TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN): P-18-0247, P-18-0248, P-18-0249, P-18-0250, P-18-0251, and P-18-0252

Number: P-18-0247, P-18-0248, P-18-0249, P-18-0250, P-18-0251, and P-18-0252
TSCA Section 5(a)(3) Determination: These chemical substances are not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic (P-18-0247): Isocyanic acid, polymethylenepolyphenylene ester, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, polyetherpolyol, .alpha.,alpha.'-[(1- methylethylidene)di-4,1-phenylene]bis[.omega.-hydroxypoly(oxy-1,2-ethanediyl)] and 1,2-propanediol, iso-Bu alc.- and 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and Et alc.- and methanol- and 1-methoxy-2-propanol-blocked,

Generic (P-18-248): Isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol blocked,

Generic (P-18-249): Isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol and 1-methoxy-2-propanol-blocked

Generic (P-18-0250): Isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and 1(or2)-(2-methoxymethylethoxy)propanol-blocked

Specific (P-18-0251): Isocyanic acid, polymethylenepolyphenylene ester, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol- and 1(or2)-(2-methoxymethylethoxy)propanol-blocked

Specific (P-18-0252): Isocyanic acid, polymethylenepolyphenylene ester, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol- and 1-methoxy-2-propanol-blocked

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

[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

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Intended conditions of use (specific): Manufacture for use as a crosslinker for automotive electrocoat, consistent with the manufacturing, processing, use, distribution, and disposal information described in these 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: These 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 these new chemical substances could be very persistent, these new chemical substances have a low potential for bioaccumulation, such that repeated exposures are not expected to be cumulative. Based on test data on analogous chemical substances, EPA estimates that these chemical substances have a moderate environmental hazard and potential for the following human health hazards: sensitization and lung effects based on surfactancy. EPA concludes that these 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 may present an unreasonable risk. EPA estimated a number of physical-chemical and fate properties of these new chemical substances using data for these new chemical substances and analogous chemical substances. These chemical substances are estimated to be removed during wastewater treatment with an efficiency of 90% via sorption. Removal by biodegradation is estimated to be negligible. 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 low estimated vapor pressure and Henry's law constant. Overall, these estimates were indicative of low potential for these chemical substances to volatilize into the air and a low potential for these chemicals 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

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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.

[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)

present a risk if the substance presents a hazard to human health or the environment. Based on data for these new chemical substances and analogous chemical substances, EPA estimated aerobic and anaerobic biodegradation half-lives to be greater than six months. These estimates indicate that the new chemical substances 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. These new chemical substances have low bioaccumulation potential based on data for analogous chemical substances in addition to large predicted molecular volume and low water solubility, which limit bioavailability and bioaccummulation. Although EPA estimated that the new chemical substances may be very persistent, they 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[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 these chemical substances based on physical/chemical properties, chemical structure, and submitted data on the new chemical substances. Absorption of these new chemical substances is expected to be nil to poor by all routes for the species with molecular weight greater than 1,000 g/mol and poor to moderate by all routes for the species with molecular weight less than 1,000 g/mol based on physical/chemical properties. For these chemical substances, EPA identified concerns for lung

[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 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.

effects based on surfactant properties and skin sensitization based on submitted test data. Test data on these new chemical substances were positive for skin sensitization; negative for skin irritation; negative for germ cell mutagenicity; and the acute oral LD_{50} was 1,049 mg/kg. A LOAEC of 0.08 mg/m^3 was identified for lung effects including increased lung weight, inflammation, LDH release, and hemorrhage in a 21-day inhalation repeated-dose study (non-guideline) on an analogue.

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 these new chemical substances using hazard data on an analogous chemical substance and submitted test data on the new chemical substance described in P-18-0248. Acute toxicity values measured or estimated for fish, aquatic invertebrates, and algae are > 100 mg/L (data for the P-18-0248 chemical substance), 61 mg/L (data for the P-18-0248 chemical substance), and 400 mg/L (data for an analogue), respectively. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are 3 mg/L (based on data for the P-18-0248 chemical substance), 2 mg/L (based on data for the P-18-0248 chemical substance), and 141 mg/L (data for an analogue), respectively. These toxicity values indicate that the new chemical substance is expected to have moderate 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 12.2 mg/L (12,200 ppb) and 0.2 mg/L (200 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.

[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).

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 these new chemical assessments, EPA assessed exposure to workers via the dermal route. Inhalation exposure to workers is expected to be negligible. Releases to water were estimated and exposure to the general population was assessed via drinking water and fish ingestion. Exposure to the general population via inhalation was not assessed because releases to air were expected to be negligible (below modeling thresholds). Exposures to consumers were not assessed because consumer uses were not identified as conditions of use.

Risk Characterization: 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 qualitatively. Risks for lung effects for workers were not evaluated, as workers are not expected to be exposed via the inhalation route. Sensitization hazards to workers via dermal contact were identified based on data on the new chemical substances. Risks for this endpoint were not quantified due to a lack of dose-response for this hazard. However, risks will be mitigated if exposures are controlled by the use of appropriate PPE, including impervious gloves. EPA expects that employers will require and workers will use appropriate personal protective equipment (PPE) (i.e., impervious gloves), consistent with the Safety Data Sheet prepared by the new chemical submitter, in a manner adequate to protect them.

Risks to the general population were not identified. Lung effects are only expected via inhalation exposures, which are expected to be negligible (below modeling thresholds). Risks for sensitization are not expected from oral exposures via drinking water or fish ingestion since the new chemical substances are not expected to be present at levels that would cause this effect. Risks to consumers were not evaluated because consumer uses were not identified as conditions of use.

Risks to the environment were evaluated by comparing estimated surface water concentrations with the acute and chronic concentrations of concern. Risks to the environment were not identified due to estimated surface water concentrations that did not exceed the acute or chronic concentrations of concern.

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 substances are not likely to present unreasonable risk to human health or the environment under the conditions of use.

4/29/19
Date:

/s/
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