TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0100 and P-18-0102

Number: P-18-0100 and P-18-0102
TSCA Section 5(a)(3) Determination: The chemical substances are not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic:
P-18-0100: Substituted alkanoic acid polymer with alkylcarbonate, alkanediols and isocyanate substituted carbomonocycles, sodium salt, alkenoic acid substituted polyol reaction products-blocked.
P-18-0102: Alkenoic acid, ester with [oxybis(alkylene)]bis[alkyl-substituted alkanediol], polymer with alkylcarbonate, alkanediols, substituted alkanoic acid and isocyanate and alkyl substituted carbomonocycle, sodium salt.

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (generic): Import for processing and use as UV curable coating resins for industrial use (no consumer use), consistent with the processing, use, distribution, and disposal information described in the PMNs.
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. Although EPA estimated that the new chemical substances could be very persistent, the chemical substances have 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 Acrylates/Methacrylates,[2] test data on analogous chemical substances, and the SAR chemical class of anionic polymers, EPA estimates that the chemical substances have low environmental hazard and the potential for the following human health hazards: irritation of eyes and skin, sensitization, developmental toxicity, and liver toxicity. EPA determines 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 substance is likely to present an unreasonable risk. EPA estimated a number of physical-chemical and fate properties of these new chemical substances using data for analogous chemicals. Based on these estimates, the new chemical substances are expected to be removed with an efficiency of 90% during wastewater treatment due to sorption. Sorption to sludge is estimated to be strong, and sorption to soil and sediment is estimated to be very strong. Volatilization to air is estimated to be negligible. Overall, these estimates are indicative of low potential for these chemical substances to volatilize into the air and a low potential for these chemicals 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. EPA estimated biodegradation half-lives of these new chemical substances using data on analogous chemicals. EPA estimated the aerobic and anaerobic biodegradation half-lives to be greater than six months based on data on analogous chemical substances, in addition to large predicted molecular volume and low water solubility, which limit bioavailability and biodegradation. These estimates for biodegradation indicate that the chemical substances may be very persistent in aerobic environments (e.g., surface water) and very persistent in 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

[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 substances have low bioaccumulation potential based on data for analogous chemicals as well as large molecular volume and low water solubility, which limit bioavailability and bioaccumulation. Although EPA estimated that the new chemical substances could be very persistent, the chemical 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 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 these chemical substances based on their estimated physical/chemical properties, analogue data, structural information, and the TSCA New Chemicals Program Chemical Category for Acrylates/Methacrylates. For these new chemical substances, absorption is estimated to be nil via all routes and poor via all routes for the low molecular weight fractions based on physical/chemical properties. Based on the presence of multiple acrylate groups, there is concern for irritation of eyes and skin, sensitization, developmental toxicity, and liver toxicity. EPA quantitatively assessed hazard for the new chemical substances using data from acrylate analogues that are expected to exhibit a similar mode of action. Both of the analogues are negative for genotoxicity. One analogue, [claimed CBI], is not considered carcinogenic and the other, [claimed CBI], was not carcinogenic via inhalation exposure up to 773 mg/m^3. For the worst case analogue, [claimed CBI], EPA identified a NOAEL of 1,081 mg/kg-day from a published dermal lifetime study and a NOAEC of 225 mg/m^3 based on liver effects in a published 90-day inhalation study.The NOAEC for developmental effects was higher. For the other analogue, [claimed CBI], EPA also identified a NOAEL of 111 mg/kg-day based on a 90-day drinking water study. The toxicity values were matched to routes of exposure assessed to derive exposure route- and population-specific points of departure for quantitative risk assessment (i.e., dermal NOAEL used for dermal exposure, inhalation NOAEC used for inhalation exposure and oral NOAEL used for drinking water exposure), described below.

[5] A chemical substance is considered to have low human health hazard if effects are observed in animal studies with a 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. The new chemical substance falls within the SAR chemical class of anionic polymers. EPA estimated environmental hazard of these new chemical substances using the Ecological Structure Activity Relationships (ECOSAR) Predictive Model (https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-releationships-ecosar-predictive-model); specifically the QSAR for anionic polymers. The acute toxicity values for fish, aquatic invertebrates, and algae are estimated to be >100 mg/L, and chronic toxicity values for fish, aquatic invertebrates, and algae are estimated to be >10 mg/L. Based on these toxicity values, EPA expects these new chemical substances to have low hazard. Application of assessment factors of 5 and 10 to acute and chronic toxicity values results in an estimated acute concentration of concern (COCs) 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 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.

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[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).

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0100 and P-18-0102

For these new chemical asessments, EPA assessed exposure via the dermal and inhalation routes to workers during processing and exposure to the general population via drinking water. Exposures to consumers were not assessed because consumer uses were not identified as conditions of use.

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 hazards. 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 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 substances were evaluated using the route-specific effect levels (i.e., NOAELs and NOAEC) described above. The exposures predicted under the intended conditions of use are not expected to present unreasonable risk because the MOEs calculated using the analogues exceeded the benchmark MOEs (100 for inhalation, dermal and oral exposures). EPA did not identify risk to workers for systemic toxicity from dermal exposure because MOEs (P-18-100 MOE = 1,456 and P-18-102 MOE = 512) exceeded the benchmark MOE of 100. EPA did not identify risk to workers for systemic toxicity from inhalation exposure because the MOEs (P-18-100 MOE = 1,156 and P-18-102 MOE = 898) exceeded the benchmark MOE of 100. EPA identified risk to workers for irritation of eyes and skin, and sensitization via dermal and inhalation exposures based on the presence of multiple acrylate groups. Risks for these hazard endpoints were not quantified due to a lack of dose-response information for these hazards. Risks will be mitigated if exposures are controlled by the use of appropriate PPE, including impervious gloves, eye protection, and a respirator, as described in the SDSs submitted with the PMNs (i.e., a NIOSH-certified respirator with an APF of at least 50 for non-spray applied operations or an APF of 1,000 respirator for spray applications). EPA expects that workers will use appropriate personal protective equipment (i.e., impervious gloves, eye protection and a respirator), consistent with the Safety Data Sheet prepared by the PMN submitter, in a manner adequate to protect them.

EPA did not identify risk to the general population for systemic effects from oral exposure because the calculated MOEs exceeded the benchmark MOEs (P-18-0100 MOE_{Adult} = 1,105,247 and MOE_{Infant} = 265,047; P-18-0102 MOE_{Adult} = 388,112 and MOE_{Infant} = 93,072; benchmark MOE = 100). Risks were not estimated for the general population for systemic effects via inhalation because releases are expected to be low (below modeling thresholds). EPA did not evaluate risk to consumers because consumer uses were not identified as conditions of use.

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0100 and P-18-0102

Risks to the environment are evaluated by comparing the estimated surface water concentrations with the acute and chronic concentrations of concern. Risks to the environment are not expected due to the low hazard of these new chemical substances.

Because worker exposures can be controlled by PPE, there are no expected consumer exposures, no unreasonable risks to the general population were identified, and environmental hazard is expected to be low, 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.

10/5/18
Date:

/s/
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