TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-19-0162

Number: P-19-0162
TSCA Section 5(a)(3) Determination: The chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic: Fatty acid alkyl amide, (dialkyl) amino alkyl, alkyl quaternized, salts

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 oil production, 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 anion could have limited persistence and a low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms. Further, although EPA estimated that the cation could be persistent, the substance has 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 Cationic Surfactants[2], test data on

[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.

the new chemical substance, and test data on analogous chemical substances, EPA estimates that the chemical substance has moderate environmental hazard for marine ecosystems and high environmental hazard for freshwater ecosystems and potential for the following human health hazards: skin irritation, skin corrosion, eye irritation, skin sensitization, reproductive toxicity, and specific target organ toxicity. EPA concludes 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 anion using data for analogue(s) ([claimed CBI]) and EPI (Estimation Program Interface) Suite™ (http://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface) and of the cation using data for analogue(s) ([claimed CBI]) and EPI Suite™. In wastewater treatment, the anion is expected to be removed with an efficiency of 90% due to biodegradation and the cation is expected to be removed with an efficiency of 90% due to sorption and biodegradation. Removal of the anion by biodegradation is high and removal of the cation by biodegradation is moderate to high. Sorption of the anion to sludge, soil, and sediment is expected to be low and sorption of the cation to sludge is expected to be strong and to soil and sediment is expected to be very strong. Migration of the anion to groundwater is expected to be negligible due to low sorption to soil and sediment, mitigated by biodegradation and migration of the cation to groundwater is expected to be negligible due to very strong sorption to soil and sediment. Due to low estimated vapor pressure and Henry's law constant, the anion and the cation are expected to undergo negligible volatilization to air. Overall, these estimates indicate that the anion and the cation have low potential to volatilize to air and low potential to migrate to 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. EPA estimated degradation half-lives of the anion using data for analogue(s) ([claimed CBI]) and EPI Suite™ and of the cation using data for analogue(s) ([claimed CBI]) and EPI Suite™. EPA estimated that the anion's aerobic and anaerobic biodegradation half-lives are < 2 months; and that the cation's aerobic and anaerobic biodegradation half-lives range from < 2 months to 6 months. These estimates indicate that the anion may have limited persistence in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment). Further, these estimates indicate that the cation may be persistent in aerobic environments and anaerobic environments.

[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 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)

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. EPA estimated the potential for the anion and the cation to bioaccumulate using EPI Suite™. EPA estimated that the anion and the cation have low bioaccumulation potential based on BCFBAF model result < 1000 (anion bioconcentration factor = 3 [estimated] and bioaccumulation factor = 1 [estimated]; cation bioconcentration factor = 71 [estimated] and bioaccumulation factor = 661 [estimated]). EPA estimated that the anion could have limited persistence and a low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms. Further, although EPA estimated that the cation could be persistent, the substance has 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[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 chemical substance based on its estimated 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 is expected to be poor to moderate through the skin and poor through the gastrointestinal tract and lungs, based on physical/chemical properties. EPA identified the following hazards for the cationic component: lung effects (surfactancy) if respirable droplets are inhaled based on potential surfactant properties; irritation to all tissues, skin sensitization, neurological, systemic, reproductive, and developmental effects based on analogue data. For the

[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 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)

[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.

anionic component, EPA identified irritation, corrosion to skin and eyes and irritation to lungs based on structure and neurological and developmental effects based on potential release of [claimed CBI]. No data were submitted on the new chemical substance. EPA identified a lowest-observed-adverse-effect-concentration (LOAEC) of 0.08 mg/m^3 based on lung effects (surfactancy) in a repeated dose inhalation study in rats and a NOAEL of 1 mg/kg/day based on systemic effects in a developmental toxicity study in rabbits, which were protective for all systemic effects and were used to derive exposure route- and population-specific points of departure. EPA qualitatively evaluated irritation, corrosion and sensitization 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 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 marine toxicity data submitted for the new chemical substance and the Ecological Structure Activity Relationships (ECOSAR) Predictive Model (https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model) for freshwater organisms; specifically the QSAR for amides. This substance falls within the TSCA New Chemicals Category of Cationic Surfactants. Marine acute toxicity values measured for fish, aquatic invertebrates, and algae are 3.75 mg/L (submitted test data), 1.67 mg/L (submitted test data), and 1.31 mg/L (submitted test data), respectively. Freshwater acute toxicity values estimated for fish, aquatic invertebrates, and algae are 0.02 mg/L (ECOSAR), 0.011 mg/L (ECOSAR), and 0.02 mg/L (ECOSAR), respectively. Marine chronic toxicity values estimated for fish, aquatic invertebrates, and algae are 0.38 mg/L (acute to chronic ratio (ACR) 10), 0.17 mg/L (ACR10), and 0.88 mg/L (submitted test data). Freshwater chronic toxicity values estimated for fish, aquatic invertebrates, and algae are 0.0025 mg/L (ECOSAR), 0.01 mg/L (ECOSAR), and 0.09 mg/L (ECOSAR), respectively. These toxicity values indicate that the new chemical substance is expected to have moderate environmental hazard for marine ecosystems and a high environmental hazard for freshwater ecosystems. Application of assessment factors of 4 and 10 to acute and chronic marine toxicity values, respectively, results in acute and chronic concentrations of concern of 0.328 mg/L (328 ppb) and 0.017 mg/L (17 ppb), respectively. Application of assessment factors of 5 and 10 to acute and chronic freshwater toxicity values, respectively, results in acute and chronic concentrations of concern of 0.002 mg/L (2 ppb) and 0.001 mg/L (1 ppb), respectively. Due to uncertainties in the modeling estimates for this substance (e.g., log Kow, toxicity values) and the limitations of analytical tools (e.g., HPLC, GC), the chronic COC is rounded up to 1 ppb. Per methodology used by the Office of Water generally an acute LC50 value is used in conjunction with the marine offshore model estimate

[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 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 surface water releases, therefore this assessment will also use the accepted acute marine mysid shrimp 96-hr LC50 of 1.67 mg/L (1,670 ppb) to characterize risk for marine organisms.

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 new chemical assessment, EPA assessed worker exposure via dermal exposure, and inhalation exposure to workers is not expected. Releases to water, air, and landfill were estimated. Exposures to the general population were not assessed via drinking water and fish ingestion because releases are via offshore platforms. 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). 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 (MOE) 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 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., NOAEL) described above. Risks were identified for workers for systemic effects via dermal contact based on quantitative hazard data for an analogues (MOE = 0.085; Benchmark MOE = 100). However, due to the expected corrosive nature of the new chemical substance, long-term repeated exposures are not likely. Risks were not evaluated for workers via inhalation exposure because exposures are expected to be negligible. Irritation, corrosion and sensitization hazards to workers via dermal contact were identified. Risks for these endpoints were not quantified due to a lack of dose-response for these hazards. Exposures can be mitigated by the use of appropriate personal protective equipment (PPE), including impervious gloves, eye protection, and protective clothing. 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 evaluated for the general population via drinking water, fish ingestion or groundwater impacted by landfill leaching or inhalation because exposures are expected to be negligible (below modeling thresholds). Risks to consumers were not evaluated because consumer uses were not identified as conditions of use.

Risks to the freshwater environment were not identified due to no releases to freshwater. Risks to the marine environment were evaluated by comparing estimated surface water concentrations with the acute and chronic concentrations of concern. Risks to the marine environment were not identified due to releases to water that did not exceed the acute COC, chronic COC, or the mysid shrimp 96-hr LC50.

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.

9/29/2020
Date:

/s/
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