UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DATE: June 22, 2006

ACTION MEMORANDUM

SUBJECT: Inert Reassessments: One Exemption from the Requirement of a Tolerance for Glycerol-Propylene Oxide Polymer (CAS Reg. No. 25791-96-2)

FROM: Pauline Wagner, Chief Pauline Wagner 6/26/06
Inert Ingredient Assessment Branch
Registration Division (7505P)

TO: Lois A. Rossi, Director
Registration Division (7505P)

I. FQPA REASSESSMENT ACTION

Action: Reassessment of one inert ingredient exemption from the requirement of a tolerance. Current exemption will be maintained.

Chemicals: Glycerol-propylene oxide polymer

Table 1. CFR and CAS Registry Numbers and Names

40 CFR	Inert Ingredients	Limits	Uses (Pesticidal)	CAS Reg. No. and Names
180.920	Glycerol-propylene oxide polymer (CAS Reg. No. 25791-96-2)	None	Component in water-soluble film	25791-96-2 Poly(oxy(methyl-1,2-ethanediyl)), alpha,alpha',alpha"-1,2,3-propanetriyltris)omega-hydroxy-

Use Summary: Glycerol-propylene oxide polymer is used in hairstyling products. It is also used as an inert ingredient (component in water-soluble film) in pesticide formulations.

Background: In the Federal Register of August 25, 1993 (58 FR 44764), EPA issued a final rule establishing an exemption from the requirement of a tolerance for glycerol-propylene oxide

polymer when used as an inert ingredient (component in water-soluble film). The Agency concluded in the final rule that, based on the available information, when used in accordance with good agricultural practice, glycerol-propylene oxide polymer is useful and a tolerance is not necessary to protect the public health. A review of the available information developed since the establishment of the inert ingredient tolerance exemption did not reveal any data that would alter the original risk conclusion for the use of glycerol-propylene oxide polymer in water-soluble film. Therefore, the conclusions of the final rule still apply. Because the final rule was published prior to the enactment of FQPA, additional safety findings are now required and are provided below.

Special Considerations for Infants and Children: In the final rule, the basis for approval of glycerol-propylene oxide polymer was a review of its chemical structure by the Office of Pollution, Prevention, and Toxics (OPPT) Structure Activity Team (SAT). Based on its chemical structure, glycerol-propylene oxide polymer is "not expected to be absorbed by any route," thus "eliminating any concern for toxicity including carcinogenicity, mutagenicity, and developmental toxicity." Based on the available information, there is no concern, at this time, for increased sensitivity to infants and children to glycerol-propylene oxide polymer when used as an inert ingredient in pesticide formulations. For the same reason, a safety factor analysis has not been used to assess risk and, therefore, the additional tenfold safety factor for the protection of infants and children is also unnecessary.

Aggregate Exposure: In examining aggregate exposure, the FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water (from ground water or surface water) and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). For glycerol-propylene oxide polymer, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given the lack of human health concerns associated with exposure to this chemical as an inert ingredient in pesticide formulations.

Cumulative Exposure: Section 408(b)(2)(D)(v) of the 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." 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 glycerol-propylene oxide polymer and any other substances, and this material does not appear to produce toxic metabolites produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that glycerol-propylene oxide polymer 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.

Human Health Risk Characterization: According to the final rule, based on its chemical structure, glycerol-propylene oxide polymer is "not expected to be absorbed by any route," thus

"eliminating any concern for toxicity including carcinogenicity, mutagenicity, and developmental toxicity." Based on the expected low absorption and its use as a component in water-soluble film in pesticide formulations on growing crops only, dietary and residential exposures of concern are not expected. Taking into consideration the available information on glycerol-propylene oxide polymer, there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure when considering dietary exposure and all other non-occupational sources for which there is reliable information. Therefore, it is recommended that the one exemption from the requirement of a tolerance established for residues of glycerol-propylene oxide polymer when used under 40 CFR 180.920 can be considered reassessed as safe under section 408(q) of the FFDCA.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the one exemption from the requirement of a tolerance for the inert ingredient glycerol-propylene oxide polymer (CAS Reg. No. 25791-96-2). I consider the one exemption established in 40 CFR 180.920 to be reassessed for purposes of FFDCA's section 408(q) as of the date of my signature, below. A Federal Register Notice regarding this tolerance exemption reassessment decision will be published in the near future.

Lois A. Rossi

Lois A. Rossi, Director
Registration Division

Date: June 26, 2006

CC: Debbie Edwards, SRRD
Joe Nevola, SRRD