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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Mr. Jay Bartley
ArrowStar, LLC
1815 S. Hamilton Street
PO Box 2686
Dalton, GA 30720

OCT 0 5 2018

[redacted]

Re: PMN P-18-0070

Dear Mr. Bartley:

This letter responds to the above-referenced Premanufacture Notice (PMN), received by the Environmental Protection Agency (EPA) on January 4, 2018. The PMN described the chemical substance as waste plastics, polyester, depolymd. with glycols, polymers with dicarboxylic acids.

EPA has determined in accordance with section 5(a)(3)(C) that the PMN substance is not likely to present an unreasonable risk of injury to health or the environment under the intended and reasonably foreseen conditions of use. Attached to this letter is a summary of the basis of EPA's determination.

Under TSCA section 5(g), you may begin manufacture of these PMN substance immediately and do not need to wait for the 90-day review period to expire.

Please note that 40 CFR 720.102 requires you, within the first 30 days of commencement of manufacture (which includes import) of a PMN substance, to submit a Notice of Commencement (NOC) to EPA. If you wish the chemical identity to be listed on the Confidential Inventory, any prior claim of confidentiality must be reasserted and substantiated in accordance with 40 CFR 720.85(b) and 720.90(b).

Because you submitted your PMN to EPA after the effective date of the electronic-PMN ("eTSCA/ePMN") final rule (75 FR 773), you must use the eTSCA/ePMN software to submit your NOC. After April 6, 2012, all submissions are required to be submitted electronically via the internet using the Central Data Exchange (CDX). Please see www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn for more information on the e-PMN software and directions on how to register and submit notices via CDX.

If you have any questions or comments, please contact me at (202) 564-8469.

Sincerely,

Greg Schweer, Chief
New Chemicals Management Branch

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0070

Number: P-18-0070
TSCA Section 5(a)(3) Determination: The new chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Specific: [redacted]
Generic: Waste plastics, polyester, depolymd. with glycols, polymers with dicarboxylic acids

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (specific): Manufacture, process and use in [redacted] as a [redacted] at a maximum concentration of [redacted] in the final product, [redacted] at a maximum concentration of [redacted] in the final product, [redacted] at a maximum concentration of [redacted] in the final product, and [redacted] at a maximum concentration of [redacted] in the final product, consistent with the manufacturing, processing, use, distribution, and disposal information described in the PMN.
Intended conditions of use (generic): Manufacture, process, and use as a chemical intermediate for the polyurethane industry, 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 new 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

[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.

[redacted]

the Administrator under the conditions of use, based on the risk assessment presented below. Although EPA estimated that the new chemical substance could be very persistent, the new chemical substance has low potential for bioaccumulation, such that repeated exposures are not expected to be cumulative. Based on EPA's TSCA New Chemicals Program Chemical Category for Esters[2] and test data on analogous chemical substances, EPA estimates that the new chemical substance has moderate environmental hazard and the potential for the following human health hazards: blood, bladder and developmental toxicity, and eye irritation. EPA determines 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 this new chemical substance using data for analogous chemicals 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 new chemical substance is estimated to be removed with an efficiency of 75-90% during wastewater treatment due to biodegradation. Removal by biodegradation in wastewater treatment is moderate to high based on variable composition of the new chemical substance, with smaller components of the molecule expected to biodegrade. Sorption to sludge and sorption to soil and sediment is estimated to be low. Volatilization to air is expected to negligible because the new chemical substance is estimated to have low vapor pressure and a low Henry's Law constant. Overall, these estimates are indicative of low potential for this new chemical substance to volatilize into the air and a low potential for this chemical to migrate into groundwater (due to biodegradation).

Persistence[3]: 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 the biodegradation half-lives of this new chemical substance using 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) and data on analogous chemicals. EPA estimated the aerobic biodegradation half-life to be between two and six months and the anaerobic biodegradation half-life to be greater than six months. These estimates for biodegradation indicate that the new chemical substance may be persistent in aerobic environments (e.g., surface water) and very persistent in anaerobic environments (e.g., sediment).

