

and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

#### List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 10, 2003.

**Debra Edwards,**

*Director, Registration Division, Office of Pesticide Programs.*

#### Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by Nichino America and represents the view of Nichino America. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

#### Nichino America

PP 3E6753

EPA has received a pesticide petition (3E6753) from Nichino America, 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.960, by establishing a tolerance exemption for residues of formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) when used as an inert ingredient in a pesticide product. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA;

however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

#### A. Residue Chemistry

Nichino America is petitioning that formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) be exempt from the requirement of a tolerance based upon the definition of a low risk polymer under 40 CFR 723.250(e). Consequently, Nichino America believes that the analytical method to determine residues, the residues present in plant material, and the magnitude of formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) in raw agricultural commodities, is not relevant.

#### B. Toxicological Profile

1. Formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) is a polymer as defined 40 CFR 723.250(2)(b). It is composed of at least 3 monomer units and 1 other reactant.

2. Formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) consists of a simple weight majority of the polymer molecules. The monomer sequences form uninterrupted strings in the polymer and distribution of the molecular weight of the polymer is due largely to the number of monomer units in the individual molecules.

3. Formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) consists of a number average molecular weight of 1,803 with less than 0.45% of its oligomeric material weighing below 500 daltons and less than 0.45% of its oligomeric material weighing less than 1,000 daltons.

4. Formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) will not become cationic in an aquatic environment. It contains no moieties capable of obtaining a cationic charge.

5. Formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) is composed of carbon, hydrogen, and oxygen; therefore, it meets the criteria of elemental composition. Namely it must be composed of at least two of the following elements (and no other elements than those listed); carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.

6. Formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) is not designed nor reasonably expected to degrade, decompose, or depolymerize under normal use conditions.

7. Formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) is composed of molecules that are listed on the TSCA Inventory or manufactured under an applicable TSCA section 5 exemption.

8. Although, formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) does not exceed the number average molecular weight of 10,000 and therefore is not subject to the water absorption limitation, it nonetheless still satisfies the criteria of being a non-water absorbing species.

#### C. Aggregate Exposure

1. *Dietary exposure.* The physical-chemical characteristics of formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) leads to the conclusion that there is a reasonable certainty of no harm from exposure to the polymer from food or drinking water nor from an aggregate exposure.

2. *Non-dietary exposure.* The physical-chemical characteristics of formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) lead to the conclusion that there is a reasonable certainty of no harm from exposure to the polymer from non-dietary means.

#### D. Cumulative Effects

At this time there is no information to indicate that any toxic effects produced by formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) would be cumulative with any other chemical. Given the compound's categorization as a low risk polymer, and its proposed use in pesticide formulations, there is no expectation of increased risk due to cumulative exposure.

#### E. Safety Determination

1. *U.S. population.* Based on the polymer's physical-chemical properties, and that it meets or exceeds the polymer exemption criteria at 40 CFR 723.250 for low-risk polymers, adverse effects are not expected.

2. *Infants and childrens.* Based on the polymer's physical-chemical properties, and that it meets or exceeds the polymer exemption criteria at 40 CFR 723.250 for low-risk polymers, adverse effects are not expected.