TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0222

Number: P-18-0222
TSCA Section 5(a)(3) Determination: The chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic: Silane, alkenylalkoxy-, polymer with alkene and alkene

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use(s) (specific): Import for use as a reactive polymer for use in adhesive applications, 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 that the new chemical substance is imported for use as an adhesive used in industrial applications based on another submission.
Reasonably foreseen conditions of use(s): Applying such factors as described in footnote 1, EPA evaluated whether there are reasonably foreseen conditions of use and found the following reasonably foreseen uses, based on patent searches: chemical intermediate for crosslinked thermoplastic elastomers; chemical intermediate for fire retardant/flame retardant crosslinked thermoplastics; and chemical intermediate for plastic foam.

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 and the terms of the proposed Significant New Use Rule (SNUR) signed by EPA.[2] The new

[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] Reasonably foreseen conditions of use subject to a proposed SNUR are not likely to present an unreasonable risk of injury to health or the environment. Based on EPA's experience, it is the Agency's judgment that a new use

chemical substance is not persistent and has low potential for bioaccumulation, such that repeated exposures are not expected to be cumulative. Based on test data on analogous chemical substances, EPA estimates that the chemical substance has low environmental hazard and potential for the following human health hazards: lung toxicity for the low molecular weight fractions based on the Alkoxysilane category and neurotoxicity based on the release of [claimed CBI]. The PMN describes conditions of use that mitigate the human health risks. Therefore, EPA concludes that the new chemical substance is not likely to present an unreasonable risk under the intended conditions of use.

As set forth below, the information available to EPA is sufficient to permit the Agency to conduct a reasoned evaluation of the health and environmental effects of the chemical substance under the conditions of use that are not subject to the proposed SNUR, in order to determine that the chemical substance is not likely to present an unreasonable risk under those conditions of use. As such, EPA does not need to impose testing requirements to conduct this evaluation. Whether testing is needed to evaluate the effects of the intended, known, or reasonably foreseen conditions of use of a chemical substance subject to a PMN is determined on a case-by-case basis. To the extent that testing may be necessary to conduct a reasoned evaluation of the health or environmental effects of the reasonably foreseen conditions of use that are subject to the proposed SNUR, EPA will make the appropriate determination if a SNUN is submitted following finalization of the SNUR.

EPA previously assessed the known conditions of use, assessed the intended conditions of use, and addressed reasonably foreseen conditions of use by proposing a SNUR. Therefore, EPA determines the new chemical substance is not likely to present unreasonable risk to human health or the environment.

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 this new chemical substance and its hydrolysis products using data for the chemical substance and data for analogous chemical substances. The chemical substance is estimated to be removed during wastewater treatment with an efficiency of 90-99% due to rapid hydrolysis of the parent compound. The hydrolysis products are expected to be removed with an efficiency of 90% during wastewater treatment due to sorption. For both the

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would not commence during the pendency of a proposed SNUR because web posting of a proposed SNUR serves as the cut-off date for a significant new use. Therefore, manufacturers and processors would not commence a prohibited new use that would be legally required to cease upon the finalization of the SNUR. Once a SNUR is final and effective, no manufacturer or processor – including the PMN submitter – may undertake the conditions of use identified as a significant new use of the PMN substance in the SNUR. EPA must first evaluate the new use in accordance with the requirements of TSCA Section 5 and (a) either conclude that the new use is not likely to present an unreasonable risk under the conditions of use; or (b) take appropriate action under section 5(e) or 5(f). If EPA were not to finalize the proposed SNUR, then that decision would be based on information and data provided to the Agency during the comment period demonstrating that the reasonably foreseen conditions of use subject to the proposed SNUR are not likely to present an unreasonable risk. Under either scenario, the reasonably foreseen condition of use is not likely present an unreasonable risk.

new chemical substance and its hydrolysis products, removal by biodegradation is estimated to be negligible. Sorption to sludge is estimated to be strong, and sorption to soil and sediment is estimated to be very strong, resulting in negligible migration to groundwater for both the new chemical substance and its hydrolysis products. Due to low vapor pressure and Henry's law constant, volatilization to air is expected to be negligible for both the new chemical substance and its hydrolysis products. Overall, these estimates are indicative of low potential for this chemical substance and its hydrolysis products to volatilize to air and low potential for this chemical substance 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. Based on data for analogous chemicals, EPA estimated the hydrolysis half-life of the new chemical substance to be hours to days. EPA estimated the aerobic and anaerobic biodegradation half-lives of the hydrolysis products to be greater than six months. These estimates indicate that the new chemical substance will not be persistent in the environment, but the hydrolysis products will be very persistent in aerobic environments (e.g., surface water) and anaerobic environments (e.g.,sediment).

