilization to air is expected to be negligible because the substance has a low vapor pressure.

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 biodegradation half-lives of this new chemical substance using data for analogous chemicals. EPA estimated the aerobic and anaerobic biodegradation half-lives to be greater than six months. These estimates for biodegradation indicate that the chemical substance may be persistent in aerobic environments (e.g., surface water) and very persistent in 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 species pose the potential for elevated exposures to humans and other organisms via food chains. The chemical substance has low bioaccumulation potential based on estimates from analogous polymers and large predicted molecular volume, which inhibits bioavailability. Although EPA estimated that the new chemical substance could be very persistent, the chemical 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 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

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 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 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 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 there are equivalent or analogous data. (64 FR 60194; November 4 1999)

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

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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 by comparing it to structurally analogous chemical substances for which there is information on human health hazard. EPA did not identify any potential concerns for the substance when manufactured to meet the polymer exemption criteria described under 40 CFR §723.250(e)(1) and concludes there is low human health hazard for the chemical substance.

Environmental Hazard⁵: Environmental hazard is 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 estimated environmental hazard of this new chemical substance using hazard data on analogous chemicals. The new chemical substance falls within the TSCA New Chemicals Program Chemical Category of Polyanionic Polymers⁶ which indicates potential aquatic toxicity. However, under the expected conditions of manufacture, the polymer has very low water solubility, and is predicted to have no effects at saturation (i.e., the water solubility is expected to be lower than the effect concentration). EPA therefore concludes that this chemical substance has low environmental hazard under the conditions of use.

Exposure and Risk Characterization: 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. Due to low hazard, EPA believes that this chemical

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>).

⁶ 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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substance would be unlikely to present an unreasonable risk even if potential exposures were high.

Potentially Exposed or Susceptible Subpopulation(s) (PESS): EPA considers workers to be a 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 PMN substance, no use is expected by consumers. Given the low hazard of this chemical substance, EPA finds that this chemical substance is not likely to present unreasonable risk to any PESS.

7/27/2018
Date: _____

/s/

Jeffery T. Morris, Director
Office of Pollution Prevention and Toxics