TSCA Section 5(a)(3)(C) Determination for Premanufacture Number (PMN) P-16-0302

Number: P-16-0302
TSCA Section 5(a)(3) Determination: Chemical substance not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic: Organic modified propyl silsesquioxane

Assessed Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended use(s) (generic): Plastic additive
Known and reasonably foreseen use(s): Finishing agent

Summary: The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental toxicity. Although EPA estimated that the new chemical substance would be very persistent, this did not indicate 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.

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 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-suitetm-estimation-program-interface). Overall, EPI Suite 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[2]: 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 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-suitetm-estimation-program-

[1] 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.

[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)

interface). The chemical substance is very persistent based on physical/chemical properties and structure-activity relationships.

Bioaccumulation[3]: 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 would be bioavailable based on the molecular volume and water solubility of the chemical substance. These characteristics indicate low absorption across membranes resulting in low bioaccumulation potential.

Human Health Hazard[4]: 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. There is low concern for human health hazard for this chemical substance based on physical/chemical properties of the chemical, as well as estimates of potential hazard based on analogous chemical substances/structure-activity relationships.

Environmental Hazard[5]: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risks because the significance of the risk is dependent

[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, 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

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). There is evidence from ECOSAR that similar chemical substances present a low environmental hazard; therefore, EPA concludes that this chemical substance has 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.

In this case, EPA did not estimate the potential for exposure because EPA determined 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): Workers are potentially exposed. Given the low hazard of this chemical substance, EPA finds that this chemical substance is not likely to present unreasonable risk to workers.

7/20/2016 /s/

Date: Director, Office of Pollution Prevention and Toxics

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/publicdisplydocumentpdf?cote=env/jm/mono(2014)4&doclanguage=en)