**TSCA Section 5(a)(3) Determination for Significant New Use Notice (SNUN) S-15-0009**

**Number: S-15-0009**
**TSCA Section 5(a)(3) Determination**: The significant new use is not likely to present an unreasonable risk (5(a)(3)(C))

**Chemical Name:**
Generic: Fatty acid amide.

**Significant New Use:** Release to water resulting in surface water concentrations above 1 part per billion (ppb). The significant new use rule for this chemical substance requires notification to EPA for any release to water above 1 ppb.

**Conditions of Use (intended, known, or reasonably foreseen)[1]:**
Intended conditions of use (generic): Import for use as a polymer additive, consistent with the manufacturing, processing, use, distribution, and disposal information described in the SNUN, including release to water resulting in surface water concentrations above 1 ppb.
Known conditions of use (generic): Import for use as a polymer additive, consistent with the manufacturing, processing, use, distribution, and disposal information described in the PMN, including no release to water.
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 significant new use is not likely to present an unreasonable risk of injury to health or the environment under the conditions of use, 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, based on the risk assessment presented below. EPA estimated that the chemical substance could be persistent, and the chemical substance has potential for bioaccumulation, such that repeated exposures could be cumulative.

[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.

Based on acute and chronic aquatic toxicity testing for the substance, EPA estimates that the chemical substance has low environmental hazard. Based on acute testing and a 28-day repeated dose test for the substance, EPA estimates that the chemical substance has low human health hazard. EPA concludes that the significant new use 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 substance 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 significant new use of a chemical substance may present an unreasonable risk. EPA estimated physical/chemical and fate properties of this chemical substance using data for analogous chemicals and a submitted biodegradation study for the substance. The chemical substance is estimated to be removed during wastewater treatment with an efficiency of 90% via sorption and biodegradation. Sorption to soil and sediment is estimated to be strong, resulting in slow migration to groundwater. Volatilization to air is estimated to be negligible because of low estimated vapor pressure. Overall, these estimates are indicative of low potential for this chemical substance to volatilize into the air and a low potential for this chemical substance to migrate into groundwater.

**Persistence[2]:** Persistence is relevant to whether a significant new use of a 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 and a biodegradation study for the substance, EPA estimated the biodegradation half-lives to be greater than 2 months but less than or equal to 6 months. These estimates for biodegradation indicate that the chemical substance may be persistent in aerobic environments (e.g., surface water) or anaerobic environments (e.g., sediment).

**Bioaccumulation[3]:** Bioaccumulation is relevant to whether a significant new use of a 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 high bioaccumulation potential based on a modeled bioconcentration factor (BCF) of 6,950. The bioaccumulation factor (BAF) model relies on a metabolism rate estimate that may not have properly accounted for potential

[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 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)

[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 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)

branching of this chemical's structures so the BAF model was not considered as relevant for this chemical as the BCF model. Although EPA estimated that the substance is persistent and could bioaccumulate, because the substance demonstrates low toxicity, 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 significant new use of a 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 and submitted data on the chemical substance, including studies on mutagenicity, acute oral and dermal toxicity, irritation to the eye and skin, dermal sensitization and a 28-day repeated dose study. Absorption is estimated to be nil through the skin and poor to moderate through the lung and GI tract based on physical/chemical properties.

EPA did not identify any systemic health hazards based on submitted test data on the chemical substance. Test data on the chemical substance were negative for the following hazards: mutagenicity, irritation to the eyes and skin, and skin sensitization. A NOAEL of 1000 mg/kg-bw/day was identified based on no treatment-related adverse effects at the highest dose tested in a 28-day oral repeated-dose toxicity study (OECD 407). EPA concludes that this chemical substance has low human health hazard.

**Environmental Hazard[5]:** Environmental hazard is relevant to whether a significant new use of a chemical substance is likely to present unreasonable risk, because the significance of the risk is

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[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 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

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 chemical substance based on acute and chronic toxicity data submitted for the chemical substance in conjunction with physical/chemical and fate properties. Acute and chronic toxicity values measured for fish, aquatic invertebrates, and algae are all no effects at saturation in the aqueous environment. The chronic toxicity value measured for sediment-dwelling invertebrates is > 788 mg/kg dry weight (LOEC). These toxicity values indicate that the new chemical substance is expected to have low environmental hazard. Because hazards are not expected up to the water solubility limit in the aqueous environment nor in sediment exposures acute and chronic concentrations of concern are not identified.

**Exposure and Risk Characterization:** The exposure to a chemical substance is potentially relevant to whether a significant new use of that chemical substance is likely to present unreasonable risks under the conditions of use, 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. Due to low hazard, EPA believes that this chemical substance would be unlikely to present an unreasonable risk even if exposures were high.

**Potentially Exposed or Susceptible Subpopulation(s) (PESS):** EPA considers workers to be a 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. Given the low hazard of this chemical substance, EPA finds that the significant new use is not likely to present unreasonable risk to human health or the environment.

12/12/2018
Date:

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

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ChVs is less than 0.1 mg/L (Sustainable Futures https://www.epa.gov/sustainable-futures/sustainable-futures-p2-framework-manual).