TSCA Section 5(a)(3) Determination for Significant New Use Notice (SNUN) S-19-0005

Number: S-19-0005
TSCA Section 5(a)(3) Determination: The significant new use is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic: Functionalized multi-walled carbon nanotubes

Significant New Use: The significant new use rule (SNUR) at 40 CFR 721.10633 for this chemical substance requires notification to EPA for any use other than as described in PMN P-12-0044, release to water, or any manufacture, processing, or use as a powder.

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (generic): Manufacture for use in conductive ink, consistent with the manufacturing, processing, use, distribution, and disposal information described in the SNUN.
Known conditions of use: This chemical is used as an anticorrosion agent and strengthening agent for epoxy compounds in coatings, paints, and composites as described in SNUN S-18-0004 for the chemical. The submitter of S-19-0005 is the same submitter as S-18-0004. The submitter is subject to a TSCA 5(e) consent order that: requires use of dermal and inhalation personal protective equipment (PPE) when there is potential exposure; does not allow manufacturing, processing, and use as a powder; does not allow release to water; and only allows the uses described in P-12-0044 and S-18-0004.This chemical is also used as a [claimed CBI] as described in PMN P-12-0044, submitted for the same chemical substance.
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 significant new use is not likely to present an unreasonable risk of injury to

[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.

health or the environment, without consideration of costs or other non-risk 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 order issued previously for this chemical substance. Although EPA estimated that the chemical substance could be very persistent, the chemical substance has low potential for bioaccumulation, such that repeated exposures are not expected to be cumulative. 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, and other structural information, EPA estimates potential for the following human health hazards: lung effects (i.e., lung overload and lung cancer), mutagenicity, immunotoxicity, and eye irritation. EPA was unable to estimate the environmental hazard of this chemical substance. Acute and chronic toxicity values for fish, aquatic invertebrates, and algae are unknown due to insufficient information; however, the SNUR for this chemical substance requires notification and review by EPA prior to release of the chemical substance to water. EPA concludes that the significant new use of the 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 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 and measured literature data for carbon nanotubes. In wastewater treatment, the chemical substance is expected to be removed with an efficiency of 75 - 90% via sorption. Removal of the chemical substance by biodegradation is negligible. Sorption of the chemical substance to sludge is strong and to soil and sediment is 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 and low potential to migrate to groundwater.

Persistence[2]: 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 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 measured literature data for carbon nanotubes. EPA estimated that aerobic and anaerobic biodegradation half-lives of the chemical substance are > 6 months. These estimates indicate that

[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 chemical substance will be very persistent in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment).

Bioaccumulation[3]: 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 measured literature data for carbon nanotubes. EPA estimated that the chemical substance has low bioaccumulation potential based on bioconcentration or bioaccumulation data reported for nanotubes. 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[4]: 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 an analogous chemical substance for which there is information on human health hazard. Absorption is expected to be poor through the skin, lungs, and GI tract based on analogues. For the new chemical substance, EPA identified lung effects (i.e., lung overload and lung cancer) as hazards if poorly soluble respirable particulates and fibers are inhaled. EPA also identified mutagenicity and immunotoxicity as hazards based on information on nanomaterials (NIOSH Chemical Intelligence Bulletin 65) and test data on analogous multi-walled carbon nanotubes as

[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.

well as eye irritation based on analogue data. EPA quantitatively assessed the new chemical substance using test data from studies on analogues. EPA identified a no-observed-adverse-effect-level ($NOAEL_{Maternal}$) of 200 mg/kg-bw/day based on treatment-related adverse effects observed (decreased absolute and relative thymus weights) in an oral (gavage) developmental toxicity study in rats, which were used to derive exposure route-specific points of departure (POD) for quantitative risk assessment, described below.

Environmental Hazard[5]: Environmental hazard is relevant to whether 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 was unable to estimate the environmental hazard of this chemical substance. Acute and chronic toxicity values for fish, aquatic invertebrates, and algae are unknown due to insufficient information.

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 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 human health risk assessment, EPA assessed worker exposure via dermal contact. Inhalation exposures to workers are not expected because the new chemical substance is manufactured and processed as a wet cake such that particulate exposure is not expected and because inhalation exposures are expected to be negligible based on vapor pressure (VP<0.001 torr) during use in a liquid from. Releases to water are not expected due to conditions of the existing SNUR and releases to air negligible due to the form of new chemical substance during manufacturing and processing. Risks to the general population were not evaluated because exposures to general population were not expected.

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 of a chemical substance 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 were not identified for workers via dermal exposure based on quantitative hazard data for an analogue (MOE = 7,273; Benchmark MOE = 100). Risks were not evaluated for workers via inhalation, because the new chemical substance is manufactured and processed as a wet cake such that particulate exposure is not expected and because inhalation exposures are expected to be negligible based on vapor pressure (VP<0.001 torr) during use in a liquid form. Eye irritation to workers was identified based on analogue data. Mutagenicity hazards were identified for workers via dermal exposure 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 personal protective equipment (PPE), including impervious gloves and eye protection. EPA expects that employers will require and that workers will use appropriate PPE consistent with the Safety Data Sheet (SDS) prepared by the new chemical submitter, in a manner adequate to protect them. The submitter of the SNUN is subject to a consent order for this chemical substance which requires dermal protection.

Risks to the general population were not evaluated because exposures to general population were not expected.

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

Risks to the environment were not identified due to no releases to water as required by the SNUR.

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 of the chemical substance is not likely to present unreasonable risk to human health or the environment under the conditions of use.

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Date:

/s/
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