

EPA REGISTRATION DIVISION COMPANY NOTICE OF FILING FOR PESTICIDE PETITIONS PUBLISHED IN THE FEDERAL REGISTER

EPA Registration Division contact: Kerry Leifer (202-566-2812)

Tessara Ltd.

Petition **IN-11735**

EPA has received a pesticide petition (**IN-11735**) from Tessara Ltd., 35 Kimball Avenue Epping 2 Cape Town 7460 S. Africa requesting, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180. 960 to establish an exemption from the requirement of a tolerance in or on all raw agricultural commodities for the inert ingredient Poly(oxy-1,2-ethanediyl), polymer with 1,2-ethandiol, 2-methyl-1,3-propanediol, hexanedioic acid, 1,4-benzenedicarboxylic acid, 1,3-benzenedicarboxylic acid, 1,1'-methylenebis[4-isocyanatobenzene] and 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (No CAS No. available), with a minimum number average molecular weight of 1400. EPA has determined that the petition contains data or information regarding the elements set forth in section 408 (d)(2) of FDDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* Plant metabolism data are not required for the establishment of a tolerance exemption for inert ingredients.

2. *Analytical method.* An analytical method is not required when proposing an exemption from the requirement of a tolerance for inert ingredients.

3. *Magnitude of residues.* Magnitude of the residue studies are not required for the establishment of a tolerance exemption for inert ingredients.

B. Toxicological Profile

Polyurethane polymers produced by the reaction of Poly(oxy-1,2-ethanediyl), polymer with 1,2-ethandiol, 2-methyl-1,3-propanediol, hexanedioic acid, 1,4-benzenedicarboxylic acid, 1,3-benzenedicarboxylic acid, 1,1'-methylenebis[4-isocyanatobenzene] and 2-ethyl-2-(hydroxymethyl)-1,3-propanediol conform to the definition of a polymer given in 40 CFR 723.250(b) and meet the following criteria that are used to identify low-risk polymers:

1. The polymer is not a cationic polymer nor is it reasonable anticipated to become a cationic polymer in a natural aquatic environment.
2. The polymer does contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.

3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).
4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.
5. The polymer is manufactured from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory.
6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 Daltons.
7. The polymer does not contain certain perfluoroalkyl moieties consisting of a CF₃- or longer chain length as listed in 40 CFR 723.250(d)(6).

Additionally, the polymer meets as required the following exemption criteria specified in 40 CFR 723.250(e): The polymer's minimum number average MW of 1400 is greater than 1,000 and less than 10,000 daltons. The polymer contains less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000, and the polymer does not contain any reactive functional groups.

Poly(oxy-1,2-ethanediyl), polymer with 1,2-ethandiol, 2-methyl-1,3-propanediol, hexanedioic acid, 1,4-benzenedicarboxylic acid, 1,3-benzenedicarboxylic acid, 1,1'-methylenebis[4-isocyanatobenzene] and 2-ethyl-2-(hydroxymethyl)-1,3-propanediol meet the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to Poly(oxy-1,2-ethanediyl), polymer with 1,2-ethandiol, 2-methyl-1,3-propanediol, hexanedioic acid, 1,4-benzenedicarboxylic acid, 1,3-benzenedicarboxylic acid, 1,1'-methylenebis[4-isocyanatobenzene] and 2-ethyl-2-(hydroxymethyl)-1,3-propanediol.

1. *Acute toxicity.* The proposed polymers meet the definition of a low risk polymer, therefore, these data are not required.
2. *Genotoxicity.* The proposed polymers meet the definition of a low risk polymer, therefore, these data are not required.
3. *Reproductive and developmental toxicity.* The proposed polymers meet the definition of a low risk polymer, therefore, these data are not required.
4. *Subchronic toxicity.* The proposed polymers meet the definition of a low risk polymer, therefore, these data are not required.
5. *Chronic toxicity.* The proposed polymers meet the definition of a low risk polymer, therefore, these data are not required.
6. *Animal metabolism.* Polymers of this size would be poorly absorbed through the intact gastrointestinal tract.
7. *Metabolite toxicology.* The proposed polymers meet the definition of a low risk polymer, therefore, these data are not required.
8. *Endocrine disruption.* The proposed polymers meet the definition of a low

risk polymer, therefore, these data are not required.

C. Aggregate Exposure

For the purposes of assessing potential exposure under this petition, EPA normally considers that inert ingredients could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational nondietary exposure is possible. However, the number average MW of polyurethane type polymers is 1450 to 1500 Daltons. A polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since Poly(oxy-1,2-ethanediyl), polymer with 1,2-ethandiol, 2-methyl-1,3-propanediol, hexanedioic acid, 1,4-benzenedicarboxylic acid, 1,3-benzenedicarboxylic acid, 1,1'-methylenebis[4-isocyanatobenzene] and 2-ethyl-2-(hydroxymethyl)-1,3-propanediol conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential dietary (food and drinking water) and non-dietary exposure scenarios that are reasonably foreseeable. Therefore, a tolerance is not necessary to protect the public health.

1. *Dietary exposure.* Dietary exposures of concern are not anticipated for low risk polymers.
 - i. *Food.* Exposure levels of concern in food are not anticipated for low risk polymers
 - ii. *Drinking Water.* Exposure levels of concern in drinking water are not anticipated for low risk polymers
2. *Non-dietary exposure.* Non-dietary exposures of concern are not anticipated for low risk polymers.

D. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not made a common mechanism of toxicity finding for the proposed polyurethane polymers, which meet the definition of a low risk polymer. Polyurethane polymers do not appear to produce a toxic metabolite produced by other substances.

E. Safety Determination

1. *U.S. population.* The proposed polymers meet the definition of a low risk polymer. Therefore, there is reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of these polymers.

2. *Infants and children.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA concludes that a different margin of safety will be safe for

infants and children. Due to the expected low toxicity of polyurethane polymers, a safety factor analysis to assess the risk is not required. The proposed polymers meet the definition of a low risk polymer, therefore, an additional safety factor is unnecessary

F. International Tolerances

There are no known CODEX or international tolerances or tolerance exemptions established for this proposed low risk polymer.