



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

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

August 2, 2006

ACTION MEMORANDUM

SUBJECT: Reassessment of One Exemption from the Requirement of a Tolerance for Isobutylene-butene copolymers

FROM: Pauline Wagner, Chief *Pauline Wagner 8/2/06*
Inert Ingredient Assessment Branch
Registration Division (7505P)

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

I. FQPA REASSESSMENT ACTION

Action: Reassessment of one inert ingredient exemption from the requirement of a tolerance.

Chemical: See Table 1 below

Table 1. Tolerance Exemption Expression

| CFR Citation | | | | CAS Reg. No. and Name |
|----------------------|-------------------------------|---------------------------|--------|---|
| 40 CFR | Inert Ingredient | Limits | Uses | |
| 180.920 ^a | Isobutylene-butene copolymers | For soil application only | Binder | 9044-17-1 Butene, polymer with 2-methyl-1-propene- |

^aResidues listed in 40 CFR 180.920 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only.

Use Summary: Isobutylene-butene copolymers are used as lubricants, adhesives, coking material, sealing material, electrical insulation material, rubber, asphalt, ink, fertilizers and dispersants. They are also used as inert ingredients (binders) in pesticide formulations applied to the soil in growing crops only.

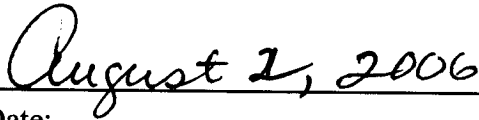
List Classification Determination: Because EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to these chemicals when used as an inert ingredient in pesticide formulations for soil application only, the List Classification for isobutylene-butene copolymers will be List 4B.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the exemption from the requirement of a tolerance for the inert ingredient isobutylene-butene copolymers, as well as the List Classification determination described above. I consider the one exemption established in 40 CFR 180.920 to be reassessed for purposes of FFDCCA'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:

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD




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MEMORANDUM

SUBJECT: Reassessment of the Exemption from the Requirement of a Tolerance for Isobutylene-Butene Copolymers

FROM: Kerry Leifer 
Inert Ingredient Assessment Branch
Registration Division (7505P)

TO: Pauline Wagner, Chief
Inert Ingredient Assessment Branch
Registration Division (7505P)

BACKGROUND

Attached is the science assessment for isobutylene-butene copolymers. The purpose of this document is to reassess the existing exemption from the requirement of tolerance for residues of isobutylene-butene copolymers as required under the Food Quality Protection Act (FQPA). This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profile, environmental fate, and ecotoxicity of isobutylene-butene copolymers.

EXECUTIVE SUMMARY

This document evaluates the exemption from the requirement of a tolerance for isobutylene-butene copolymers. This substance is exempted from the requirement of a tolerance under 40 CFR 180.920 when used as an inert ingredient (binder) in pesticide formulations for soil application only.

Isobutylene-butene copolymers have been evaluated by the Office of Pollution Prevention and Toxics (OPPT) Structure Activity Team (SAT). The OPPT SAT assessment concluded that isobutylene-butene copolymers are not likely to be absorbed by any route of exposure and are of low concern for human health effects. In addition, the OPPT SAT concluded that isobutylene-butene copolymers are of low concern for effects to nontarget aquatic species, primarily based upon the insolubility of

isobutylene-butene copolymers. A Reregistration Eligibility Document (RED) on polybutene did not identify any ecological risks of concern.

Taking into consideration all available information on isobutylene-butene copolymers, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to isobutylene-butene copolymers when used as an inert ingredient in pesticide products applied before the crop emerges from the soil when considering dietary (i.e. food and water) exposure and all other nonoccupational sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that the exemption from the requirement of a tolerance established for residues of isobutylene-butene copolymers under 40 CFR 180.920 be considered reassessed as safe under section 408(q) of FFDCFA.

I. INTRODUCTION

This report provides a qualitative assessment for isobutylene-butene copolymers. This substance is exempted from the requirement of a tolerance under 40 CFR 180.920 when used as an inert ingredient (binder) in pesticide formulations for soil application only. Isobutylene-butene copolymers are used as lubricants, adhesives, coking material, sealing material, electrical insulation material, rubber, asphalt, ink, fertilizers and dispersants (NOF, 2006).

Isobutylene-butene copolymers are sometimes also referred to as polybutene, as commercial forms of polybutene are not butene homopolymers, but rather polymers containing both isobutylene and butene monomeric units in varying ratios. As used herein, the term "isobutylene-butene copolymers" will apply to the polymer formed from isobutylene and butene whereas "polybutene" will apply to the unspecified polymer of one or more of the four isomeric forms of butene, which are 1-butene, cis-2-butene, trans-2-butene, and isobutylene.

