TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0212

Number: P-18-0212
TSCA Section 5(a)(3) Determination: The chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic: Substituted carbomonocycle, polymer with alkyl alkenoate, alkenyl substituted carbomonocycle, substituted alkanediol, heteropolycycle, alkylene glycol and alkenoic acid, compd. with alkylamino alkanol; 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 conditions of use: Import in formulation for industrial use as a coating resin for improved appearance and adhesion, 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 new chemical substance could be very persistent, the new chemical substance has low potential for bioaccumulation, such that repeated exposures are not

[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.

expected to be cumulative. Based on EPA's TSCA New Chemicals Program Chemical Category for Polyanionic Polymers (Monomers)[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: irritation to all tissues, as well as systemic effects and reproductive/developmental effects. EPA concludes that the new chemical substance is not likely to present an unreasonable risk when manufactured to meet the polymer exemption criteria. The PMN describes conditions of use consistent with these criteria.

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 this new chemical substance based on data for analogous polymers. The chemical substance is estimated to be removed during wastewater treatment with an efficiency of 90% via sorption. Removal by biodegradation is estimated to be negligible based on data for analogous polymers. Sorption to sludge is estimated to be strong, and sorption to soil and sediment is estimated to be very strong, resulting in negligible migration to groundwater. Volatilization to air is estimated to be negligible based on data for analogous polymers. Overall, these estimates are indicative of low potential for this chemical substance to volatilize into the air and a low potential for this chemical substance to migrate into 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. Based on data for analogous polymers, EPA estimated the biodegradation half-lives of this new chemical substance. EPA estimates the aerobic and anaerobic half-lives to be greater than six months. These estimates for biodegradation indicate that the new chemical substance may be very persistent in aerobic environments (e.g., surface water) and anaerobic environmental (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

[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 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)

[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 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)

terrestrial species pose the potential for elevated exposures to humans and other organisms via food chains. The new chemical substance is estimated to have low bioaccumulation potential based on data for analogous polymers and large predicted molecular volume, which limits bioavailability and biodegradation. Although EPA estimates that the new chemical substance could be very persistent, the new 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 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 and data on analogues and a component of the new chemical substance. Absorption of the new chemical substance as the neat material is expected to be negligible through the skin, lungs and the gastrointestinal tract based on physical/chemical properties, and when the new chemical is in solution, absorption is expected to be poor via all exposure routes. EPA identified the following human health hazards: irritation to all tissues, as well as stomach ulcers and reproductive/developmental effects. EPA identified a LOAEL of 300 mg/kg/day for stomach ulcers in dams, increased post-implantation loss and increased resorptions in an OECD 414/421 reproductive/developmental study in rodents with the cation. EPA also identified a NOAEC of 36.4 mg/m^3 for maternal toxicity (reduced body weight in dams) based on a non-guideline reproductive/developmental study in rodents with the cation. The LOAEL and the NOAEC were used to derive exposure route- and population-specific points of departure for quantitative risk assessment of the new chemical substance.

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

[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.

[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

upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. The new chemical substance falls within the TSCA New Chemicals Program Chemical Category of Polyanionic Polymers (Monomers). EPA estimated environmental hazard of this new chemical substance using hazard data on analogous chemicals, based on SAR predictions for polyanionic polymers-[claimed CBI] (special class within ECOSAR v.2.0). Acute toxicity values estimated for fish, aquatic invertebrates, and algae are >100 mg/L. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are >10 mg/L. These toxicity values indicate that the new chemical substance is expected to have low environmental hazard. Application of assessment factors of 5 and 10 to acute and chronic toxicity values, respectively, results in acute and chronic concentrations of concern of 20 mg/L (20,000 ppb) and 1 mg/L (1,000 ppb), respectively. EPA did not identify potential environmental hazards for the new chemical substance when manufactured as described in the PMN and to meet the polymer exemption criteria described under 40 CFR §723.250(e)(1).

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 new chemical assessment, EPA assessed worker exposure via the inhalation and dermal routes. Releases to water, stack air, and landfill were estimated. EPA assessed general population exposure via the inhalation and drinking water routes. Exposure to the general population via fish consumption was not assessed because the new chemical substance is estimated to have low

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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).

bioaccumulation potential. Exposure to the general population via stack air was not assessed because releases were below modeling thresholds, and exposure via landfill releases was not assessed as negligible migration is expected. Exposures to consumers were not assessed because consumer uses were not identified as conditions of use.

Risk Characterization: EPA applies a margin of exposure approach to calculate potential human health risks of new chemicals. A benchmark (acceptable) margin of exposure is derived by applying uncertainty factors for the following types of extrapolations: intra-species extrapolation (UF_H = 10 to account for variation in sensitivity among the human population), inter-species extrapolation (UF_A = 10 to account for extrapolating from experimental animals to humans) and LOAEL-to-NOAEL extrapolation (UF_L = 10 to account for using a LOAEL when a NOAEL is not available). Hence, in the New Chemicals Program, a benchmark MOE is typically 100 and 1000 when NOAELs and LOAELs, respectively, are used to identify hazard. When allometric scaling or pharmacokinetic modeling is used to derive an effect level, the UF_H may be reduced to 3, for a benchmark MOE of 30. The benchmark MOE is used to compare to the MOE calculated by comparing the toxicity NOAEL or LOAEL to the estimated exposure concentrations. When the calculated MOE is equal to or exceeds the benchmark MOE, the new chemical substance is not likely to present an unreasonable risk. 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 for the new chemical substance were evaluated using the points of departure (i.e., NOAEC for inhalation exposures and LOAEL for oral/dermal exposures) described above. For the new chemical substance, risks were identified for workers for systemic effects via inhalation exposure because the calculated MOE (MOE = 80) did not exceed the benchmark MOE of 100. Risks were not identified for workers for reproductive/developmental effects via dermal exposure because the calculated MOE (MOE = 2,660) exceeded the benchmark MOE of 1,000. Hazards to workers for portal of entry/contact effects to the eyes, lungs and skin following ocular, inhalation, and dermal exposures were identified. Risks for these hazard endpoints were not quantified due to a lack of dose-response data for these effects. The risks and hazards identified will be mitigated if exposures are controlled by the use of appropriate PPE, including impervious gloves, respirators with an APF of at least 10, and eye protection. EPA expects that workers will use appropriate personal protective equipment (i.e., impervious gloves, respirator with an APF of at least 10, and eye protection), consistent with the Safety Data Sheet submitted with the PMN, in a manner adequate to protect them.

For the new chemical substance, risks were not identified for the general population for reproductive or developmental effects via inhalation or oral exposure because the calculated MOEs (drinking water $MOE_{infants}$ = 2,324,921; drinking water MOE_{adults} = 9,764,671) exceeded the benchmark MOE of 1,000. Risks were not identified for the general population for portal of entry and systemic effects via inhalation exposure because the calculated MOE (inhalation MOE = 3,000,000) exceeded the benchmark MOE of 100. Risks to consumers were not evaluated because consumer uses were not identified as conditions of use.

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Due to low environmental hazard, EPA believes that this chemical substance is not likely to present an unreasonable risk to the environment even if potential exposures were high.

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 if manufactured in accordance with the polymer exemption criteria at 40 CFR §723.250.

11/30/2018 /s/

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