TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0260

Number: P-18-0260
TSCA Section 5(a)(3) Determination: The chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic: Fatty acids, polymers with alkanoic acid and substituted carbomonocycle, peroxide-initiated, polymers with alkanoic acid esters and substituted carbomonocycle, ammonium salts; 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 (specific): Manufacture, process for use, and use as a binder for wood stains in consumer and commercial applications, 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 [claimed CBI][2] and test data on analogous chemical substances, and when manufactured to meet the polymer exemption criteria, EPA estimates that the chemical substance has low environmental hazard and potential for the following human health hazards: irritation, and neurological, immunological, developmental, and blood effects. EPA concludes that the new chemical substance is not likely to present an unreasonable risk under the conditions of use and 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 the new chemical substance using data for analogues (dispersible polymers). In wastewater treatment, the new chemical substance is expected to be removed with an efficiency of 90% via sorption. Removal of the new chemical substance by biodegradation is negligible. Sorption of the new chemical substance to sludge is strong and to soil and sediment is very strong. Migration of the new chemical substance 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 is expected to undergo negligible volatilization to air. Overall, these estimates indicate that the new chemical substance has low potential to volatilize to air, has low potential to migrate to groundwater, and is likely to be removed in wastewater treatment.

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 (dispersible polymers). EPA estimated that aerobic and anaerobic biodegradation half-lives of the new chemical substance are > 6 months. These estimates indicate that the new chemical substance will 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

[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

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 (dispersible polymers). EPA estimated that the new chemical substance has low bioaccumulation potential based on large predicted molecular volume, which limits bioavailability. Although EPA estimated that the new chemical substance could be very persistent, the substance has a 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 by comparing it to structurally analogous chemical substances for which there is information on human health hazard. Based on physical/chemical properties, absorption is expected to be nil by all routes for the parent polymer, and nil to poor by all routes for the low molecular weight fractions. EPA identified neurological effects and irritation as hazards based on the [claimed CBI]. Immunological, developmental, and blood effects were identified as hazards based on structural alerts for [claimed CBI] leading to possible chelation of nutrient metals. Developmental effects were identified as hazards based on the possible release of the [claimed CBI]. EPA qualitatively evaluated irritation effects. EPA identified a LOAEL of 100 mg/kg-day for increased fetal variations based on an oral developmental toxicity study (non-guideline) on a component of the new chemical substance. EPA also identified a NOAEL of 39.5 mg/kg-day for body weight loss based on a 90-day oral repeated-dose study (non-guideline) and a NOAEC of 13.6 mg/m^3 for decreased lung function and respiratory symptoms based on a study in workers for an analogue for a component of the new chemical substance, which was used to derive exposure route- and population-specific points of departure for quantitative risk assessment described below.

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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)

[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.

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 [claimed CBI] (special class within ECOSAR v.2.0). Acute toxicity values estimated for fish, aquatic invertebrates, and algae are all > 100 mg/L. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are all > 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.

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 exposure to workers via the dermal and inhalation routes. Releases to water were estimated. Exposure to the general population was

[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).

assessed via drinking water. Exposure to the general population via inhalation was not assessed because releases to air are expected to be negligible (below modeling thresholds). Exposures to consumers were assessed via inhalation and dermal routes.

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 1,000 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 route-specific effect levels (i.e., NOAEL, LOAEL, and NOAEC) described above. Risks were identified for workers for developmental effects via dermal contact when poor absorption (15%) is assumed based on quantitative hazard data for a component of the new chemical. (MOE = 947; benchmark MOE = 1000). Risks are not identified for workers via dermal exposure when nil (0.1%) absorption is assumed. Risks were identified for workers for body weight effects (for the [claimed CBI]) via dermal contact based on quantitative hazard data for a component of the new chemical. (MOE = 48; benchmark MOE = 100). Risks were not identified for workers for developmental effects via inhalation exposures based on quantitative data for a component of the new chemical substance (MOE = 1600; Benchmark MOE = 1000). Risks were not identified for workers for lung effects or irritation via inhalation based on quantitative hazard data for a component of the new chemical (the [claimed CBI]). (MOE = 444; benchmark MOE = 10).

Irritation hazards to workers via dermal contact were identified based on the [claimed CBI]. Risks for these endpoints were not quantified due to a lack of dose-response for these hazards. However, exposures can be mitigated by the use of appropriate personal protective equipment (PPE), including impervious gloves, eye protection, and respiratory protection. EPA expects that employers will require and that workers will use appropriate PPE consistent with the Safety Data Sheet prepared by the new chemical submitter, in a manner adequate to protect them.
Risks were not identified for the general population for developmental effects via drinking water ingestion based on quantitative hazard data for a component of the new chemical substance (MOE = 2726; benchmark MOE = 1000). Risks were not identified for the general population for body weight effects via ingestion of drinking water based on quantitative hazard data for a component of the new chemical. (MOEs > 8547; benchmark MOE = 100). Risks were not

identified for the general population for irritation via drinking water since these concerns are expected to be mitigated by dilution in the media.

Risks were not identified for consumers for developmental effects via inhalation or dermal contact based on quantitative hazard data for a component of the new chemical ($MOE_{inhalation}$ = 1517, MOE_{dermal} = 1661; benchmark MOE = 1000). Risks were not identified for consumers for lung effects via inhalation based on quantitative hazard data for a component of the new chemical (MOE = 653; benchmark MOE = 10). Risks were not identified for consumers for body weight effects via dermal contact based on quantitative hazard data for a component of the new chemical. (MOE= 560; benchmark MOE = 100). Risks were not identified for consumers for irritation via dermal or inhalation contact. Although risks could not be quantified for irritation due to lack of dose-response information, calculated risks were not identified using a POD which also identified irritating effects for a component of the new chemical substance. Therefore, irritation effects are unlikely for consumers for the estimated exposures.

Risks to the environment were not identified based on low hazard.

Because worker exposures can be controlled by PPE, and no unreasonable risks to the general population, consumers, or 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 when manufactured to meet the polymer exemption, consistent with the conditions of use described in the PMN.

6/14/19
Date:

/s/
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