II. USE INFORMATION

A. PESTICIDE USES

The exemption from the requirement of a tolerance for isobutylene-butene copolymers is provided in Table 1 below.

Table 1. CFR Citation, CAS Registry Number, and CAS 9th Collective Index (9CI) Name for Isobutylene Butene Copolymers

| 40 CFR | Chemical Name | CFR Citation | Use | CAS Reg. No. and 9CI Name |
|----------------------|-------------------------------|---------------------------|--------|--|
| 180.920 ^a | Isobutylene-butene copolymers | For soil application only | Binder | 9044-17-1 Butene, polymer with 2-methyl-1-propene |

^aResidues listed in 40 CFR 180.920 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only.

B. OTHER USES

Isobutylene-butene copolymers are used as lubricants, adhesives, coking material, sealing material, electrical insulation material, rubber, asphalt, ink, fertilizers and dispersants (NOF, 2006).

III. PHYSICAL AND CHEMICAL PROPERTIES

Some of the physical and chemical characteristics of isobutylene-butene copolymer, along with its structure and nomenclature, are found in Table 2.

Table 2. Physical and Chemical Properties of Isobutylene Butene Copolymers

| Structure | $\text{---}(-\text{CH}_2-\text{C}(\text{CH}_3)_2-\text{C}_4\text{H}_8\text{---})_n\text{---}$ | |
|---|---|-------------|
| CAS Reg. No. and 9CI Name | 9044-17-1 Butene, polymer with 2-methyl-1-propene | CAS, 2006 |
| Empirical Formula | $(\text{C}_4\text{H}_8)_n$ ($n \geq 6$) | |
| Molecular Weight | >400 | |
| Physical State | Liquid | Amoco, 1997 |
| Melting Point | Not determined | |
| Boiling Point | Not determined | |
| Water Solubility | Negligible | Amoco, 1997 |
| Vapor Pressure | $<1 \times 10^{-6}$ mmHg @ 25°C (E) | EPA, 1995 |
| Octanol-Water Partition Coefficient Log K_{ow} | >9 (E) | EPA, 1995 |
| Henry's Law Constant | $< 1 \times 10^{-8}$ atm m ³ /mol (E) | EPA, 1995 |

(E)=Estimated

IV. HAZARD ASSESSMENT

A. HAZARD PROFILE

Hazard information in the form of toxicity data on isobutylene-butene copolymers *per se* are not available, therefore a structure activity relationship analysis of isobutylene-butene copolymers was conducted by the Office of Pollution Prevention and Toxics (OPPT) Structure Activity Team (SAT). Based on the structure and the physical/chemical properties of the isobutylene-butene copolymers, the OPPT assessment concluded that isobutylene-butene copolymers are not absorbed by any route of exposure and are of low concern for human health effects, with no identified health concerns (EPA, 1995)

Polybutene, a close analog of isobutylene-butene copolymer, has uses as a pesticide active ingredient and was the subject of a January 1994 Reregistration Eligibility Decision (RED). According to the RED, polybutenes are of relatively low acute toxicity via the dermal and oral routes of exposure. They are non-irritating to the

skin but moderately irritating to the eyes, and are non-mutagenic. 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" (EPA, 1994).

Additionally, an exemption from the requirement of a tolerance for an inert ingredient use of polybutene, as a sticker agent under 40 CFR 180.1037, was reassessed as safe on July 7, 2006 (EPA, 2006).

Based on the OPPT SAT evaluation, the conclusions in the RED document for polybutenes, and the reassessment determination made on the inert ingredient use of polybutenes, it is determined that isobutylene-butene copolymers are low toxicity substances.

B. SPECIAL CONSIDERATIONS FOR INFANTS AND CHILDREN

Isobutylene-butene copolymers are likely poorly absorbed via all routes of exposure. Therefore the isobutylene-butene copolymers are of low concern for human health effects, and a safety factor analysis has not been used to assess the risks resulting from the use of isobutylene-butene copolymers as inert ingredients. The additional tenfold safety factor for the protection of infants and children is currently unnecessary.

V. ENVIRONMENTAL FATE CHARACTERIZATION AND DRINKING WATER CONSIDERATIONS

Isobutylene-butene copolymers are nonvolatile liquid compounds that are insoluble in water. Based on the insolubility of the isobutylene-butene copolymers, concentrations of isobutylene-butene copolymers in drinking water are not anticipated.

VI. EXPOSURE ASSESSMENT

Based on use of isobutylene-butene copolymers as a binder in pesticides applied to soil only, poor absorption via any route of exposure, as well as the lack of water solubility, anticipated exposures would be expected to be negligible. Therefore, a dietary (food and drinking water) and residential exposure assessment is not necessary.

VII. AGGREGATE EXPOSURE

In examining aggregate exposure, the Federal Food, Drug, And Cosmetic Act (FFDCA) section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other nonoccupational 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 isobutylene-butene copolymers, 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 isobutylene-butene copolymers.

