TSCA Section 5(a)(3) Determination for Premanufacture Notices (PMNs) P-21-0039, P-21-0040, P-21-0041

Numbers: P-21-0039, P-21-0040, P-21-0041
TSCA Section 5(a)(3) Determination: The chemical substances are not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Names:
Specific (P-21-0039): 1,2,4,5-Benzenetetracarboxamide, N1,N2,N4,N5-tetrahexyl-; CASRN: 1142038-73-0

Specific (P-21-0040): 1,2,4,5-Benzenetetracarboxamide, N1,N2,N4,N5-tetraoctyl-; CASRN: 1416081-40-7

Specific (P-21-0041): 1,2,4,5-Benzenetetracarboxamide, N1,N2,N4,N5-tetradodecyl-; CASRN: 911127-84-9

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (specific): Import and process for use as and use as viscosity modifiers in commercial and consumer engine oil, 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 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 the following based on a patent search and use information for analogous chemical substances:

- Gelling agent;
- Thixotropic agent for use in coatings;
- Use in the synthesis of pyromellitic tetraalkylamine;

[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.

- Rheology modifier;
- Coating for machine parts with sliding surfaces;
- Viscosity modifier;
- Temperature indicator; and,
- Plasticizer.

Summary: The chemical substances are 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 substances could be very persistent, the substances have low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms. EPA estimates that the chemical substances have low environmental hazard and no identified human health hazards. EPA concludes that the new chemical substances are 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 the new chemical substances using data submitted for one of the new chemical substances (P-21-0039), data for analogues (chemicals with large molecular volume), and EPI (Estimation Program Interface) Suite™ (http://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface). In wastewater treatment, the new chemical substances are expected to be removed with an efficiency of 90% due to sorption. Removal of the new chemical substances by biodegradation is negligible. Sorption of the new chemical substances to sludge is expected to be strong and to soil and sediment is expected to be very strong. Migration of the new chemical substances to groundwater is expected to be negligible due to very strong sorption to soil and sediment. Due to low estimated vapor pressure and Henry's law constant, the new chemical substances are expected to undergo negligible volatilization to air. Overall, these estimates indicate that the new chemical substances have low potential to volatilize to air or migrate to 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. EPA estimated degradation half-lives of the new chemical substances using data submitted for one of

[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)

the new chemical substances (P-21-0039) and data for analogues (chemicals with large molecular volume). EPA estimated that the new chemical substances' aerobic and anaerobic biodegradation half-lives are > 6 months. These estimates indicate that the new chemical substances may be very persistent in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment).

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 potential for the new chemical substances to bioaccumulate using data submitted for one of the new chemical substances (P-21-0039), data for analogues (chemicals with large molecular volume), and EPI Suite™. For P-21-0039, EPA estimated that the new chemical substance has low bioaccumulation potential based on BCFBAF model result < 1000 (bioconcentration factor = 520 [estimated by linear regression from log Kow] and bioaccumulation factor = 1 [estimated by the Arnot-Gobas method (2003)[4]]. For P-21-0040 and P-21-0041, EPA estimated that the new chemical substances have low bioaccumulation potential based on large predicted molecular volume, which limits bioavailability. Although EPA estimated that the new chemical substances could be very persistent, the substances 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[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

[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] 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.

[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.

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, available data on one of the new chemical substances (P-21-0039), by comparing them to structurally analogous chemical substances for which there is information on human health hazard, and other structural information. Absorption of the new chemical substances is expected to be nil to poor through the skin when neat, poor through the skin when in solution, and nil through the lungs and gastrointestinal (GI) tract based on physical/chemical properties. For the new chemical substances, EPA did not identify any hazards. Submitted test data for P-21-0039 reported the test substance as non-irritating to rabbit skin (OECD 404), non-sensitizing to the skin of guinea pigs (OECD 406), non-mutagenic in vitro (OECD 471), and did not identify any effects in an acute oral study in rats (OECD 425).

Environmental Hazard[6]: 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 chemical substance and the extent of exposure to the substance. EPA estimated environmental hazard using predictions based on the negligible water solubility of the new chemical substances and hazard data for an analogous chemical. 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 substances are 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 Characterization: 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. Due to low hazard, EPA believes that these chemical substances are not likely to present an unreasonable risk even if potential exposures were high.

For this assessment, EPA did not assess worker, general population or consumer exposure because no human health hazards were identified.

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).

[6] 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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Risks to human health for the new chemical substances were qualitatively evaluated. Based on the hazard determination and available qualitative risk information, EPA did not identify risks for the new chemical substances.

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

Due to low hazard, EPA believes that these chemical substances would be not likely to present an unreasonable risk even if potential exposures were high. Therefore, EPA concludes that the new chemical substances are not likely to present unreasonable risk to human health or the environment under the conditions of use.

06/30/21
Date:

/s/
Madison H. Le, Director
New Chemicals Division