TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-20-0090

Number: P-20-0090
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-1,2-ethanediyl), .alpha.-(alkyl-hydroxyalkyl)-.omega.-hydroxy-, .omega.-alkyl ethers

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (specific): Import and process for use as and use as a surfactant in automatic dishwashing detergents at a maximum level of 25%, 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. EPA estimated that the new chemical substance could have limited persistence and low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms. Based on estimated and experimental physical/chemical properties and test data on the new chemical substance and analogous chemical substances, EPA estimates that the chemical substance has moderate environmental hazard and potential for the following human health hazards: eye irritation and specific target organ toxicity. EPA concludes

[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.

that the new chemical substance is 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 physical/chemical and fate properties of the new chemical substance using data for analogue(s) (alcohol ethoxylates) and data submitted for the new chemical substance. In wastewater treatment, the new chemical substance is expected to be removed with an efficiency of 95% due to sorption and biodegradation. Removal of the new chemical substance by biodegradation is high. Sorption of the new chemical substance to sludge, soil, and sediment is expected to be strong. Migration of the new chemical substance to groundwater is expected to be negligible due to biodegradation. 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 or migrate to groundwater.

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. EPA estimated degradation half-lives of the new chemical substance using data for analogue(s) (alcohol ethoxylates) and data submitted for the new chemical substance. EPA estimated that the new chemical substance's aerobic and anaerobic biodegradation half-lives are < 2 months. These estimates indicate that the new chemical substance may have limited persistence 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. EPA estimated the potential for the new chemical substance to bioaccumulate using data for analogue(s) (alcohol ethoxylates). EPA estimated that the new chemical substance has low bioaccumulation potential based on bioconcentration or bioaccumulation data reported for alcohol ethoxylates. EPA estimated that the new chemical substance could have limited

[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 if 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 if 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 if 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 if there are equivalent or analogous data. (64 FR 60194; November 4 1999)

persistence and 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 available data on the new chemical substance, estimated and experimental physical/chemical properties, by comparing it to structurally analogous chemical substances for which there is information on human health hazard, and other structural information. Absorption of both the new chemical substance and the low molecular weight (LMW) fraction ([claimed CBI]% < 1,000 Da) is expected to be poor to moderate through the skin and nil through the gastrointestinal (GI) tract and lungs based on physical/chemical properties. For the new chemical substance, EPA identified hazards for lung effects (surfactancy) based on the intended use, physical/chemical properties (surface tension test data for the new chemical substance), and the structural alert for polyethers; and irritation to the eyes and respiratory tract based on submitted data on the new chemical substance, analogue data, and the structural alert for surfactants. Submitted test data on the new chemical substance reported the test substance as non-toxic in an acute oral study in rats (Oraganisation for Economic Co-operation and Development (OECD) 423), not irritating to skin in vitro (OECD 439), mildly irritating to eyes in rabbits (OECD 405), not irritating to eyes in vitro (OECD 437), not a dermal sensitizer in guinea pigs (OECD 406), and negative for mutagenicity in bacteria with and without metabolic activation (OECD 471). EPA identified a No Observed Adverse Effect Concentration (NOAEC) of 10 mg/m^3 based on lung effects (increased alveolar macrophage levels) in a 5-day nose-only inhalation study in rats. The selected value was used to derive an exposure route- and population-specific point of departure. EPA qualitatively evaluated irritation effects.

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

[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.

[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

upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA determined the environmental hazard for this new chemical substance based on acute/chronic toxicity data submitted for P-20-0090 and on analogous chemicals ([claimed CBI]). This substance falls within the TSCA New Chemicals Category of Nonionic Surfactants.[6] Acute toxicity values estimated for fish, aquatic invertebrates, and algae are 28 mg/L ([claimed CBI]), 3.86 mg/L (test data for P-20-0090), and 4.3 mg/L ([claimed CBI]), respectively. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are 5.6 mg/L (Acute-to-Chronic Ratio (ACR)5 for [claimed CBI]), 0.77 mg/L (ACR5 P-20-0090), and 1.07 mg/L (ACR 4 for [claimed CBI]), 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 0.772 mg/L (772 ppb) and 0.077 mg/L (77 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 assessment, EPA assessed worker exposures via the dermal and inhalation routes. Releases to water, air, and landfill were estimated. Exposures to the general population were

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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).

[6] 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.

assessed via drinking water and fugitive air inhalation. Exposure to the general population was not assessed via fish ingestion because bioaccumulation potential was evaluated to be low or via groundwater impacted by landfill leachate or stack air inhalation because releases were expected to be negligible (below modeling thresholds). Exposures to consumers were assessed via the dermal and inhalation 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 (MOE) is derived by applying uncertainty factors (UF) 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 Lowest Observed Adverse Effect Level (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 level (i.e., NOAEC), described above. Risks were identified for workers for lung effects via inhalation exposures based on quantitative hazard data for an analogue ($MOE_{Respirable}$ = 15; MOE_{Total} = 5; Benchmark MOE = 100; Fold $Factor_{Respirable}$ = 7; Fold $Factor_{Total}$ = 21). Risks were not evaluated for workers for lung effects via dermal exposure because the hazard is not relevant to the exposure route. No relevant systemic hazards were identified for the new chemical substance via dermal contact; therefore, risks were not calculated. Based on no identified hazards, risks are not expected. Irritation hazards to workers via inhalation and dermal contact were identified based on submitted data on the new chemical substance, analogue data, and the structural alert for surfactants. 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 (SDS) prepared by the new chemical submitter, in a manner adequate to protect them.

Risks were not identified for the general population for lung effects via inhalation of fugitive air based on quantitative hazard data for an analogue (MOE >2 million; Benchmark MOE = 100). Irritation hazards to the general population are not expected via drinking water ingestion or fugitive air releases due to dilution of the chemical substance in the media. Risks were not evaluated for the general population for lung effects via drinking water because the hazard is not relevant to the exposure route. No relevant hazards were identified for the new chemical

substance via drinking water ingestion because of nil absorption; therefore, risks were not calculated. Based on no identified hazards, risks are not expected. Risks were not evaluated for the general population via fish ingestion because bioaccumulation potential was evaluated to be low or via groundwater impacted by landfill leachate and inhalation of stack air, because exposures were expected to be negligible (below modeling thresholds).

Risks were not identified for consumers for lung effects via inhalation of machine dishwashing detergent based on quantitative hazard data for an analogue (MOE = 5,482; Benchmark MOE = 100). Irritation hazards to consumers via inhalation and dermal contact were identified based on submitted data on the new chemical substance, analogue data, and the structural alert for surfactants. Risks for these endpoints were not quantified due to a lack of dose-response for these hazards. However, the concern for the irritation hazard is reduced by the results of the submitted OECD 437 (Bovine Corneal Opacity and Permeability Test Method), which showed 20% concentration of the test substance was not corrosive or severely irritating the eye. Note that per the submitter, the weight fraction of the new chemical substance in consumer products could be up to 25% by weight, per the new chemical substance notification. No systemic hazards were identified for the new chemical substance via dermal contact; therefore, risks were not calculated. Based on no identified hazards, risks via dermal exposure are not expected.

Risks to the environment were evaluated by comparing estimated surface water concentrations with the acute and chronic concentrations of concern. Risks from acute exposure to the environment were not identified due to releases to water that did not exceed the acute COC. Risks from chronic exposure to the environment were not identified for this new chemical substance because releases to water were less than 20 days.[7]

Although irritation via inhalation and dermal contact is possible from exposure to the consumer product, the final product will contain no more than 25% by weight of the new chemical substance. The new chemical substance will be contained in consumer products that limit consumer exposure under the intended conditions of use, therefore EPA concludes that unreasonable risk to consumers from irritation via inhalation and dermal contact is not likely.

Because worker exposures can be controlled by PPE and no unreasonable risks to the general population, environment, or consumers were identified, 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.

7/30/20
Date:

/s/
Madison H. Le, Director
Chemical Control Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

[7] The 20-day criterion for concluding chronic risk is not likely is based on partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration.