Number: P-17-0119
TSCA Section 5(a)(3) Determination: The new chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic: Alkyl alkenoic acid, alkoxyalkyl ester, polymer with alkyl alkenoate, alkyl alkyl alkenoate and tris alkyl silyl alkyl alkenaote

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (generic): Import as a component of industrial coatings, consistent with the manufacturing, processing, use, distribution, and disposal information described in the PMN. The manufacture (import) and processing are subject to TSCA and the end use final product is subject to regulation under another regulatory authority.
Known conditions of use: Applying such factors as described in footnote 1, EPA evaluated whether there are known conditions of use and found none.
Reasonably foreseen conditions of use: Applying factors as described in footnote 1, EPA evaluated whether there are reasonably foreseen conditions of use, and based on identification of twenty literature references for use of the substance in [claimed CBI], concludes there are reasonably foreseen uses of the new chemical substance. These uses are the same or similar to the intended conditions of use described in the PMN.

Summary: The new 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

[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 new chemical 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.

the Administrator under the conditions of use, based on the risk assessment presented below. Although EPA estimated that the hydrolysis products of the new chemical substance could be very persistent, the new chemical substance and its hydrolysis products both have low potential for bioaccumulation, such that repeated exposures are not expected to be cumulative. Based on information on analogous chemical substances and estimated negligible water solubility, EPA estimates that the new chemical substance has low environmental hazard and potential for the following human health hazards: irritation to the eyes, skin, lung, and mucous membranes and lung effects from lung overload. EPA concludes that the new chemical substance 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 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 using data for analogous chemicals. The new chemical substance is estimated to be removed with an efficiency of 90% during wastewater treatment due to sorption. The new chemical substance is estimated to strongly adsorb to sludge. Volatilization to air is estimated to be negligible based on high molecular volume. The hydrolysis products of the new chemical substance are estimated to be removed with an efficiency of 90% during wastewater treatment due to sorption. Sorption to sludge is estimated to be strong, and sorption to soil and sediment is estimated to be very strong. Volatilization to air is estimated to be negligible for the hydrolysis products, and removal by biodegradation is estimated to be negligible. Overall, these estimates are indicative of low potential for this new chemical substance and its hydrolysis products to volatilize into the air and a low potential for this chemical and its hydrolysis products to migrate into groundwater.

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. Based on data for analogous chemicals, EPA estimates that the new chemical substance will undergo rapid hydrolysis but that the aerobic and anaerobic biodegradation half-lives of the hydrolysis products will be greater than six months. These estimates for biodegradation indicate that the hydrolysis products of the new chemical substance may be very persistent in aerobic environments (e.g., surface water) and very persistent in anaerobic environments (e.g., sediment).

[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)

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. The new chemical substance and its hydrolysis products have low bioaccumulation potential based on data on analogous chemicals, large predicted molecular volume and low water solubility, which limit bioavailability and bioaccumulation. Although EPA estimated that the hydrolysis products of the new chemical substance could be very persistent, they are expected to have low potential for bioaccumulation, such that 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 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 new chemical substance and the extent of exposure to the substance. EPA estimated the human health hazard of this new chemical substance based on its estimated physical/chemical properties and data submitted on the new chemical substance. Absorption of the parent polymer is expected to be nil all routes based on the high molecular weight. Poor absorption by all routes is expected for a silane hydrolysis product based on physical chemical properties. Test data submitted for the new chemical substance included mutagenicity (Ames assay) and sensitization (OECD TG 429), and indicated negative results. An acute oral toxicity test (OECD TG 423) with the new chemical substance indicated it has low acute toxicity (LD_{50} > 2000 mg/kg). EPA identified irritation to the eyes, skin, lung, and mucous membranes as a possible hazard, but determined that it is unlikely due to the large size and low

[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. 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.

water solubility of the new chemical substance. EPA also identified lung effects from lung overload as a hazard of the new chemical substance.

Environmental Hazard[5]: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the new chemical substance and the extent of exposure to the substance. EPA estimated environmental hazard of this new chemical substance using predictions based on the negligible water solubility of the new chemical substance (insoluble nonionic polymer). Acute and chronic toxicity values estimated for fish, aquatic invertebrates, and algae are all no effects at saturation. 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, acute and chronic concentrations of concern are not 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 new 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, consumer, and environmental exposures.

EPA considers workers to be a potentially exposed or susceptible subpopulation (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.

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

For this new chemical assessment, EPA assessed dermal exposure to workers during processing. Inhalation exposure is not expected for workers during processing under the conditions of use described in the PMN. The end use ([claimed CBI]) is solely subject to regulation under another authority, so exposures to workers during end use were not considered in EPA's determination. There were no estimated environmental releases to water, and releases to air were estimated, but exposures to the general population were negligible (below modeling thresholds). Consumer exposure was not assessed because consumer use was not identified as a condition of use.

Risk Characterization: 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 then considers whether the risks would be mitigated by the use of PPE (e.g., impervious gloves, respirator).

Risks to workers for lung effects were not evaluated based on estimated negligible inhalation exposures during processing. Risks to workers for irritation via dermal exposure cannot be quantified due to lack of dose-response information for this hazard. However, exposures can be controlled by the appropriate use of personal protective equipments (PPE), such as impervious gloves. EPA expects that workers will use appropriate PPE consistent with the Safety Data Sheet prepared by the submitter, in a manner adequate to protect them.

Risks to the general population are not expected because environmental exposures are not expected from waters and are expected to be negligible from air. Risks to consumers were not evaluated for the new chemical substance because consumer uses were not identified as conditions of use.

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

EPA has also identified reasonably foreseen uses of this chemical substance. Because the reasonably foreseen uses identified are the same or similar to the intended conditions of use described in the PMN, EPA does not believe exposures would differ significantly from those assessed for this PMN. Therefore, EPA concludes that the reasonably foreseen conditions of use are not likely to present unreasonable risk.

Because no unreasonable risks to workers, the general population or the environment were identified, EPA has determined that the new chemical substance is not likely to present unreasonable risk to human health or the environment under the conditions of use.

02/28/19
Date:

/s/
Jeffery T. Morris, Director
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