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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 30, 2005

ACTION MEMORANDUM

SUBJECT: Inert Ingredient Tolerance Reassessment - 1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline (CAS Reg. No. 91-53-2)

FROM: Dan Rosenblatt, Chief
Minor Use, Inerts, and Emergency Response Branch

TO: Lois A. Rossi, Director
Registration Division

I. FQPA REASSESSMENT ACTION

Action: Reassessment of one (1) inert ingredient exemption from the requirement of a tolerance. The tolerance exemption is to be maintained.

Chemical: 1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline
CFR: 40 CFR § 180.910 [formerly 40 CFR § 180.1001(c)]
CAS #: CAS Reg. No. 91-53-2
PC #: 855501

Use Summary: The predominant use of this chemical is as a pesticidal wrap on pears, as a preservative on animal feed and as an antioxidant in certain spices. The tolerance for the active ingredient use of ethoxyquin is addressed in the 2004 Reregistration Eligibility Decision. It also has an inert ingredient use as an antioxidant to preserve insecticides used on certain vegetables, fruits and nuts, on ornamental trees and shrubs, in residential homes and gardens, in livestock-consumable mineral blocks, and on mosquito-infested standing waters.

List Reclassification Determination: Ethoxyquin is classified as a list 4B inert ingredient. Based on the reasonable certainty of no harm safety finding and the existing 40 CFR §180.910 use limitation, the List 4B classification for ethoxyquin is affirmed.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the one (1) exemption from the requirement of a tolerance for the inert ingredient 1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline, and with the List determination, as described above. I consider the one (1) exemption from the requirement of a tolerance for ethoxyquin established in 40 CFR §180.910 [formerly 40 CFR§180.1001(c)] to be reassessed as of the date of my signature, below.

Lois A. Rossi

Lois A. Rossi, Director
Registration Division

Date: 4/13/05

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD

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MEMORANDUM

SUBJECT: Reassessment of the Exemption from the Requirement of a Tolerance for 1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline

FROM: R. Tracy Ward
Minor Use, Inerts and Emergency Response Branch
Registration Division (7505C)

THRU: Pauline Wagner, Inerts Coordinator Pauline Wagner 3/30/05
Minor Use, Inerts and Emergency Response Branch
Registration Division (7505C)

TO: Dan Rosenblatt, Chief
Minor Use, Inerts and Emergency Response Branch
Registration Division (7505C)

Executive Summary

The purpose of this assessment is to evaluate the existing inert ingredient tolerance exemption for 1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline (CAS Reg. No. 91-53-2), the preferred chemical name for ethoxyquin. Ethoxyquin is a pesticide inert ingredient for which exemption from the requirement of a tolerance exists for its residues when used in pesticide formulations applied to growing crops or raw agricultural commodities under 40 CFR Part 180.910.

A Reregistration Eligibility Document (RED) performed in 2004 by the Agency evaluated the pesticidal uses of ethoxyquin as the active ingredient for post-harvest/indoor uses on pears, as a preservative on animal feed and as an antioxidant in certain spices. The RED concluded that the risks associated with the active ingredient use of ethoxyquin are well below the Agency's level of concern, and that there is a reasonable certainty of no harm to the general population, infants and children from aggregate exposure to residues of ethoxyquin on agricultural commodities. A complete description of the toxicological profile and endpoints, uncertainty factors, the exposure assessment for food, the aggregate and chronic risk for

ethoxyquin is provided in the July 2, 2004 RED at http://www.epa.gov/pesticides/reregistration/status.htm.

Exposures resulting from the use of ethoxyquin as an inert ingredient in pesticide formulations do not increase aggregate exposure risks above the Agency's level of concern. Based on the RED assessment document, information on ethoxyquin, its expected use patterns as an inert ingredient, its safe history of use as a preservative and its low toxicity, the Agency has determined that a quantitative risk assessment is not required for this chemical.

Taking into consideration all available information on ethoxyquin, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to ethoxyquin 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 residues of ethoxyquin in/on raw agricultural commodities can be considered reassessed as safe under section 408(q) of the FFDCA

I. Background

The purpose of this document is to reassess the existing exemption from the requirement of a tolerance for residues of ethoxyquin (CAS Reg. No. 91-53-2) as required under the Food Quality Protection Act (FQPA). On July 2, 2004, the Agency issued a RED for the active ingredient use of ethoxyquin that did not include an evaluation of its use as an inert ingredient in agricultural pesticides.

This assessment summarizes available information on the use, physical and chemical properties, toxicological effects, and exposure profile of ethoxyquin as provided by the RED. It also evaluates the environmental fate and ecotoxicity of ethoxyquin. Based on this assessment, the Agency has concluded that ethoxyquin does not pose a significant risk to human health or the environment.

