TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-17-0347, P-17-0348, P-17-0349, P-17-0350 P-17-0351, P-170-352

Number: P-17-0347, P-17-0348, P-17-0349, P-17-0350 P-17-0351, P-17-0352
TSCA Section 5(a)(3) Determination: The chemical substances are not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Specific:
P-17-0347: Oxirane, 2-methyl-, polymer with oxirane, mono(2-butyloctyl) ether; CASRN:252756-20-0
P-17-0348: Oxirane, 2-methyl-, polymer with oxirane, mono(2-hexyldecyl) ether; CASRN: 125005-52-9
P-17-0349: Oxirane, 2-methyl-, polymer with oxirane, mono(2-octyldodecyl) ether; CASRN: 102640-44-8
P-17-0350: Oxirane, 2-methyl-, polymer with oxirane, mono(2-decyltetradecyl) ether; CASRN: 72484-69-6
P-17-0351: Oxirane, 2-methyl-, polymer with oxirane, mono(2-dodecylhexadecyl) ether; CASRN: 102640-42-6
P-17-0352: Oxirane, 2-methyl-, polymer with oxirane, mono(2-tetradecyloctadecyl) ether; CASRN: 102640-46-0

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (generic): Import for use as an oilfield surfactant, consistent with the manufacturing, 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.

[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.

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Reasonably foreseen conditions of use: Applying such factors as described in footnote 1, EPA evaluated whether there were reasonably foreseen conditions of use, and based on a patent search and information from another TSCA submission, identified uses other than the use as described in the PMNs, including in textile processes and paints and as a lubricant, surfactant, and chemical intermediate.

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 and the terms of the proposed Significant New Use Rule (SNUR) signed by EPA.[2] Although EPA estimated that the new chemical substances could be very persistent, the substances have a low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms. Based on EPA's TSCA New Chemicals Program Chemical Category for Nonionic Surfactants[3], physical/chemical properties and test data on the chemical substances and analogous chemical substances, EPA estimates that the chemical substances have high environmental hazard and and potential for the following human health hazards: severe irritation to the eyes, surfactant effects on the lungs, irritation to skin (chronic), mucous membranes and lungs and eye damage. The PMNs describe conditions of use that mitigate the human health and environmental risks. Therefore, EPA concludes that the new chemicals are not likely to present unreasonable risk to human health or the environment under the intended conditions of use.

As set forth below, the information available to EPA is sufficient to permit the Agency to conduct a reasoned evaluation of the health and environmental effects of the chemical substances under the conditions of use that are not subject to the proposed SNUR, in order to determine that the chemical substances are not likely to present an unreasonable risk under those conditions of use. As such, EPA does not need to impose testing requirements to conduct this evaluation. Whether testing is needed to evaluate the effects of the intended, known, or reasonably foreseen conditions of use of a chemical substance subject to a PMN is determined on a case-by-case basis. To the extent that testing may be necessary to conduct a reasoned evaluation of the health

[2] Reasonably foreseen conditions of use subject to a proposed SNUR are not likely to present an unreasonable risk of injury to health or the environment. Based on EPA's experience, it is the Agency's judgment that a new use would not commence during the pendency of a proposed SNUR because web posting of a proposed SNUR serves as the cut-off date for a significant new use. Therefore, manufacturers and processors would not commence a prohibited new use that would be legally required to cease upon the finalization of the SNUR. Once a SNUR is final and effective, no manufacturer or processor – including the PMN submitter – may undertake the conditions of use identified as a significant new use of the PMN substance in the SNUR. EPA must first evaluate the new use in accordance with the requirements of TSCA Section 5 and (a) either conclude that the new use is not likely to present an unreasonable risk under the conditions of use; or (b) take appropriate action under section 5(e) or 5(f). If EPA were not to finalize the proposed SNUR, then that decision would be based on information and data provided to the Agency during the comment period demonstrating that the reasonably foreseen conditions of use subject to the proposed SNUR are not likely to present an unreasonable risk. Under either scenario, the reasonably foreseen condition of use is not likely present an unreasonable risk.

[3] 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.

or environmental effects of the reasonably foreseen conditions of use that are subject to the proposed SNUR, EPA will make the appropriate determination if a SNUN is submitted following finalization of the SNUR.

EPA found no known conditions of use, assessed the intended conditions of use, and addressed reasonably foreseen conditions of use by proposing a SNUR. Therefore, EPA determines the new chemical substances are not likely to present unreasonable risk to human health or the environment.

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 biodegradation data submitted for the substance described in P-17-0347 and analogues (surfactants) of the new chemical substances. 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 negligible to high. Sorption of the new chemical substances to sludge is expected to be strong and to soil and sediment is expected to be very strong. Migration of the new chemical substances to groundwater is expected to be negligible due to very strong sorption to soil and sediment, in addition 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[4]: 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 biodegradation data submitted for the substance described in P-17-0347 and analogues (surfactants) of the new chemical substances. EPA estimated that the new chemical substances' aerobic biodegradation half-lives are < 2 months and anaerobic biodegradation half-lives are > 6 months. These estimates indicate that the new chemical substances may have limited persistence in aerobic environments (e.g., surface water) and may be very persistent in anaerobic environments (e.g., sediment).

[4] 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)

Bioaccumulation[5]: 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 data submitted for analogue(s) (surfactants). EPA estimated that the new chemical substances have low bioaccumulation potential based on bioconcentration or bioaccumulation data reported for surfactants and expected metabolism for the low molecular weight portion of the chemical substances. Although EPA estimated that the new chemical substances could be very persistent, the substances have a low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms.

Human Health Hazard[6]: 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 nil for the neat material; if in solution, absorption of the low molecular weight fraction is expected to be poor via all routes based on physical/chemical properties. For these new chemical substances, EPA identified lung toxicity (surfactant effects) and irritation to the eye, skin (chronic), mucous membranes and lung as hazards based on analogue data and surfactant properties. EPA qualitatively evaluated irritation hazards.

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[5] 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)

[6] 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.

Environmental Hazard[7]: Environmental hazard is 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 determined environmental hazard for these new chemical substances based on SAR predictions for nonionic surfactants (special class within ECOSAR v.2.0) and using hazard data on analogous chemicals (C16-18 linear alkyl-2 PO-10 EO and C16 linear alkyl-7PO-7EO). These substances fall within the TSCA New Chemicals Category of Nonionic Surfactants. Acute toxicity values estimated for fish, aquatic invertebrates, and algae are 0.4 mg/L (SAR for nonionic surfactants), 0.4 mg/L (analogue; C16 linear alkyl-7PO-7EO test data), and 42.1 mg/L (analogue; C16-18 linear alkyl-2 PO-10 EO), respectively. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are 0.04 mg/L (SAR for nonionic surfactants with an ACR 10), 0.04 mg/L (C16 linear alkyl-7PO-7EO analogue test data with an ACR 10), and > 10 mg/L (C16-18 linear alkyl-2 PO-10 EO analogue test data with an ACR 4), respectively. These toxicity values indicate that the new chemical substances are expected to have high 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 0.08 mg/L (80 ppb) and 0.004 mg/L (4 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 PMNs 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

[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).

basis of greater exposure potential compared to the general population who do not use specific products.

For this assessment, EPA assessed worker exposure via dermal exposure. Worker exposure via inhalation was not assessed because exposure is expected to be negligible. Releases to water and landfill were estimated. Exposure to the general population was assessed via drinking water ingestion. Exposure to the general population via fish ingestion and ground water ingestion (via landfill leaching) were not assessed because releases to landfill were expected to be negligible (below modeling thresholds), and the new chemical substances are not expected to bioaccumulate. Exposure to the general population via inhalation was not assessed because there are no expected releases to air. Consumer exposures 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 substances were evaluated qualitatively. Risks were not evaluated for workers via inhalation because inhalation exposures are expected to be negligible. Irritation hazards to workers via dermal contact were identified based on analogue data and surfactant properties. Risks for this endpoint 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 and eye protection. EPA expects that employers will require and that workers will use appropriate PPE consistent with the Safety Data Sheet prepared by the new chemical submitter, in a manner adequate to protect them.

Risks were not identified for the general population for irritation to the eyes, skin, and mucous membranes via drinking water since these concerns are expected to be mitigated by dilution in the media. Risks were not evaluated for the general population via inhalation because inhalation exposures are expected to be negligible. Risks to consumer 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 from acute and chronic exposures to the environment were not identified due to releases to water that did not exceed the acute or chronic COC.

It is reasonably foreseen, based on a patent search and information from another TSCA submission, that these substances could be used other than as described in the PMNs with greater human exposure and releases to the environment. The SNUR that has been proposed for these chemical substances defines certain conditions of use as significant new uses. The proposed significant new uses include use other than the confidential use described in the PMNs. Conditions of use that fall under the restrictions of the proposed SNUR are not likely to present unreasonable risk of injury to health or the environment because (1) those conditions of use are

not likely to be commenced during the pendency of the proposed SNUR, and (2) upon finalization of the SNUR, those conditions of use would be prohibited unless and until EPA makes an affirmative determination that the significant new use is not likely to present an unreasonable risk or takes appropriate action under section 5(e) or 5(f).

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Date:

/s/
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