

certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.* * * and specifies factors EPA is to consider in establishing an exemption.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own) Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers,

including infants and children. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers that should present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b). The following exclusion criteria for identifying these low risk polymers are described in 40 CFR 723.250(d).

1. The polymer, α -hydro- ω -hydroxypoly(oxyethylene) C8-C18-alkyl ether citrates, poly(oxyethylene) content is 4–12 moles, is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. The polymer does contain as an integral part of its composition the atomic elements carbon, hydrogen, and oxygen.

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 or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

Additionally, the polymer, α -hydro- ω -hydroxypoly(oxyethylene) C8-C18-alkyl ether citrates, poly(oxyethylene) content is 4–12 moles, also meets as required the following exemption criteria specified in 40 CFR 723.250(e).

7. The polymer's minimum number average MW of 1,100 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.

Thus, α -hydro- ω -hydroxypoly(oxyethylene) C8-C18-alkyl ether citrates, poly(oxyethylene) content is 4–2 moles meet all the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the above criteria, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to α -hydro- ω -hydroxypoly(oxyethylene) C8-C18-alkyl ether citrates, poly(oxyethylene) content is 4–12 moles.

V. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that α -hydro- ω -hydroxypoly(oxyethylene) C8-C18-alkyl ether citrates, poly(oxyethylene) content is 4–12 moles could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of α -hydro- ω -hydroxypoly(oxyethylene) C8-C18-alkyl ether citrates, poly(oxyethylene) content is 4–12 moles is 1,100 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since α -hydro- ω -hydroxypoly(oxyethylene) C8-C18-alkyl ether citrates poly(oxyethylene) content is 4–12 moles conform to the criteria that identify a low risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

VI. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider "available information" concerning the cumulative effects of a particular chemical's residues and "other substances that have a common mechanism of toxicity." The Agency has not made any conclusions as to whether or not α -hydro- ω -hydroxypoly(oxyethylene) C8-C18-alkyl ether citrates, poly(oxyethylene) content is 4–12 moles share a common mechanism of toxicity with any other chemicals. However, α -hydro- ω -hydroxypoly(oxyethylene) C8-C18-alkyl ether citrates, poly(oxyethylene) content is 4–12 conform to the criteria that identify a low risk polymer. Due to the expected lack of toxicity based on the above conformance, the Agency has determined that a cumulative risk assessment is not necessary.

VII. Determination of Safety for U.S. Population

Based on the conformance to the criteria used to identify a low risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population from aggregate exposure to residues of α -hydro- ω -hydroxypoly(oxyethylene) C8-C18-alkyl ether citrates, poly(oxyethylene) content is 4–12 moles.