As an inert ingredient, ethoxyquin is used as an antioxidant to preserve insecticides used on certain vegetables, fruits and nuts, on ornamental trees and shrubs, in residential homes and gardens, in livestock-consumable mineral blocks, and on mosquito-infested standing waters. Table 1 gives the tolerance exemption for the inert use.

Table 1. Tolerance Exemption Being Reassessed in this Document

Tolerance Exemption Expression	CAS Reg. No.	40 CFR Part 180	PC Code	Use Patterns (Pesticidal)	List Classification
1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline	91-53-2	910[1]	855501 (Inert)	Antioxidant (Inert Ingredient) (Not more than 0.02% of formulation)	4B

1. Residues listed in 40 CFR § 180.910 [formerly 40 CFR § 180.1001(c)] are exempted from the requirement of a tolerance when used as inert ingredients in pesticide formulations when applied to growing crops or raw agricultural commodities after harvest.

II. Hazard Assessment

The Agency completed a risk assessment utilizing ethoxyquin's toxicological database. For the complete risk assessment, see the RED. The ethoxyquin toxicology database provided adequate information for determining ethoxyquin's risk to human health within the guidelines of FIFRA and FQPA.

The toxicity endpoints for the dietary exposure risk assessment are conservative for the active use of ethoxyquin, but both the acute and chronic dietary risks are well below the Agency's level of concern. The dietary exposures resulting from the inert use of ethoxyquin as an antioxidant are significantly less than those exposures resulting from the active use and are below the Agency's level of concern. There are no adverse health effects expected from dietary exposure to ethoxyquin for the general U.S. population or for infants and children under the age of 2 years.

Ethoxyquin has not been tested for its carcinogenic potential. However, it is structurally similar to Fleetol H, a substance with evidence of carcinogenicity in male rats. To satisfy any concerns about cancer risks, HED calculated a hypothetical Q* for lifetime exposure cancer risk for ethoxyquin and determined that the risk is far below the EPA's level of concern. With a 0.02% pesticide formulation limit for the inert ingredient, the exposure risk does not increase significantly, and the cancer risk is expected to still be below the EPA's level of concern.

III. Environmental Fate/Ecotoxicity/Drinking Water Considerations

The RED does not characterize environmental fate or exposure risks for 1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline because it is only applied indoors when used as an active ingredient. There are very few environmental fate or effects data for it's inert use, but ethoxyquin has low application rates and low volume of use. A single study suggests that ethoxyquin as an inert ingredient in pesticide formulations is not acutely toxic to birds. Two studies indicate that ethoxyquin is toxic to aquatic invertebrates and moderately toxic to fish. However, the inert comprises 0.02% of pesticide formulations used on agricultural food crops, and no more than 0.2% of formulations fed to livestock. Ethoxyquin residues are strongly adsorbed and retained by soils, so this substance will likely reach surface water sorbed onto soils where it will partition to aquatic sediments. This compound is unlikely to leach into groundwater. In addition, ethoxyquin is insoluble in water, and a hydrolysis study indicates that ethoxyquin degrades in water in less than 10 days. Larvicidal pesticides that have ethoxyquin as an inert ingredient are applied to targeted non-agricultural areas in stagnant or marsh waters and are therefore not a concern for drinking water. Because of the physical and chemical properties of this inert ingredient, ecotoxicity and drinking water contamination risks are below the Agency's level of concern.

IV. Human Health Risk Characterization

Considering all routes of exposure likely from the pesticide uses of the chemical, there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to the chemical 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 exemption from the requirement of a tolerance established for residues of 1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline in/on raw agricultural commodities and animals be considered a candidate for reassessment under section 408(q) of the FFDCA.

References:

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MRID No. 43978101 Palmer, S.; Martin, K.; Beavers, J. (1996) Ethoxyquin Technical: A Dietary LC50 Study with the Northern Bobwhite: Lab Project Number: 442-101. Unpublished study prepared by Wildlife Int'l. Ltd. 45 p.

MRID No. 43978301 Drottar, K.; Swigert, J. (1996) Ethoxyquin: A 96-Hour Flow-Through Acute Toxicity Test with the Rainbow Trout (Oncorhychus mykiss): Final Report: Lab Project Number: 442A-101A: 442/122095/RBT-96H2/CHP107: 442A-101. Unpublished study prepared by Wildlife International Ltd. 65 p.

MRID No. 43978401 Drottar, K.; Swigert, J. (1996) Ethoxyquin: A 48-Hour Flow-Through Acute Toxicity Test with the Cladoceran (Daphnia magna): Final Report: Lab Project Number: 442A-102: 442/122095/DAP-48H2/CHP107. Unpublished study prepared by Wildlife Int'l. Ltd. 66 p.