

## TSCA Section 5(a)(3)(C) Determination for Premanufacture Number (PMN) P-16-0281

**Number: P-16-0281**

**TSCA Section 5(a)(3) Determination:** Chemical substance not likely to present an unreasonable risk (5(a)(3)(C))

**Chemical Name:**

Generic: Fatty alcohols-dimers, trimers, polymers

**Assessed Conditions of Use (intended, known, or reasonably foreseen)<sup>1</sup>:**

Intended use(s) (generic): Reactive polyol (generic)

Known and reasonably foreseen use(s): Lubricant and lubricant additive.

**Summary:** The chemical substance is not likely to present an unreasonable risk based on low health hazard concern and low environmental toxicity.

**Fate:** Environmental fate is relevant to whether a new chemical substance is likely to present an unreasonable risk because a greater potential for the chemical substance to volatilize into the air, migrate into ground water, or persist in surface water, sediments or soil generally reflects a greater cause for concern regarding exposure to the substance. EPA estimated a number of physical-chemical and fate properties of this new chemical substance using EPI (Estimation Programs Interface) Suite, a suite of physical/chemical property and environmental fate estimation programs (<https://www.epa.gov/tsca-screening-tools/epi-suite-estimation-program-interface>). Overall, these estimates were indicative of low potential for this chemical substance to volatilize into the air or migrate into ground water and that the substance would be effectively removed should it be released into wastewater.

**Persistence<sup>2</sup>:** 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 significant substantial exposure to them (including their buildup in the environment) may present a risk if the substance presents a hazard to human health or the environment. EPA estimated the half-lives for this chemical substance in environmental media (i.e., air, water and soil) using EPI Suite (<https://www.epa.gov/tsca-screening-tools/epi-suite-estimation-program-interface>). The chemical substance is persistent based on physical/chemical properties and structure-activity relationships.

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<sup>1</sup> Intended uses are those identified in the section 5(a) notification. EPA identifies “known” and “reasonably foreseen” of the new chemical substance based on evidence of current use of the new chemical substance outside the United States and evidence of the current uses of chemical substances that are structurally analogous to the new chemical substance. EPA identifies uses based on searches of internal CBI EPA PMN databases (containing use information on analog 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.

<sup>2</sup> 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)

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Although EPA estimated that the new chemical substance would be persistent, this did not indicate a likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health hazard, and low environmental hazard.

**Bioaccumulation<sup>3</sup>:** 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 extent to which this chemical substance will partition to octanol (log Kow) and estimated a fish bioconcentration factor (Fish BCF) using EPI Suite (<https://www.epa.gov/tsc-screening-tools/epi-suite-tm-estimation-program-interface>). These modeling estimates indicate that this chemical substance has low bioaccumulation potential.

**Human Health Hazard<sup>4</sup>:** 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 (which indicate that it will not be absorbed if inhaled, ingested or by dermal contact) and by comparing it to structurally analogous chemical substances for which there is information on human health hazard. This new chemical substance is similar to other fatty alcohol polymers. There is evidence that similar fatty alcohol polymers present a low human health hazard.

**Environmental Hazard<sup>5</sup>:** Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risks because the significance of the risk is dependent

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<sup>3</sup> 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)

<sup>4</sup> A chemical substance is considered to have low human health hazard if no concerns identified or systemic toxicity with No Observed Adverse Effect Level (NOAEL) greater than 1,000 mg/kg/day; only minor clinical signs of toxicity; liver and/or kidney weight increase or clinical chemistry changes with Lowest Observed Adverse Effect Level (LOAEL) greater than or equal to 500 mg/kg/day. A chemical substance is considered to have moderate human health hazard if suggestive animal studies for chemical substances, analogous chemicals, or chemical class is known to product toxicity or organ pathology (gross and/or microscopic) with a LOAEL greater than 500 mg/kg/day; clinical chemistry changes and organ weight changes at greater than 500 mg/kg/day, or a NOAEL of less than 1,000 mg/kg/day. 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; death, organ pathology (microscopic) with a LOAEL less than or equal to 100 mg/kg/day, multiple organ toxicity; or a NOAEL of less than or equal to 10 mg/kg/day.

<sup>5</sup> 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 higher 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,

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upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated the environmental hazard of this chemical substance by comparing it to structurally analogous chemical substances using the Ecological Structure Activity Relationships (ECOSAR) Predictive Model (<https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model>). This new chemical substance is similar to fatty alcohol polymers. There is evidence from ECOSAR that similar fatty alcohol polymers present a low environmental hazard.

**Potential Exposures:** The potential for 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. However, in this case it was unnecessary to estimate the potential for exposure because EPA estimated that the chemical substance presents both low human health hazard and low environmental hazard. Due to low hazard, EPA believes that this chemical substance would be unlikely to present an unreasonable risk even if potential exposures were high.

**Potentially Exposed or Susceptible Subpopulation(s):** Because of its intended use, workers in a certain industrial sector will be exposed to this chemical substance. Although it is foreseeable that this chemical substance might be incorporated into lubricants with the potential for exposures of workers in other industrial sectors and exposures to consumers, the chemical substance is estimated to present only a low hazard.

7/15/2016  
Date: \_\_\_\_\_

\_\_\_\_\_/s/  
James J. Jones  
Assistant Administrator  
Office of Chemical Safety and Pollution Prevention

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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).