VIII. 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 isobutylene-butene copolymers and any other substances and, isobutylene-butene copolymers do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that isobutylene-butene copolymers 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/>.

IX. HUMAN HEALTH RISK CHARACTERIZATION

Isobutylene-butene copolymers are not expected to be absorbed via any route of exposure and are of low concern for human health effects. Taking into consideration all available information on isobutylene-butene copolymers, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to isobutylene-butene copolymers when used as an inert ingredient in pesticide products applied to soil only when considering dietary (i.e. food and water) exposure and all other nonoccupational (residential) sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that the exemption from the requirement of a tolerance established for residues of isobutylene-butene copolymers under 40 CFR 180.920 be considered reassessed as safe under section 408(q) of FFDCA.

IX. ECOTOXICITY AND ECOLOGICAL RISK CHARACTERIZATION

The OPPT SAT evaluation of isobutylene-butene copolymers concluded that isobutylene-butene copolymers are of low concern for effects to nontarget aquatic species, primarily based upon the insolubility of isobutylene-butene copolymers.

The ecological risk assessment in the polybutene RED did not identify any ecological risks of concern associated with the use of polybutene, a isobutylene-butene copolymers isomer, as an active ingredient (EPA, 1994).

REFERENCES

Amoco Corporation (Amoco). 1997. Material Safety Data Sheet for Isobutylene-Butene Copolymer.

CAS (Chemical Abstracts Service). 2006. STN on the Web. <http://stnweb.cas.org/> Last updated: July 1, 2006

NOF Corporation (NOF). 2006. Functional Chemicals & Polymers--Product Information: Polybutene. <http://www.nof.co.jp/english/business/chemical/product02b.html#01>

U.S. Environmental Protection Agency (EPA). 1994. Reregistration Eligibility Decision (RED) Polybutene. EPA 738-R-95-007. <http://www.epa.gov/oppsrrd1/REDs/4076.pdf>

U.S. Environmental Protection Agency (EPA). 1995. Structure Activity Team Report Isobutylene Butene Copolymer. Office of Pollution Prevention and Toxics. October 11, 1995 (See Appendix A).

U.S. Environmental Protection Agency (EPA). 2006. Memorandum from P. Wagner to L. Rossi. Inert Reassessments: One Exemption from the Requirement of a Tolerance for Polybutenes dated July 7, 2006.

APPENDIX A

SAT Assessment of Isobutylene-butene Copolymers

SAT Date: 10/11/95

CAS No: 009003-29-6

Name: Isobutylene-butene copolymers

MW range: 320-2300

HEALTH RATING: 1

ECO RATING: 1 for MW=280 and greater; 3 for MW<280

FATE: S = Negl.; VP @ 25C (mm) < 1.0E-6(E); H < 1.00E-8(E)

POTW removal (%) = 90 via sorption

Time for complete ultimate aerobic biodeg \exists mo

Sorption to soils/sediments = v.strong

Migration to ground water = negl>

HEALTH: Expect nil absorption all routes. No significant health effects expected. OPP has a list of validated toxicity studies that include acute oral and dermal studies, skin and eye irritation studies, dermal sensitization studies, a 2-week inhalation study, a subchronic feeding study, and some mutagenicity studies. No significant toxic effects were noted; however, the molecular weights of the test materials are not identified. Low concern.

ECO: Predicted toxicity values in mg/L (ppm) are:

| Effective Concentration | di MW: 112. | tri 168. | tetra 224. | > or = penta 280. |
|-------------------------|----------------|-------------|---------------|----------------------|
| log Kow: | 4.0 | 5.8 | 7.7 | 9.6 |
| S: | 27.0 | 0.390 | 0.004 | < or = 0.001 |
| fish 96-h LC50 | = 1.1 | * | * | * |
| daphnid 48-h LC50 | = 1.3 | * | * | * |
| green algal 96-h EC50 | = 0.950 | 0.040 | * | * |
| fish ChV | = 0.200 | 0.008 | * | * |
| daphnid ChV | = 0.170 | 0.010 | 0.001 | * |
| algal ChV | = 0.300 | 0.030 | 0.003 | * |
| CC | = 0.020 | 0.001 | 0.001 | * |

* = not toxic at saturation

Predictions are based on SARs for neutral organic chemicals; log Kow via CLOGP, pH 7, hardness <180.0 mg/L as CaCO₃, 100% active ingredients, mean measured concentrations, and TOC <2.0 mg/L; high concern for dimer for acute and chronic toxicity; high concern for the trimer for chronic toxicity only; high concern for the tetramer for chronic toxicity; low concern for the pentamer and all other higher molecular weight oligomers; assessment factor = 10.0