TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0359

Number: P-18-0359
TSCA Section 5(a)(3) Determination: The chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic: Methoxy vinyl ether-vinylidene fluoride polymer

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (generic): Import for use and use in molded or extruded items, 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 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 and incineration product 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. Although EPA estimated that the photolysis product could be very persistent, the substance does not bioaccumulate by lipophilic partitioning and there is low concern that it will accumulate in organisms by other mechanisms; thus, repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms. Based on the estimated physical/chemical properties of the chemical substance and test data on analogous chemical substances, EPA

[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.

estimates that the chemical substance has moderate environmental hazard and potential for the following human health hazards: Specific Target Organ Toxicity. 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 in determining whether a chemical may present an unreasonable risk. EPA estimated physical/chemical and fate properties of the new chemical substance using data for analogues (polymers); of the photolysis product using data for analogue(s) (fluorinated chemicals); and of the incineration product using data for analogue(s) ([claimed CBI] and polyflourinated compounds). In wastewater treatment, the new chemical substance is expected to be removed with an efficiency of 90% due to sorption. Removal of the new chemical substance by biodegradation is negligible. Sorption of the new chemical substance to sludge is expected to be strong and to soil and sediment is expected to be very strong. Migration of the new chemical substance to groundwater is expected to be negligible due to very strong sorption to soil and sediment. Due to low estimated vapor pressure, 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 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 substance using data for analogues (polymers); of the photolysis product using data for analogue(s) (fluorinated chemicals); and of the incineration product using data for analogue(s) ([claimed CBI] and polyflourinated compounds). EPA estimated that the new chemical substance's aerobic and anaerobic biodegradation half-lives are > 6 months and indirect photolysis is slow and that the photolysis and incineration products' aerobic and anaerobic biodegradation half-lives are > 6 months. These estimates indicate that the new chemical substance, photolysis product, and incineration product 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

[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 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)

[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 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 than or equal to 5,000 or there are equivalent or analogous data. A chemical substance is considered

species pose the potential for elevated exposures to humans and other organisms via food chains. EPA estimated the potential for the new chemical substance to bioaccumulate using data for analogues (polymers); of the photolysis product to bioaccumulate using data for analogue(s) (fluorinated chemicals); and of the incineration product to bioaccumulate using data for analogue(s) ([claimed CBI] and polyflourinated compounds). EPA estimated that the new chemical substance has low bioaccumulation potential based on large predicted molecular volume, which limits bioavailability, while the photolysis product does not bioaccumulate by lipophilic partitioning and there is low concern that it may accumulate in organisms by other mechanisms. EPA estimated that the incineration product has low bioaccumulation potential based on high water solubility, which increases elimination. Although EPA estimated that the new chemical substance and incineration product 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. Although EPA estimated that the photolysis product could be very persistent, the substance does not bioaccumulate by lipophilic partitioning and there is low concern that it will accumulate in organisms by other mechanisms; thus, 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 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 new chemical substance is expected to be nil via all routes based on physical/chemical properties. For the new chemical substance, EPA identified hazard concerns, for respirable particles, for lung overload based on insoluble high molecular weight polymer and for lung waterproofing based on fluoropolymers. If the new chemical substance is incinerated, EPA identified hazard concerns for systemic effects (microscopic findings in the liver and kidneys, body weight loss), and

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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)

[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.

neurotoxicity (changes to neuromuscular excitability and increased body temperature). EPA also identified a LOAEC of 1.5 mg/m^3 based on lung waterproofing effects in an acute inhalation toxicity study (Test Guideline Not Specified). This value is protective for all health concerns via inhalation and was used to derive exposure route- and population-specific points of departure for quantitative risk assessment.

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 this new chemical substance using predictions based on the negligible water solubility of P-18-0359 (parent polymer) and hazard data on an analogous chemical for the degradation product. For the parent, 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 substance parent polymer 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 for the parent polymer. Acute toxicity values estimated for the degradation product for fish, aquatic invertebrates, and algae are >96.9mg/L, >100 mg/L, and >100 mg/L, respectively. Chronic toxicity values estimated for the degradation product for fish, aquatic invertebrates, and algae are 1.53 mg/L, 5.82 mg/L, and >10 mg/L, respectively. These toxicity values indicate that the new chemical substance degradation product is expected to have moderate 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 19.38 mg/L (19,380 ppb) and 0.153 mg/L (153 ppb), respectively.

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 release of the new 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 EFAST (the Exposure and Fate Assessment Screening Tool; https://www.epa.gov/tsca-

[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).

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.

For this new chemical assessment, EPA assessed worker exposures via the dermal route; inhalation exposures to workers were not assessed because exposures are not expected. Releases to landfill were estimated. Exposures to the general population were not assessed via drinking water and fish ingestion because releases to the surface water were not expected. Exposures to the general population via groundwater ingestion impacted by landfill leaching were not assessed because exposures were expected to be negligible (below modeling thresholds). Exposures to the general population were not assessed via fugitive air inhalation or incineration because releases to the air were not expected. Consumer exposures were not assessed because consumer uses were not identified as conditions of use.

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).

Risks were not evaluated for workers via inhalation because inhalation exposures are not expected; therefore, risks are not expected. Risks were not evaluated for workers for lung effects via dermal exposure because the hazards are not relevant to the exposure route; therefore, risks are not expected. Risks were not evaluated for workers from dermal exposures because no relevant hazards were identified by this route; therefore, risks are not expected.

Risks were not evaluated for the general population via drinking water and fish ingestion because releases to the surface water are not expected. Risks were not evaluated for the general population via groundwater ingestion impacted by landfill leaching because exposures are expected to be negligible (below modeling thresholds). Risks were not evaluated for the general population via fugitive air and incineration because releases to the air are 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.

Because no unreasonable risks to workers, the general population, or the environment were identified, and there are no expected consumer exposures, EPA has determined that the new chemical substance is not likely to present unreasonable risk to human health or the environment under the conditions of use.

8/13/2020
Date:

/s/
Madison H. Le, Director
Chemical Control Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency