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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DATE: July 7, 2006

ACTION MEMORANDUM

SUBJECT: Inert Reassessments: One Exemption from the Requirement of a Tolerance for Polybutenes (CAS Reg. No. 9003-29-6)

FROM: Pauline Wagner, Chief
Inert Ingredient Assessment Branch

TO: Lois A. Rossi, Director
Registration Division

I. FQPA REASSESSMENT ACTION

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

Chemical: Polybutenes

Table 1. Tolerance Exemptions Expression

40 CFR	Inert Ingredients	RAC*	Uses (Pesticidal)	CAS Reg. No. and Name
180.1037	Polybutenes	Cottonseed	(a) Sticker agent for formulations of the attractant gossyplure (1:1 mixture of (*Z,Z*)- and (*Z,E*)-7,11-hexadecadien-1-ol acetate) to disrupt the mating of the pink bollworm.	9003-29-6 Butene, homopolymer
		Artichokes	(b) Sticker agent in multi-layered laminated controlled-release dispensers of (Z)-11-hexadecenal to disrupt the mating of the artichoke plume moth.	

*Raw agricultural commodity (RAC).

Use Summary: Polybutenes are used as lubricating-oil additives, polymer modifiers, and viscosity index improvers. They are components of hot-melt adhesives, sealing tapes, special sealants, cable insulation, and films and coatings. In the cosmetics industry, they are used as ingredients for skin and hair conditioning cosmetics. Polybutenes are also inert ingredient tackifiers or sticker agents in pesticide formulations.

Background:

In the Federal Register of September 20, 1977 (42 FR 47204), EPA issued a final rule establishing an exemption from the requirement of a tolerance under 40 CFR 180.1037 for polybutene in or on cottonseed when used as a sticker agent for formulations of the attractant gossyplure. The basis for the Agency's approval of the tolerance exemption was "No reasonable expectation of residue in human food." The Agency concluded that, based on the very limited use pattern of the tolerance exemption and chemical's chemistry, "when used in accordance with good agricultural practice, these substances are useful and do not pose a hazard to the environment. It is concluded, therefore, that the proposed amendments to 40 CFR Part 180 will protect the public health..."

In the Federal Register of May 11, 1983 (48 FR 21133), the EPA issued a final rule amending 40 CFR 180.1037 to include an exemption from the requirement of a tolerance for polybutenes in or on artichokes when used as a sticker agent for multi-layered laminated controlled-release dispensers of (*Z*)-11-hexadecenal. The final rule concluded that "Data indicate that there is little likelihood of residues reaching the marketplace because of the agricultural practices of artichoke growers."

A review of the available information developed since the publication of the final rule did not reveal any data that would alter the original risk conclusions for polybutenes. A Reregistration Eligibility Decision (RED) was produced in January 1994 for the active ingredient uses of polybutenes in bird and squirrel repellants. According to the RED, polybutenes are of relatively low acute toxicity acute dermal and oral effects. They are non-irritating to the skin but moderately irritating to the eyes, and are non-mutagenic. The full risk assessment for the RED can be found at http://cfpub.epa.gov/oppref/rereg/status.cfm?show=rereg. The RED concluded that "the active ingredient polybutene, labeled and used as specified in the RED document, will not pose unreasonable risks or adverse effects to humans or the environment."

The risk conclusions from the final rules that established 40 CFR 180.1037 remain unchanged. 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: Exposure to residues of polybutene are not anticipated from it use as a sticker/tackifier agent in controlled release dispensers of attractants for 1) artichoke plume moth in artichokes and 2) pink bollworm in cottonseed. Based on this information, there is no concern, at this time, for increased sensitivity to infants and children to polybutenes when used as an inert ingredient in pesticide formulations under the use limitations of 40 CFR 180.1037. 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 polybutenes, 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 polybutenes as inert ingredients 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 polybutenes and any other substances, and these materials 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 polybutenes have 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 RED, polybutenes are of relatively low acute toxicity acute dermal and oral effects. They are non-irritating to the skin but moderately irritating to the eyes, and are non-mutagenic. The full risk assessment for the RED can be found at http://cfpub.epa.gov/oppref/rereg/status.cfm?show=rereg.

As an inert ingredient sticker agent in pesticide formulations, polybutene is applied to a dispenser that contains attractants for artichoke plume moth and pink bollworm. Dietary (food and drinking water) and residential (inhalation and dermal) exposures are not expected from the use of polybutene as an inert ingredient sticker agent under the limitations of 40 CFR 180.1037.

Taking into consideration all available information on polybutenes, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to polybutenes when considering exposure through food commodities 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 polybutenes under 40 CFR 180.1037 when used as a sticker agent 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 polybutenes. I consider the one exemption established in 40 CFR 180.1037 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: July 7, 2006

CC: Debbie Edwards, SRRD
Joe Nevola, SRRD