

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



OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

DATE: June 5, 2006

ACTION MEMORANDUM

SUBJECT: Inert Reassessments: One Exemption from the Requirement of a Tolerance for Trimethylolpropane (CAS Reg. No. 77-99-6)

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

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

I. FQPA REASSESSMENT ACTION

Action: Reassessment of one inert exemption from the requirement of a tolerance. The reassessment decision is to maintain the inert tolerance exemption "as-is."

Chemical: Trimethylolpropane

CFR and CAS Registry Number and Name:

Citation as it Appears in the CFR				CAS Registry Numbers and Names
40 CFR	Tolerance Exemption Expression	Limits	Uses	
180.920	Trimethylolpropane	Not to exceed 15% by weight	Component in water-soluble film	77-99-6 1,3-Propanediol, 2-ethyl-2- (hydroxymethyl)-

Use Summary: Trimethylolpropane is used in a large variety of commercial applications, including in the manufacturer of varnishes, resins; polyesters for polyurethane foams, textile finishes, plasticizers, and cross-linking agents for spandex fibers. As an inert ingredient in pesticides, trimethylolpropane's use is limited to a component of water-soluble films in pesticide formulations applied to growing crops.

FQPA Safety Finding: In the Federal Register of January 19, 1994, (59 FR 2751), EPA issued a final rule establishing an exemption from the requirement of a tolerance for trimethylolpropane when used as an inert ingredient (component of water-soluble film) in pesticide formulations applied to growing crops only with a limitation that it will not exceed 15% of the pesticide formulation. EPA concluded in the final rule “Based on the data and information considered, the Agency concludes that the tolerance exemption will protect the public health.” A review of 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 trimethylolpropane as a component of 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: Trimethylolpropane is of low toxicity for endpoints of concern for human health effects, including developmental and reproductive effects, based on the available information. In a developmental and reproductive toxicity study summarized in the IUCLID Dataset for trimethylolpropane (European Commission, 2000), doses of 0, 500, 1,000, and 2,000 mg/kg were administered orally to Sprague-Dawley rats. The no observed adverse effect level (NOAEL) was 500 mg/kg bw for parents and offspring. Therefore, there is no concern for potential sensitivity to infants and children. Based on this available information, a safety factor analysis has not been used to assess the risks resulting from the use of trimethylolpropane, therefore, an additional tenfold safety factor for the protection of infants and children is unnecessary.

Aggregate Exposure: In examining aggregate exposure, FFDCFA 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). In developing this assessment for trimethylolpropane, 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 these chemicals

Cumulative Exposure: Section 408(b)(2)(D)(v) of the FFDCFA 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 trimethylolpropane and any other substances, and these chemicals do not appear to produce a toxic metabolite produced by other substances. For the purpose of this tolerance action, therefore, EPA has not assumed that trimethylolpropane 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: Taking into consideration the available information on trimethylolpropane, 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 of pesticide exposure for which there is reliable information. Therefore, it is recommended that the one exemption from the requirement of a tolerance established for in/on raw agricultural commodities under 40 CFR §180.920 can be considered reassessed as safe under section 408(q) of the FFDCA.

List Reclassification Determination: The current List Classification for trimethylolpropane 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 trimethylolpropane when used as an inert ingredient in pesticide formulations, the List Classification for these chemicals 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 trimethylolpropane (CAS Reg. No. 77-99-6), and with the List reclassification determination, as described above. I consider the one exemption established in 40 CFR part 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, Director
Registration Division

Date: June 8, 2006

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD