TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0332, P-18-0333

Number: P-18-0332, P-18-0333
TSCA Section 5(a)(3) Determination: These chemical substances are not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Specific: P-18-0332: Canola meal (CASRN: 121957-95-7), P-18-0333: Flaxseed meal (CASRN: 2211120-89-5)

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (generic): Manufacture for use and use as a component in building materials, 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. Although EPA estimated that the new chemical substances could be persistent, the new chemical substances have low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms. Based on physical/chemical properties, submitted information, and data on analogous chemical substances, EPA estimates that the chemical substances have low environmental hazard and potential for the following human health hazards: skin irritation, eye irritation, respiratory sensitization, and specific target organ toxicity. EPA concludes that the new chemical substances are not likely 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.

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 data for analogue(s) (proteins, cellulose and triglycerides). In wastewater treatment, the new chemical substances are expected to be removed with an efficiency of 90% due to sorption and biodegradation. Removal of the new chemical substances by biodegradation is moderate to high and destruction (mineralization) of the new chemical substances by biodegradation are partial to complete. Sorption of the new chemical substances to sludge, soil, and sediment are expected to be strong. Migration of the new chemical substances to groundwater is expected to be slow due to strong sorption to soil and sediment. Due to low estimated vapor pressure and Henry's law constant, the new chemical substances are expected to undergo negligible volatilization to air. Overall, these estimates indicate that the new chemical substances have 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 substances using data for analogue(s) (proteins, cellulose and triglycerides). EPA estimated that the new chemical substances' aerobic and anaerobic biodegradation half-lives range from < 2 months to 6 months. These estimates indicate that the new chemical substances may be 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 species pose the potential for elevated exposures to humans and other organisms via food chains. EPA estimated the potential for the new chemical substances to bioaccumulate using data for analogue(s) (proteins, cellulose and triglycerides). EPA estimated that the new chemical substances have low bioaccumulation potential based on bioconcentration or bioaccumulation

[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)

[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)

data reported for proteins, cellulose and triglycerides. Although EPA estimated that the new chemical substances could be 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.

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 these chemical substances based on their estimated physical/chemical properties, available data on the new chemical substances, and by comparing them to structurally analogous chemical substances for which there is information on human health hazard. Absorption of the new chemical substances is expected to be nil via all routes based on physical/chemical properties. For the new chemical substances, EPA identified lung toxicity if inhaled based on respirable, poorly-soluble particulates and OSHA data on inhalation of nuisance dust; skin and eye irritation based on submitted data and information provided in the Safety Data Sheet (SDS); and respiratory sensitization based on submitted data and structural alerts, as hazards. Submitted data on the new chemical substances reported the test substances as irritants and respiratory sensitizers in humans. EPA identified an OSHA PEL of 5 mg/m3 for respirable nuisance dust, which was protective for lung toxicity and was used to derive exposure route- and population-specific points of departure for quantitative risk assessment. EPA qualitatively evaluated irritation and sensitization effects.

Environmental Hazard[5]: Environmental hazard is relevant to whether a new chemical

[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.

[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).

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 these new chemical substances using predictions based on the negligible water solubility of P-18-0332 and P-18-0333 (insoluble nonionic polymer; MW 10,000). 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 substances are 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 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-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 exposure to workers via the dermal and inhalation routes. Releases to water, air, and landfill were estimated. Exposure to the general population was assessed via drinking water ingestion, groundwater ingestion (landfill leachate), and fugitive air inhalation. Exposure to the general population via fish ingestion was not assessed because bioaccumulation potential was evaluated to be low and exposure to the general population via stack air inhalation was not assessed because releases to stack air 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 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 identified for workers via inhalation exposures based on a qualitative assessment of hazard and exposure. Based on EPA's hazard assessment, EPA had indicated that this

substance may cause skin irritation, eye irritation and potentially also cause respiratory sensitization in rare cases and/or sensitive individuals; those with known allergies to grain or seed dusts are more likely to experience adverse reactions when exposed to this dust and should take additional precautionary measures. Risks for these endpoints were not quantified due to a lack of dose-response for these hazards. However, exposures can be mitigated by adhering to the OSHA PEL for particulates not otherwise regulated (PNOR; aka nuisance dust). EPA expects that employers will require and that workers will use appropriate PPE consistent with the SDS prepared by the new chemical submitter, in a manner adequate to protect them. Risks were not evaluated for workers for lung toxicity via dermal exposure, because the hazards are not relevant to the exposure route.

Risks were not identified for the general population for lung toxicity via fugitive air inhalation based on a qualitative assessment of hazard and exposure. Sensitization and irritation hazards to the general population are not expected via drinking water ingestion, groundwater ingestion (landfill leachate), or fugitive air inhalation due to dilution of the chemical substance in the media. Risks were not evaluated for the general population via drinking water ingestion or groundwater ingestion (landfill leachate) because the hazards are not relevant to the exposure route. Risks to consumers were not evaluated because consumer uses were not identified as conditions of use.

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

Because worker exposures can be controlled by engineering controls and PPE, no unreasonable risks to the general population or 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.

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Date:

/s/
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