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. The new chemical substance has low bioaccumulation potential based on the rapid hydrolysis half-life of the parent compound (hours to days), and EPA estimated the potential for the hydrolysis products to bioaccumulate using data for compounds with large molecular volume. These estimates indicate that the hydrolysis products have low bioaccumulation potential, indicating that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms. Although EPA estimated that the hydrolysis product could be very persistent, the new chemical substance and its hydrolysis products have a low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms.

[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 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)

[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 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)

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 (and 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 by comparing it to structurally analogous chemical substances for which there is information on human health hazard. Absorption of the neat new chemical substance is expected to be nil via all routes of exposure; if in solution, absorption of the low molecular weight fractions (no more than 2.6% < 1,000 g/mol) is expected to be poor via all routes based on physical/chemical properties. Based on a [claimed CBI] FGEW of [claimed CBI] and information in the Alkoxysilanes Chemical Category, there is potential concern for lung toxicity for low molecular weight fractions, which are expected to contain molecular species with reactive [claimed CBI] groups and high solubility relative to the average molecular weight new chemical substance. EPA also identified neurotoxicity as a hazard based on the release of [claimed CBI] via hydrolysis. A NOAEC of 10 ppm (equivalent to approximately 11 mg/kg-day) based on lung effects was identified for an analogue, vinyltrimethoxysilane. EPA identified an EPA IRIS oral reference dose[6] (RfD) of 2 mg/kg-day and inhalation reference concentration[6] (RfC) of 20 mg/m^3 for neurotoxicity based on release of [claimed CBI]. The NOAEC, RfD, and RfC were used to derive exposure route-and population-specific points of departure for quantitative risk assessment, described below.

Environmental Hazard[7]: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risks because the significance of the risk is dependent

[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.

[6] EPA's Integrated Risk Information System (IRIS) Program defines reference dose (RfD) or reference concentration (RfC) as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure (RfD) or continuous inhalation exposure (RfC) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used. For more information, see https://www,epa.gov/iris/basic-information-about-integrated-risk-information-system.

[7] 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

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 hazard data for the new chemical substance and SAR predictions for nonionic polymers (special class within ECOSAR v.2.0). Acute and chronic toxicity values estimated for fish, aquatic invertebrates, and algae are all no effects at saturation. Based on these estimated toxicity values, EPA concludes that this chemical has low environmental hazard. Because no effects are expected at any concentration of the PMN substance soluble in water, no concentrations of concern were identified.

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 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 and environmental exposures.

EPA considers workers to be a potentially exposed or susceptible population (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 routes for multiple age groups, ranging from infants to adults. EPA considers consumers of specific products to be a potentially exposed or susceptible population 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 exposure to workers via inhalation and dermal routes. Releases to water, air, and landfill were estimated. Exposure to the general population was assessed via drinking water. Exposure to the general population via inhalation was not assessed because releases to air were expected to be negligible (below modeling thresholds). Exposure to consumers was not assessed because consumer uses were not identified as conditions of use.

Risk Characterization: EPA characterizes risks to human health and the environment by comparing the potential hazards and exposures for the chemical substance, estimated as

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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).

described above. EPA applies a margin of exposure approach to calculate potential human health risks of new chemicals. A benchmark (acceptable) margin of exposure 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 1000 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 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 levels (i.e., NOAEC, RfD, and RfC) described above. Risks were not identified for workers for lung effects via inhalation exposure (MOE = 6,509; benchmark MOE = 30). Risks were not identified for workers for neurotoxicity via inhalation exposure based on [claimed CBI] release (MOE = 1400; benchmark MOE = 1). Risks were not identified for workers for neurotoxicity via dermal exposure based on [claimed CBI] release (MOE = 34; benchmark MOE = 1).

Risks were not identified for the general population for neurotoxicity via drinking water exposure based on [claimed CBI] release (MOE_{Adults} =114,000, $MOE_{Infants}$ = 27,210; benchmark MOE = 1). Risks were not assessed for the general population for lung effects because inhalation exposures are expected to be negligible (below modeling thresholds). Risks to consumers were not evaluated because consumer use was not identified as a condition of use.

Risks to the environment from acute and chronic exposure are not expected at any concentration of the new chemical substance soluble in the water (i.e., no effects at saturation).

It is reasonably foreseen, based on patent searches, that the new chemical substance could be manufactured, processed and used for uses other than the use described in the PMN, which may result in greater exposures for workers. The SNUR that has been proposed for this chemical substance defines certain conditions of use as significant new uses. The proposed significant new uses are any use other than the use specified in the PMN. Conditions of use that fall under the restrictions of the proposed SNUR are not likely to present unreasonable risk of injury to health or the environment because (1) those conditions of use are not likely to be commenced during the pendency of the proposed SNUR, and (2) upon finalization of the SNUR, those conditions of use would be prohibited unless and until EPA makes an affirmative determination that the significant new use is not likely to present an unreasonable risk or takes appropriate action under section 5(e) or 5(f).

04/15/19
Date:

/s/
Tala R. Henry, Ph.D.
Acting Deputy Director for Programs
Office of Pollution Prevention and Toxics