

consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether propylene carbonate has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to propylene carbonate and any other substances and propylene carbonate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that propylene carbonate has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

#### VI. Determination of Safety for U.S. Population, Infants and Children

Based on the available data, the SAR assessment indicating low/moderate concern and the data submitted by the petitioner, Huntsman Corporation, which indicate that the chemical is of low toxicological concern, EPA concludes that propylene carbonate does not pose a dietary risk under reasonably foreseeable circumstances. Accordingly, EPA finds that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to propylene carbonate. Due to the expected low oral toxicity, a safety factor analysis has not been used to assess the risk. For the same reasons and especially considering the developmental toxicity NOAEL, the additional tenfold safety factor for the protection of infants and children is unnecessary.

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of 1,3-Dioxolan-2-one, 4-methyl- (propylene carbonate). Accordingly, EPA finds that exempting 1,3-Dioxolan-2-one, 4-methyl- (propylene carbonate) (CAS Reg.

No. 108-32-7) from the requirement of a tolerance will be safe.

#### VII. Other Considerations

##### A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . . ." EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing propylene carbonate for endocrine effects may be required.

##### B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

##### C. Existing Tolerances

There are no existing tolerances or tolerance exemptions for propylene carbonate.

##### D. International Tolerances

The Agency is not aware of any country requiring a tolerance for propylene carbonate nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

##### E. List 4A (Minimal Risk) Classification

The Agency established 40 CFR 180.950 (see the rationale in the proposed rule published January 15, 2002 (67 FR 1925) (FRL-6807-8)) to collect the tolerance exemptions for those substances classified as List 4A, i.e., minimal risk substances. As part of evaluating an inert ingredient and establishing the tolerance exemption, the Agency determines the chemical's list classification.

The available data and the SAR assessment indicated propylene carbonate is of lower toxicity. Given the NOAELs of greater than 1,000 mg/kg/day and the acute toxicity studies that were category III and IV, it has been determined that propylene carbonate, also known as 1,3-Dioxolan-2-one, 4-methyl- (CAS Reg. No. 108-32-7) is to be classified as a List 4A inert ingredient. Thus, the tolerance exemption will be established in 40 CFR 180.950 instead of 40 CFR 180.1001(c) as requested by the petitioner, Huntsman.

#### VIII. Conclusions

Based on the information in the record, summarized in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of propylene carbonate (CAS Reg. No. 108-32-7). Accordingly, EPA finds that exempting propylene carbonate from the requirement of a tolerance will be safe.

#### IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

##### A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0284 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 4, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in