

## TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-24-0034

**Number: P-24-0034**

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

**Chemical Name:**

Specific: 2,5,7,10-tetraoxaundecane, 4,8-dimethyl-; CASRN: 59039-15-5

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

Intended conditions of use (specific): Import and process for use as, and use as, a non-reactive processing aid for use in coatings and cleaners, a solvent or co-solvent in glue removers, paint strippers, and hard stain removers, and a non-reactive processing aid for use in laboratories, 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 identified none.

Reasonably foreseen conditions of use: Applying such factors as described in footnote 1, EPA evaluated whether there are reasonably foreseen conditions of use and identified use without worker protection, domestic manufacture and other additive uses based on analogues.

**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. Although EPA estimated that the new chemical substance could be very persistent, the new chemical substance has low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms. Based on its estimated physical and chemical properties and available test data on the new chemical substance, EPA estimates that the new chemical substance has low environmental hazard and low human health hazard. 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

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<sup>1</sup> 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 any condition of use of a chemical substance that EPA believes is ongoing in the United States at the time of submission of the notification, as well as 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 chemical substance may be manufactured, processed, distributed, used, or disposed of. EPA expects that the identification of “reasonably foreseen” conditions of use will be made on a fact-specific, case-by-case basis. EPA will apply its professional judgment and experience when considering factors such as evidence of current use of the new chemical substance outside the United States, information about known or intended uses of 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.

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in determining whether a chemical may present an unreasonable risk. EPA estimated physical/chemical and fate properties of the new chemical substance using data submitted for the new chemical substance and EPI (Estimation Program Interface) Suite™ (<http://www.epa.gov/tsca-screening-tools/epi-suite-estimation-program-interface>). In wastewater treatment, the new chemical substance is expected to be removed with an efficiency of 0% due to low biodegradability, low sorption, and low stripping. Removal of the new chemical substance by biodegradation is negligible. Sorption of the new chemical substance to sludge, soil, and sediment is expected to be low. Migration of the new chemical substance to groundwater is expected to be rapid due to low sorption to soil and sediment. Due to low reported vapor pressure and estimated Henry's law constant, the new chemical substance is expected to undergo negligible volatilization to air. Overall, these estimates indicate that the new chemical substance has low potential to volatilize to air and has high potential to migrate to groundwater.

**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 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 degradation half-lives of the new chemical substance using data submitted for the new chemical substance and EPI Suite™. EPA estimated that the new chemical substance's aerobic and anaerobic biodegradation half-lives are > 6 months and hydrolysis half-life is > 6 months. These estimates indicate that the new chemical substance may be very persistent in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment).

**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 that the new chemical substance has low bioaccumulation potential based on BCFBAF model result < 1000 (bioconcentration factor = 4 (estimated by linear regression from log  $K_{ow}$ ) and bioaccumulation factor = 3 (estimated by the Arnot-Gobas method (2003))).<sup>4</sup> Although EPA estimated that the new chemical substance could be very persistent, the substance has low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms.

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<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 if 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 if there are equivalent or analogous data. (64 FR 60194; November 4, 1999)

<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 if 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 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 if there are equivalent or analogous data. (64 FR 60194; November 4 1999)

<sup>4</sup> Arnot JA, Gobas FAPC. 2003. A generic QSAR for assessing the bioaccumulation potential of organic chemicals in aquatic food webs. QSAR and Combinatorial Science 22: 337-345.

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**Human Health Hazard<sup>5</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 and available data on the new chemical substance. Absorption of the new chemical substance is predicted to be poor to moderate through the skin, good through the lungs, and moderate through the gastrointestinal (GI) tract based on physical/chemical properties. For the new chemical substance, EPA did not identify hazards for the new chemical substance.

Submitted test data of the new chemical substance reported the test substance as not causing systemic effects in rats in a 28-day repeat-dose oral gavage study (OECD 407). Submitted test data of the new chemical substance reported the test substance as causing mild liver effects in a reproduction/developmental toxicity screening test (OECD 421). EPA considered the liver effects to be low for the purposes of evaluating the new chemical substance as they were only seen at the limit dose of 1000 mg/kg/day. Test data on the chemical substance did not identify acute oral toxicity in rats (OECD 423), acute dermal toxicity in rats (OECD 402), skin irritation in vitro (OECD 439), skin corrosion in vitro (OECD 431), eye irritation in rabbits (OECD 405), eye irritation or corrosion in vitro (OECD 492 and OECD 437), skin sensitization in mice (OECD 429), mutagenicity in bacteria (OECD 471), or genotoxicity in vitro (OECD 487 and OECD 490). No quantitative POD was identified for any route because the new chemical substance was considered a low hazard based on test data for the new chemical substance.

**Environmental Hazard<sup>6</sup>:** Environmental 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 determined the environmental hazard for this new chemical substance based on acute and chronic toxicity data submitted for the new chemical substance. This substance falls within the TSCA New

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<sup>5</sup> 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](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.

<sup>6</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 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>).

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Chemicals Category Neutral Organics.<sup>7</sup> Acute toxicity values for fish, aquatic invertebrates, and algae are >100 mg/L, >100 mg/L, and >100 mg/L. Chronic toxicity values for fish, aquatic invertebrates, and algae are >10 mg/L, >10 mg/L, and >10 mg/L. These toxicity values indicate that the new chemical substance is expected to have low environmental hazard. Application of assessment factors of 5 and 10 to acute and chronic toxicity values, respectively, results in acute and chronic concentrations of concern of 20 mg/L (20000 ppb) and 1 mg/L (1000 ppb).

**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 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.

**Risk Characterization:** Due to low hazard, EPA believes that this chemical substance would be not likely to present an unreasonable risk even if potential exposures were high. Therefore, EPA concludes that the new chemical substance is not likely to present unreasonable risk under the conditions of use.

4/27/2026  
Date: \_\_\_\_\_

/s/ \_\_\_\_\_  
Shari Z. Barash, Director  
New Chemicals Division  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency

<sup>7</sup> TSCA New Chemicals Program (NCP) Chemical Categories. <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemical-categories-used-review-new>.