TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0231

Number: P-18-0231
TSCA Section 5(a)(3) Determination: The chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic: Alkanoic acid, substituted alkyl-, polymer with isocyanatoalkane, alkyl carbonate, alkanediol and polyalkylene glycol ether with alkyl(substituted alkyl) alkanediol alkenoate, glycerol monoacrylate alkanoate-blocked

Conditions of Use (intended, known, or reasonably foreseen) [1]**:**
Intended conditions of use (specific): Import in [claimed CBI] in formulation for industrial use as a waterborne UV curable coating resin binder in inks or overprint varnishes used in inkjet, gravure coating, and flexo-coating processes on a variety of substrates including plastics and paper.
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 known 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 chemical

[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.

substance has low potential for bioaccumulation, such that repeated exposures are not expected to be cumulative. Based on EPA's TSCA New Chemicals Program Chemical Categories for Acrylates/Methacrylates, EPA estimates that the chemical substance has low environmental hazard and the potential for the following human health hazards: irritation and sensitization. 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.

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 on analogous dispersible, high molecular weight polymers. The chemical substance is expected to be removed with an efficiency of 75-90% during wastewater treatment due to sorption to sludge. Sorption to sludge is estimated to be strong, and sorption to soil and sediment is expected to be very strong based on expected Van der Waals interactions between the new chemical substance and solids found in sludge and soil, resulting in negligible migration to groundwater. Volatilization to air is expected to negligible because the substance is expected to have low vapor pressure and a low Henry's Law constant. Overall, these estimates are indicative of low potential for this chemical substance to volatilize into the air and a low potential for this chemical to migrate into ground water.

Persistence[2]: 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 dispersible high molecular weight polymers, 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 very persistent in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment).

Bioaccumulation[3]: 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

[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)

analogous dispersible high molecular weight polymers and large predicted molecular volume, which limits bioavailability and biodegradation. 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 Hazard[4]: 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 the New Chemicals Program Chemical Category for Acrylates/Methacrylates. There are no measured toxicity data on the PMN substance and there are no identified analogues with measured toxicity data. For this new chemical substance, absorption of the neat solid material is expected to be nil all routes; if in solution, absorption of the low molecular weight fractions (2.3% < 500 Da and 9.6% < 1000 Da) is estimated to be poor all routes based on physical/chemical properties. Based on structural alerts and the Acrylates/Methacrylates category, EPA identified systemic and developmental toxicity, carcinogenicity, and irritation and sensitization as potential hazards. The category states that, based on toxicity data submitted to the Agency, new chemical acrylates and methacrylates, especially high molecular weight and polymeric substances, are not controlled as a category for human health concerns, instead relying on a case-by-case analysis of available toxicity data. The low molecular weight fraction for the new chemical substance is 2.3% < 500 Da and 9.6% < 1000 Da, and EPA determined the functional group equivalent weight for acrylate moieties to be 537. Based on this, EPA concludes that the systemic and developmental toxicity and carcinogenicity concerns are marginal. There are no reported low molecular weight isocyanate residuals. Therefore, sensitization and irritation are the only relevant hazards for this new chemical substance. EPA qualitatively assessed irritation and sensitization because dose-response information is not available for these endpoints.

[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)), structure-activity relationships, and/or structural alerts to support characterizing human health hazards.

Environmental Hazard[5]: 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 estimated environmental hazard of this new chemical substance using the Ecological Structure Activity Relationships (ECOSAR) Predictive Model (https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model) predictions for polyanionic polymers (special class within ECOSAR v. 2.0). Acute ecotoxicity values estimated for fish (LC_{50}), aquatic invertebrates (EC_{50}) and algae (EC_{50}) are all >100 mg/L. Chronic ecotoxicity values (ChVs) estimated for fish, aquatic invertebrates and algae are all >10 mg/L. These toxicity values indicate the new chemical substance is expected to have low hazard. Application of assessment factors of 5 and 10 to acute and chronic toxicity values results in estimated acute concentration of concern (COC) of 20 mg/L (20,000 ppb) and a chronic COC of 1 mg/L (1,000) ppb.

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.

EPA estimates occupational exposure and environmental releases of the 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 assesses risks to workers considering engineering controls described in the PMN but in the absence of personal protective equipment 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).

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

[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).

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

For this assessment, EPA assessed dermal exposure to workers. Inhalation exposures to workers are predicted to be negligible. EPA assessed exposure to the general population via drinking water and fish ingestion. EPA did not estimate exposure for consumers because consumer uses were not identified as intended or reasonably foreseen.

Risks were identified for workers for irritation to the skin and eyes and sensitization via dermal contact based on the Acrylates/Methacrylates category. Risks for this hazard endpoint were not quantified due to a lack of dose-response for this hazard. Risks would be mitigated if exposures are controlled by the use of appropriate PPE, including impervious gloves and eye protection, EPA expects that workers will use appropriate personal protective equipment, including dermal protection consistent with the Safety Data Sheet submitted with the PMN, in a manner adequate to protect them. Risks were not identified for workers for irritation and sensitization via inhalation as inhalation exposures will not occur under the intended conditions of use.

Although potential general population exposures were identified for drinking water and fish consumption, the oral exposure pathway is not considered relevant for the induction of sensitization, and the exposures are not expected to be high enough to result in irritation. Risks to the general population for sensitization via inhalation were not evaluated as exposures were estimated to be low (below modeling thresholds). Risks to consumers were not evaluated for this new chemical substance because consumer uses were not identified as conditions of use.

Risks to the environment are evaluated by comparing estimated surface water concentrations with the acute and chronic COCs. No exceedances of the acute and chronic COCs are expected.

Because worker exposures can be controlled by PPE, there are no expected exceedences of acute or chronic aquatic COCs, and there are no expected consumer or general population 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.

9/26/18
Date:

/s/
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