



DATE: June 29, 2006

ACTION MEMORANDUM

SUBJECT: Inert Reassessments: One Exemption from the Requirement of a Tolerance for Ethylene Glycol (CAS Reg. No. 107-21-1)

FROM: Pauline Wagner, Chief *Pauline Wagner 6/30/06*
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 is to be maintained.

Chemicals: Ethylene glycol

Table 1. CFR and CAS Registry Numbers and Names				
40 CFR	Inert Ingredients	Crop	Uses (Pesticidal)	CAS Reg. No. and Name
180.1040	Ethylene glycol	Peanut Plants	Ethylene glycol as a component of pesticide formulations is exempt from the requirement of a tolerance when used in foliar applications to peanut plants.	107-21-1 1,2-Ethanediol

Use Summary: Ethylene glycol is used as a de-icer and anti-icer, a component in hydraulic brake fluid and inks, and as a solvent.

Background: EPA has reassessed ethylene glycol under 40 CFR 180.920 when used as an inert ingredient "Antifreeze, deactivator for all pesticides used before crop emerges from soil and in herbicides before or after crop emerges." The Agency concluded in the reassessment that, based

on the available information, when used in accordance with good agricultural practice, ethylene glycol could “be considered reassessed as safe under section 408(q) of the FFDCa.” The conclusion from the tolerance exemption reassessment of ethylene glycol under 40 CFR 180.920 also applies to its tolerance exemption under 40 CFR 180.1040, and the exemption is to be maintained. The use pattern of ethylene glycol under 40 CFR 180.1040 significantly limits its exposure potential and does not impact in any significant way the exposure potential of ethylene glycol under 40 CFR 180.920, and therefore, the risk conclusions under 40 CFR 180.920 remain unchanged.

Special Considerations for Infants and Children: According to the Agency’s reassessment of the 40 CFR 180.920 tolerance exemption for ethylene glycol, “there is negligible concern of developmental toxicity from ethylene glycol at exposures below 125 mg/kg. This dose is much greater than exposures expected from use as an inert ingredient.” This conclusion also applies to the 40 CFR 180.1040 tolerance exemption for ethylene glycol. Based on the available information, there is no concern, at this time, for increased sensitivity to infants and children to ethylene glycol 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 ethylene glycol, 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 ethylene glycol 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 ethylene glycol 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: Ethylene glycol has low acute oral, dermal, and inhalation toxicity. It also has low chronic oral toxicity, with kidney and liver toxicity occurring at high doses (NOAEL = 3,000 mg/kg/day). It was nonmutagenic in the Ames assay and in a number of other genetic toxicity tests, and a noncarcinogenic in animal study. The 40 CFR 180.920 assessment reported that “there is negligible concern of adverse developmental toxicity

from ethylene glycol at exposures below 125 mg/kg,” and there was no evidence of reproductive toxicity from ethylene glycol in lab animals.

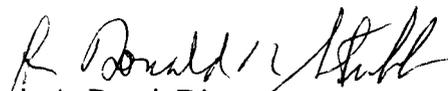
Exposure to ethylene glycol as a result of its use as an inert ingredient in pesticide products is possible through the dietary (food and/or drinking water) or residential (dermal and inhalation) routes of exposure. However, exposures (dietary and residential) to ethylene glycol are significantly limited by its restriction to use only on peanut plants under this tolerance exemption (40 CFR 180.1040). In addition, peanut plants are normally shelled as part of processing or before consumption. Ethylene glycol biodegrades quickly in soil and water, and bioconcentration in aquatic organisms is expected to be low. Considering the low chronic toxicity, ready biodegradation, and use limitations of ethylene glycol, dietary and residential exposures of concern are not anticipated.

Taking into consideration the available information on ethylene glycol, 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 ethylene glycol when used under 40 CFR 180.1040 can be considered reassessed as safe under section 408(q) of the FFDCA.

List Reclassification Determination: The current List Classification for ethylene glycol is 3. Because EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to ethylene glycol when used as an inert ingredient in pesticide formulations, the List Classification for ethylene glycol will change from List 3 to List 4B.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the one exemption from the requirement of a tolerance for the inert ingredient ethylene glycol (CAS Reg. No. 107-21-1). I consider the exemption established in 40 CFR 180.1040 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, Director
Registration Division

Date: 7/3/06

CC: Debbie Edwards, SRRD
Joe Nevola, SRRD