TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0030

Number: P-18-0030
TSCA Section 5(a)(3) Determination: The chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic: Poly[oxy(methyl-alkylendiyl)], a,a',a''-1,2,3-alkanetriyltris[w-hydroxy-, polymer with 1,1'-alkylenebis[4-isocyanatocarbomonocycle], 2-substituted ethyl acrylate- and 2-substituted ethyl methacrylate-blocked

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (specific): Import for processing and use as an acrylate resin for UV-curable industrial coatings, consistent with the manufacture, processing, use, and distribution 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 chemical 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[2] and test data on analogous chemical substances, EPA estimates that the

[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.

[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.

chemical substance has low environmental hazard and the potential for the following human health hazards: eye and skin irritation, sensitization, and developmental, liver, and kidney toxicities. EPA concludes that the new chemical 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 a number of physical-chemical and fate properties of the new chemical substance using data for analogous chemicals. Based on these estimates, the new chemical substance is estimated to be removed with an efficiency of 90% during waste water 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 based on high molecular volume. Overall, these estimates were indicative of low potential for these chemical substances to volatilize into the air and 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 chemicals, EPA estimates the aerobic biodegradation half-lives and the anaerobic biodegradation half-lives to be greater than six months for the new chemical substance. These estimates for biodegradation indicate that the chemical 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 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 large molecular volume, which limits bioavailability and bioaccumulation. 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.

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[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)

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 new chemical substance based on its estimated physical/chemical properties, analogues, EPA's TSCA New Chemicals Program Chemical Categories for Acrylates/Methacrylates, and other structural information. Absorption of the low molecular weight components of the new chemical substance is expected to be poor through the lungs, skin, and GI tract based on physical/chemical properties with decreasing absorption corresponding to increasing molecular weight. EPA identified developmental, liver, and kidney toxicities and sensitization as hazards for the LMW components, which are expected to be more bioavailable and therefore present the greatest hazard. EPA initially identified mutagenicity and carcinogenicity as potential hazards based on the potential for Michael addition of functional groups to DNA or other biological molecules, but EPA has concluded that these hazards are not expected as described below. While systemic hazards are mitigated by the high acrylate functional group equivalent weight (FGEW, 756) and negligible water solubility (<0.000001 g/L), the LMW fraction comprises [claimed CBI] of the chemical substance. As such, worst case analogues (2-ethylhexyl acrylate and butyl acrylate) were used to conduct a quantitative assessment. These worst case analogues are not genotoxic in *in vitro* and *in vivo* studies. Additionally, ethylhexyl acrylate[6] is not considered carcinogenic and butyl acrylate was not carcinogenic to rats via inhalation exposure up to 773 mg/m^3. Hence, mutagenicity and carcinogenicity are not hazards of concern for the new chemical substance.

EPA quantitatively assessed this new chemical using data on the worst case analogues 2-ethylhexyl acrylate and butyl acrylate. A NOAEL of 1,081 mg/kg/day (highest dose tested) was identified in a dermal lifetime study of 2-ethylhexyl acrylate in male mice. This NOAEL was used as the dermal point of departure for quantitative risk assessment. A NOAEC of 225 mg/m^3 for liver effects was identified based on a 90-day inhalation study of 2-ethylhexyl acrylate in rats. This NOAEC was used as the inhalation point of departure for quantitative risk assessment. A

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[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] *Draft Screening Assessment Acrylates and Methacrylates Group, Environment and Climate Change/Health Canada*

NOAEL of 111 mg/kg/day was identified based on a 90-day drinking water study of butyl acrylate. This NOAEL was used as the oral point of departure for quantitative risk assessment of the new chemical. Benchmark MOEs for all routes of exposure are 100.

Environmental Hazard[7]: 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 hazard data on analogous chemicals. Hazards from acute and chronic exposures are not expected at concentrations up to the water solubility limit of the new chemical substance (i.e., no effects at saturation). These toxicity estimates indicate the new chemical substance is expected to have low hazard. Because hazards are not expected up to the water solubility limit, acute and chronic concentrations of concern are not identified.

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 consumer, general population, 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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[7] 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).

For this assessment, EPA assessed exposure to workers via the dermal and inhalation routes during processing and use. Releases to water and air during processing and use were estimated and used to assess exposure to the general population via drinking water and inhalation of fugitive air. Consumer exposures 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 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 route-specific effect levels (i.e., NOAELs) described above. Irritation and sensitization hazards to workers are identified via inhalation and dermal exposure based on the acrylates category. Risks for these hazard endpoints cannot be quantified due to a lack of dose-response for these hazards. However, exposures can be controlled by the use of appropriate PPE, including impervious gloves and a respirator with an APF of 1000 when spray applied or an APF of 50 as described in the submitted SDS. EPA expects that workers will use appropriate personal protective equipment (i.e., impervious gloves, respirator), consistent with the Safety Data Sheet prepared by the PMN submitter, in a manner adequate to protect them. Therefore, EPA has not identified risks for the irritation and sensitization endpoints. Risks were not identified for workers for systemic effects via dermal contact (MOE = 1,171; benchmark MOE =100). Risks were not identified for workers for systemic effects via inhalation (MOE = 1,292; benchmark MOE =100).

Risks were not identified for the general population for systemic effects via inhalation (MOE = 1,437,975; benchmark MOE =100) nor via drinking water ingestion (MOE_{Adult} = 1,964,391 and MOE_{Infant} = 471,077; benchmark MOE =100). Risks were not evaluated for consumers because consumer uses were not identified as conditions of use.

Risks to the environment were not identified based on no effects expected at the limit of solubility of the new chemical substance.

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.

10/30/2018
Date:

/s/
Jeffery T. Morris, Director
Office of Pollution Prevention and Toxics