

TSCA Section 5(a)(3)(C) Determination for Premanufacture Notice (PMN) P-18-0044 & 0045

Number: P-18-0044 & P-18-0045

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-18-0044): Fatty acids

Generic (P-18-0045): Fatty acids, alkyl esters

Assessed Conditions of Use (intended, known, or reasonably foreseen)¹:

Intended use(s) (generic) (P-18-0044): Intermediate species

Intended use(s) (generic) (P-18-0045): Application coating

Known and reasonably foreseen use(s) (P-18-0044): Chemical intermediate; Lubricant and lubricant additive; Viscosity adjustor; Coating.

Known and reasonably foreseen use(s) (P-18-0045): Lubricant intermediate; Mold release agent; Plasticizer; Processing aid.

Summary: These chemical substances are not likely to present an unreasonable risk based on low/moderate human health hazard and low environmental hazard. Although EPA estimated that the new chemical substances would be persistent, this did not indicate a likelihood that the chemical substances would present an unreasonable risk, given that the chemical substances have low potential for bioaccumulation, low-moderate human health hazard, and low environmental hazard.

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 a number of physical-chemical and fate properties of these new chemical substances using data for analogous chemicals and EPI (Estimation Programs Interface) Suite, a suite of physical/chemical property and environmental fate estimation programs (<http://www.epa.gov/tsca-screening-tools/epi-suite-estimation-program-interface>). Overall, these estimates are indicative of low potential for these chemical substances to volatilize into the air and a low potential to migrate into ground water. Removal of the substances in wastewater treatment is likely due to sorption and biodegradation.

Persistence²: 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

¹ Intended uses are those identified in the section 5(a) notification. EPA identifies “known” and “reasonably foreseen” uses 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.

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

TSCA Section 5(a)(3)(C) Determination for Premanufacture Notice (PMN) P-18-0044 & 0045

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 biodegradation half-lives of these new chemical substances using data for analogous chemicals and EPI Suite. The anaerobic biodegradation estimates indicate that the chemical substances are persistent.

Bioaccumulation³: 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. The chemical substance has low bioaccumulation potential based on data for analogous chemicals and EPI Suite. These estimates indicate that these new chemical substances have low bioaccumulation potential.

Human Health Hazard⁴: 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. EPA concludes there is low-moderate concern for human health hazard for the chemical substances based on concern for serious eye damage (P-18-0044 only) and concern for irritation to all exposed tissues.

Environmental Hazard⁵: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risks because the significance of the risk is dependent

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)

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. 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^{6,7}, 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 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,

TSCA Section 5(a)(3)(C) Determination for Premanufacture Notice (PMN) P-18-0044 & 0045

upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated environmental hazard of this new chemical substance using the Ecological Structure Activity Relationships (ECOSAR) Predictive Model (<https://www.epa.gov/tsc-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model>). Based on these estimated hazard values, EPA concludes that these chemical substances have low environmental hazard.⁶

Potential Exposures: 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 estimated worker exposure to the new chemical substances via the dermal and inhalation routes and general population exposure via drinking water and fish ingestion. EPA could not quantify risk due to insufficient toxicity data but believes that exposure to the general population will be low and is unlikely to result in unreasonable risk, and EPA expects that workers will use adequate personal protective equipment. Consumer exposure is not expected.

Potentially Exposed or Susceptible Subpopulation(s): Workers are potentially exposed. Given that EPA expects workers to use adequate dermal protection (including impervious gloves, eye protection, and protective clothing), EPA finds that these chemical substances are not likely to present unreasonable risk to workers.

3/23/2018
Date:

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

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>).

⁶ TSCA New Chemicals Program (NCP) Chemical Categories (https://www.epa.gov/sites/production/files/2014-10/documents/ncp_chemical_categories_august_2010_version_0.pdf)

⁷ 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](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf?cote=env/jm/mono(2014)4&doclanguage=en))