TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) SN-19-0004

Number: SN-19-0004
TSCA Section 5(a)(3) Determination: The significant new use is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Specific: Coke (coal), secondary pitch; CASRN 94113-91-4

Significant New Use: Use other than as described in PMN P-12-0292. The significant new use rule (SNUR) at 40 CFR 721.10928 for this chemical substance requires notification to EPA for any use other than as described in PMN P-12-0292; use without personal protective equipment (PPE), including a respirator with an assigned protection factor (APF) of at least 50 or compliance with a New Chemical Exposure Limit (NCEL); or use without hazard communication; or domestic manufacture of the chemical substance.

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (specific): Import for use as a lubricating agent used in the production of automotive disc brakes, consistent with the manufacturing, processing, use, distribution, and disposal information described in the SNUN.
Known conditions of use: Import for use as an additive for diesel particulate filter manufacture to increase the porosity of the filter material (P-17-0217). The submitter of P-17-0217 is subject to a TSCA 5(e) consent order that: requires use of inhalation personal protective equipment (PPE) when there is potential exposure; does not allow domestic manufacturing; does not allow process or use the PMN substance involving an application method that generates a vapor, mist, or aerosol; and only allows the uses described in P-17-0217.

[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.

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, based on a previous TSCA submission (i.e., P-12-0292) the following reasonably foreseen use: use in the carbon graphite industry under the terms specified in the consent order.

Summary: The significant new use 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 SNUR and consent orders issued previously for this chemical substance. Although EPA estimated that the chemical substance could be very 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. Based on EPA's TSCA New Chemicals Program Chemical Category for Respirable, Poorly Soluble Particulates[2], its estimated physical/chemical properties, and by comparing it to structurally analogous chemical substances for which there is information on human health hazard, EPA estimates that the chemical substance has low environmental hazard and potential for the following human health hazards: lung effects (chronic inflammation, fibrosis, and cancer). EPA concludes that the significant new use 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 significant new use of a chemical substance may present an unreasonable risk. EPA estimated physical/chemical and fate properties of the chemical substance using data for analogues (compounds with large molecular volume). In wastewater treatment, the chemical substance is expected to be removed with an efficiency of 90% due to sorption. Removal of the chemical substance by biodegradation is negligible. Sorption of the chemical substance to sludge is expected to be strong and to soil and sediment is expected to be very strong. Migration of the chemical substance 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 chemical substance is expected to undergo negligible volatilization to air. Overall, these estimates indicate that the chemical substance has low potential to volatilize to air or migrate to groundwater.

Persistence[3]: Persistence is relevant to whether a significant new use of a 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

[2] 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.

[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)

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

Bioaccumulation[4]: Bioaccumulation is relevant to whether a significant new use of a 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 chemical substance to bioaccumulate using data for analogues (compounds with large molecular volume). EPA estimated that the chemical substance has low bioaccumulation potential based on large predicted molecular volume, which limits bioavailability. Although EPA estimated that the chemical substance could be very 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[5]: Human health hazard is relevant to whether a significant new use of a 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 by comparing it to structurally analogous chemical substances for which there is information on human health hazard. Absorption of the chemical substance is expected to be nil to poor through the skin and nil through the GI tract and

[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)

[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.

lungs based on physical/chemical properties. For the chemical substance, EPA identified lung effects as hazards, if respirable, based on EPA's TSCA New Chemicals Program Chemical Category for Respirable, Poorly Soluble Particulates. EPA identified a lowest-observed-adverse-effect-concentration (LOAEC) of 2.5 mg/m^3 based on lung effects (chronic inflammation, fibrosis, cancer) which was used to derive exposure route- and population-specific points of departure for quantitative risk assessment, described below.

Environmental Hazard[6]: Environmental hazard is relevant to a significant new use of a 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 this new chemical substance using predictions based on the negligible water solubility of the 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 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 chemical substance is potentially relevant to whether a significant new use of a 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 SNUN 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

[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).

basis of greater exposure potential compared to the general population who do not use specific products.

For this risk assessment, EPA assessed worker exposure via inhalation and dermal contact. Releases to air were estimated. Releases to water and landfill were not estimated since no relevant hazards were identified. Exposure to the general population was assessed via fugitive air inhalation. Exposures to the general population via stack air inhalation were not assessed because these exposures were expected to be negligible (below modeling thresholds). Exposures to consumers were not assessed because consumer uses were not identified as conditions of use.

Risk Characterization: EPA applies a margin of exposure approach to calculate potential human health risks of significant new uses of 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 1,000 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 significant new use is not likely to present an unreasonable risk. EPA assesses risks to workers considering engineering controls described in the SNUN 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 human health for the significant new use were evaluated using the route-specific effect levels (i.e., LOAEC) described above. Risks were not identified for workers for lung effects (chronic inflammation, fibrosis, cancer) via chronic inhalation exposure based on quantitative hazard data for an analogue (MOE=3,118; benchmark MOE=1,000). No adverse effects from acute exposures are expected since fibrosis and lung cancer are presumed to occur as a result of chronic inflammation and cell proliferation which require chronic exposure scenarios. Risks were not evaluated for workers for lung effects via dermal exposure because the hazards are not relevant to the exposure route.

Risks to the general population via drinking water and fish ingestion were not evaluated because no relevant hazards were identified for oral routes of exposure. Risks to the general population via stack air inhalation were not evaluated because exposures are expected to be negligible (below modeling thresholds). Risks were not evaluated for the general population for lung effects (chronic inflammation, fibrosis, cancer) via inhalation of fugitive air because chronic exposures were expected to be negligible (below modeling thresholds). No adverse effects from acute exposures are expected since fibrosis and lung cancer are presumed to occur as a result of chronic inflammation and cell proliferation which require chronic exposure scenarios.

Risks to consumers were not evaluated because consumer uses were not identified as conditions of use.

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

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

09/13/19
Date:

/s/
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