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[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)

[redacted]

Bioaccumulation[4]: 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. The new chemical substance has low bioaccumulation potential based on estimates from analogous chemicals and EPI Suite (BCF = 3; BAF = 1). Although EPA estimated that the new chemical substance could be very persistent, the new chemical substance has 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 both the hazard (or toxicity) of the new chemical substance and the extent of exposure to the substance. EPA estimated the human health hazard of this new chemical substance based on comparison to structurally analogous chemical substances for which there is information on human health hazard, and/or other structural information. For this new chemical substance, absorption is estimated to be poor through skin and GI tract and good through the lung based on physicochemical properties. EPA identified blood, bladder and developmental toxicity as human health hazards based on data on a metabolite [redacted] Eye irritation was indicated on the submitted SDS. EPA quantitatively assessed this new chemical substance using data on the metabolite [redacted] A NOAEL of 280 mg/kg/day based on blood, bladder toxicity and developmental toxicity in a one-generation reproduction feeding study (not a guideline study) was used to derive exposure route- and population-specific points of departure for quantitative risk assessment, described below.

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[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.

[redacted]

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 new chemical substance and the extent of exposure to the substance. The new chemical substance falls within the TSCA New Chemicals Program Chemical Category of Esters. EPA estimated environmental hazard of this new chemical substance using 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 esters. ECOSAR estimates acute toxicity values of 93, >100 and 78 mg/L and chronic toxicity values of 6.7, >10 and >10 mg/L, for fish, daphnia and algae, respectively. These toxicity values indicate that the new chemical substance 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 18.6 mg/L (18,600 ppb) and 0.67 mg/L (670 ppb), respectively.

Exposure and Risk 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 new 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-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014) to estimate general population 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.

[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).

[redacted]

For this new chemical assessment, EPA assessed exposure via dermal route to workers during manufacturing, processing and use, and assessed exposure via inhalation route to workers during use as a [redacted] (inhalation exposure to workers during manufacturing and processing is not expected). EPA assessed exposure to the general population via drinking water, fish ingestion, and inhalation. EPA estimated exposures for consumers via ingestion and inhalation.

EPA applies a margin of exposure approach to calculate potential human health risks of new 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 new chemical substance is not likely to present an unreasonable risk. EPA assessed risks to workers considering engineering controls described in the PMN but in the absence of personal protective equipment 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, respirators).

Risks to human health for the new chemical substance were evaluated using the points of departure (i.e., NOAEL) described above. Risks to workers were not identified for blood, bladder toxicity and developmental toxicity via inhalation exposure (MOE = 280; benchmark MOE = 100). Risks were identified for workers for eye irritation based on information in the SDS. Risks were identified for workers for blood, bladder toxicity and developmental toxicity via dermal exposure (MOE = 64; benchmark MOE = 100). Risks will be mitigated with the use of appropriate PPE, including skin and eye protection. EPA expects that workers will use appropriate personal protective equipment (i.e., impervious gloves and eye protection), consistent with the Safety Data Sheet prepared by the PMN submitter, in a manner adequate to protect them.

Risks were not identified for the general population for blood, bladder toxicity and developmental toxicity via inhalation exposure (MOE =750; benchmark MOE = 100). Risks were not identified for the general population for blood, bladder toxicity and developmental toxicity via drinking water ($MOE_{Adult} = 36{,}920$ and $MOE_{Infant} = 8{,}854$; benchmark MOE = 100) or fish ingestion (MOE = 336,538; benchmark MOE = 100). Risks were not identified for consumers for blood, bladder toxicity and developmental toxicity via oral or inhalation exposure ($MOE_{oral} = 2{,}734$ and $MOE_{inhalation} = 68{,}359$; benchmark MOE = 100).

Risks to the environment were evaluated by comparing estimated surface water concentrations with the estimated acute and chronic concentrations of concern. Risks to the environment were not identified based on no exceedences of the acute or chronic COCs under the conditions of use.

[redacted]

Because worker exposures can be controlled by PPE, there are no expected consumer exposures, and no unreasonable risks to the general population or environment were identified, 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.

10/05/18
Date:

Jeffery T. Morris, Director
Office of Pollution Prevention and Toxics

[redacted]