TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-20-0018-0021

Number: P-20-0018-0021
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-20-0018-0020: Fatty acid dimers, polymers with glycerol and triglycerides
P-20-0021: Fatty acid dimers, polymers with glycerol and fatty acids

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (generic): Manufacture and process for use as and use as a component in candles, 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 use as a gear lubricant and use as a softener based on analogue uses.

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. EPA estimated that the new chemical substances could have limited persistence in the environment and that the new chemical substances have low potential for bioaccumulation; therefore, repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms. Based on physical/chemical properties, and test data on analogous chemical substances, EPA estimates that the chemical substances have low environmental hazard and potential for the following human health hazards: Skin Irritation, Eye Irritation, Reproductive Toxicity, and Specific Target Organ Toxicity. EPA concludes that the new chemical substances

[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 chemical substance may be manufactured, processed, distributed, used, or disposed of. EPA expects that the identification of "reasonably foreseen" conditions of use will be made on a fact-specific, case-by-case basis. EPA will apply its professional judgment and experience when considering factors such as evidence of current use of the new chemical substance outside the United States, information about known or intended uses of 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.

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 physical/chemical and fate properties of the new chemical substances using data submitted on the P-20-0018 chemical substance and EPI (Estimation Program Interface) Suite™ (http://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface). In wastewater treatment, the new chemical substances are expected to be removed with an efficiency of 90% due to sorption and biodegradation. Removal of the new chemical substances by biodegradation is high. Sorption of the new chemical substances to sludge, soil, and sediment is expected to be low to strong. Migration of the new chemical substances to groundwater is expected to be negligible due to biodegradation. Due to low estimated vapor pressure and Henry's law constant, the new chemical substances are expected to undergo negligible volatilization to air. Overall, these estimates indicate that the new chemical substances have 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 substances using data submitted on the P-20-0018 chemical substance and EPI Suite™. EPA estimated that the new chemical substances' aerobic and anaerobic biodegradation half-lives are < 2 months. These estimates indicate that the new chemical substances 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 substances to bioaccumulate using EPI Suite™. EPA estimated that the new chemical substances have low bioaccumulation potential based on BCFBAF model result < 1,000 (lower molecular weight components) and large predicted molecular volume, which limits bioavailablity (higher molecular weight components)

[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)

(bioconcentration factor = 123 [estimated by linear regression from log Kow] and bioaccumulation factor = 11 [estimated by the Arnot-Gobas method (2003)])[4]. EPA estimated that the new chemical substances 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.

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 and by comparing them to structurally analogous chemical substances for which there is information on human health hazard. Absorption of the new chemical substances is expected to be poor to moderate through the skin for the neat material, moderate through the skin when in solution, and poor through the gastrointestinal (GI) tract and lungs based on physical/chemical properties. For the new chemical substances, EPA identified hazards for lung effects (surfactancy) if inhaled and irritation to the skin, eyes, and respiratory tract based on the surfactant-like properties of the new chemical substances and on test data for an analogue. EPA also identified hazards for systemic toxicity and developmental effects based on test data for analogues. EPA identified a Benchmark Concentration Lower Bound (BMCL) of 0.6 mg/m^3 based on lung effects (surfactancy) and a NOAEL of 855 mg/kg-bw/day based on systemic toxicity, which was protective for blood effects and developmental toxicity, and were used to derive exposure route- and population-specific points of departure for quantitative risk assessment. EPA qualitatively evaluated irritation effects.

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

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[4] Arnot JA, Gobas FAPC. 2003. A generic QSAR for assessing the bioaccumulation potential of organic chemicals in aquatic food webs. *QSAR and Combinatorial Science* 22: 337-345.

[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] 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

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 acute/chronic hazard data for an analogous chemical. These substances fall within the TSCA New Chemicals Category of Esters.[7] Acute toxicity values estimated for fish, aquatic invertebrates, and algae are all >100 mg/L. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are all >10 mg/L. These toxicity values indicate that the new chemical substances are expected to have low 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 20 mg/L (20,000 ppb) and 1 mg/L (1,000 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 substances 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 new chemical assessment, EPA assessed worker exposure via dermal exposure; inhalation exposures to workers are not expected. Releases to water, air, and landfill were estimated. Exposure to the general population was assessed via drinking water and fish ingestion. Exposure to the general population via groundwater impacted by landfill leaching and inhalation were not assessed because releases to landfill and air were expected to be negligible (below modeling thresholds). Exposure to consumers was assessed via inhalation.

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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).

[7] 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.

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 substances were evaluated using the route-specific effect levels (i.e., BMCL and NOAEL) described above. Risks were not identified for workers for systemic effects via dermal exposure based on quantitative hazard data for an analogue (MOE = 156; Benchmark MOE = 100). Risks were not evaluated for workers via inhalation because exposures are expected to be negligible. Irritation hazards to workers via dermal contact were identified based on analogue data. Risks for these endpoints were not quantified due to a lack of dose-response for these hazards. Risks were not identified for the general population for systemic effects via drinking water or fish ingestion based on quantitative hazard data for an analogue ($MOE_{\text{Adult Drinking Water (DW)}}$ = 36,261; $MOE_{\text{Infant DW}}$ = 8,634; $MOE_{\text{Fish ingestion}}$ = 193,592; Benchmark MOE = 100). Risks were not evaluated for the general population via groundwater impacted by landfill leaching or inhalation because exposures are expected to be negligible. Irritation hazards to the general population are not expected via drinking water ingestion or fish ingestion due to dilution of the chemical substances in the media. Risks were not identified for consumers for lung effects via inhalation exposure based on quantitative hazard data for an analogue (MOE = 112; Benchmark MOE = 30).

Risks to the environment were not identified because the new chemical substances are expected to have low environmental hazard.

Although use as a softener and as a gear lubricant were identified as reasonably foreseen conditions of use based on analogue uses, these uses are not likely to present unreasonable risk to human health or the environment. Due to the low environmental hazard of the new chemical substances, environmental risk is not likely, even if exposures are high. EPA identified potential human health hazards associated with the new chemical substances. However, the chemicals are expected to have relatively low systemic hazards (i.e., a NOAEL of 855 mg/kg-bw/day was identified). EPA's quantitative risk assessment under the intended conditions of use did not identify any unreasonable risk to human health, and given the large margins of exposure compared to the benchmark MOE, even large increases in oral or dermal exposure are not likely to result in unreasonable risk. Higher inhalation exposure could potentially result in unreasonable

risk from lung effects; however, inhalation exposure is not expected under the reasonably foreseen conditions of use based on physical/chemical properties of the new chemical substances (i.e., they are [claimed CBI] and not volatile under ambient conditions), and risks were not identified via inhalation exposure under the intended conditions of use.

Therefore, 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.

12/20/2021
Date:

/s/
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