TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-19-0056, P-19-0060, and P-19-0061

Number: P-19-0056, P-19-0060, and P-19-0061
TSCA Section 5(a)(3) Determination: The chemical substances are not likely to present an unreasonable risk (5(a)(3)(C)).

Chemical Name:
Generic:
P-19-0056: Aliphatic hydrocarbons, C8-C20-branched and linear
P-19-0060: Aliphatic hydrocarbons, C8-C18-branched and linear
P-19-0061: Aliphatic hydrocarbons, C16-20-branched and linear

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (generic):
P-19-0056: Import as a raw material for manufacturing other aliphatic hydrocarbons, consistent with the manufacturing, processing, use, distribution, and disposal information described in the PMN.
P-19-0060 and P-19-0061: Manufacture for use as a fuel, 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 found none.

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.

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[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.

Although EPA estimated that the new chemical substances could be bioaccumulative, the new chemical substances are not expected to be persistent. Based on hazard data on analogous chemicals, EPA estimates that the chemical substances have low environmental hazard and potential for the following human health hazard: irritation. 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 submitted data for an analogue and EPI (Estimation Programs Interface) Suite™, a suite of physical/chemical property and environmental fate estimation programs (http://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface). The chemical substances are estimated to be removed with 90-95% efficiency (P-19-0060 and P-19-0061) and 95 - 99% efficiency (P-19-0056) based on sorption, biodegradation, and stripping. Sorption to sludge, soil, and sediment is estimated to be moderate to strong, and removal by biodegradation is expected to be moderate to high, resulting in slow migration to groundwater. Volatilization to air is expected to be moderate to high because these substances are estimated to have a moderate to high vapor pressure and Henry's law constant. Overall, these estimates indicate that the new chemical substances have moderate to high potential to volatilize to air and low potential to 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 biodegradation half-lives of the new chemical substances using submitted data for an analogue and EPI Suite™. EPA estimates the aerobic and anaerobic half-lives of the chemical substances described in P-19-0056 and P-19-0060 to be less than two months. These estimates indicate that these substances will have limited persistence in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment). EPA estimates the aerobic half-life of the new chemical substance described in P-19-0061 to be less than two months and anaerobic half-life to be between two to six months. These estimates indicate that the P-19-0061 chemical substance is expected to have limited persistence in aerobic environments (e.g., surface water) and may be persistent in anaerobic environments (e.g., sediment). Based on the log K_{OW} submitted on an analogue, the new chemical substances are expected to partition primarily to sediments. Thus, persistence was evaluated based on the expected half-life in anaerobic environments.

[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. EPA estimated the bioaccumulation potential for the new chemical substances using data for branched and linear aliphatic hydrocarbons (i.e., [claimed CBI]) and submitted data for an analogue. These estimates indicate that the P-19-0056 new chemical substance has bioaccumulation potential based on uncertain bioconcentration and expected metabolism. Although EPA estimated that the P-19-0056 new chemical substance could be bioaccumulative, the substance has a low potential for persistence, such that environmental releases are not expected to cause food-chain effects via accumulation in exposed organisms. The P-19-0060 chemical substance has low to moderate potential based on BCFBAF modeling, mitigated by expected metabolism (bioconcentration factor = 1023 and bioaccumulation factor = 5000). Although EPA estimated that the P-19-0060 new chemical substance could be bioaccumulative, the substance has a low potential for persistence, such that environmental releases are not expected to cause food-chain effects via accumulation in exposed organisms. The P-19-0061 chemical substance has low bioaccumulation potential based on BCF modeling results (bioconcentration factor = 372). Although EPA estimated that the P-19-0061 new chemical substance could be persistent, the substance has a 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 chemical substance and the extent of

[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.

exposure to the substance. EPA estimated the human health hazard of the chemical substances 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 is expected to be poor through the skin and lungs, and moderate through the GI tract based on physical chemistry properties and information on aliphatic hydrocarbons (OECD SIDS for C14-20 aliphatic hydrocarbons). EPA initially identified aspiration, dermal irritation, and hydrocarbon pneumonia as hazards based on analogue information but did not consider the aspiration and hydrocarbon pneumonia in the risk assessment based on analogue data that did not identify any respiratory effects at any tested concentration. Submitted OECD 473, 471, 402, and 423 tests on a close analogue of the new chemical substances were negative for chromosomal aberration, mutagenicity, no defatting or systemic effects in the acute dermal and oral studies, respectively. EPA qualitatively evaluated irritation effects in the risk assessment, described below.

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 chemical substance and the extent of exposure to the substance. EPA estimated environmental hazard of the new chemical substances using hazard data on analogous chemicals, the Ecological Structure Activity Relationships (ECOSAR) Predictive Model (https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-releationships-ecosar-predictive-model), specifically the QSAR for neutral organics. Based on QSAR predictions and data on analogous chemical substances, the acute and chronic toxicity values estimated for fish, aquatic invertebrates, and algae are all no effects at saturation (no effects up to the water solubility limit). Based on these toxicity values, EPA expects the new chemical substances 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 releases 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

[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).

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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 has assessed risks to workers under the conditions of use of the new chemical substances and identified potential risk concerns for this PESS under the conditions of use. 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.

For these new chemical assessments, EPA assessed exposure to workers via inhalation and dermal routes. Releases to water and air were estimated and used to assess exposure to general population via drinking water, fish ingestion, ground water ingestion (landfill leaching), and inhalation from fugitive air emissions. Consumer exposures were not assessed for the P-19-0056 and P-19-0060 chemical substances because consumer uses were not identified as conditions of use. Consumer dermal exposures are possible for the P-19-0061 chemical substance based on an identified condition of use as a diesel fuel.

Risk Characterization: EPA assesses risks to workers considering engineering controls described in the PMNs 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).

Irritation hazards to workers via inhalation and dermal contact were identified based on analogue data. Risks for these endpoints were not quantified due to a lack of dose-response for these hazards. However, exposures can be mitigated by the use of appropriate PPE, including impervious gloves, eye protection, and respiratory protection. EPA expects that employers will require and workers will use appropriate PPE consistent with the Safety Data Sheet prepared by the new chemical submitter, in a manner adequate to protect them.

Risks were not identified for the general population via drinking water, fish ingestion, ground water ingestion (landfill leaching), or fugitive air inhalation since effects are expected to be mitigated by dilution. For P-19-0056 and P-19-0060, risks to consumers were not evaluated because consumer use was not identified as a condition of use. For P-19-0061, irritation hazards to consumers via dermal contact were identified based on analogue data and risks for these endpoints were not quantified due to a lack of dose-response for these hazards.

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

Because worker exposures can be controlled by PPE and no unreasonable risks to the general population, consumers, or the environment were identified, EPA has determined that the new chemical substances are not likely to present unreasonable risk to human health or the environment under the conditions of use.

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