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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DATE: June 19, 2006

ACTION MEMORANDUM

SUBJECT: Inert Reassessments: One Exemption from the Requirement of a Tolerance for 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine (CAS Reg. No. 52836-31-4

FROM: Pauline Wagner, Chief Pauline Wagner 6/20/06
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.

Chemical: 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine

Table 1. CFR and CAS Registry Number and Name

40 CFR	Inert Ingredients	Limits	Uses (Pesticidal)	CAS Reg. No. and Name
180.1052	2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine	A maximum of 0.5 pound of the inert ingredient per acre.	In formulations of the herbicides *S*-ethyl dipropylthiocarbamate, *S*-propyl dipropylthiocarbamate, and *S*-ethyl diisobutylthiocarbamate applied to corn fields before the corn plants emerge from the soil	52836-31-4 Oxazolidine, 3-(dichloroacetyl) -2,2,5-trimethyl-

Use Summary: There was no available information on industrial or consumer uses for 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine. As an inert ingredient, it is limited to no more than 0.5 pounds per acre in herbicide formulations applied to corn.

Background: In the Federal Register of August 1, 1980, (45 FR 51200), EPA issued a final rule establishing an exemption from the requirement of a tolerance for 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine when used as an inert ingredient (with no more than 0.5 pounds of inert ingredient per acre) in formulations of the herbicides *S*-ethyl dipropylthiocarbamate, *S*-propyl dipropylthiocarbamate, and *S*-ethyl diisobutylthio-carbamate applied to corn fields before the corn plants emerge from the soil. The Agency concluded in the final rule, based on the available information, "that this regulation will protect the public health." A review of the available information developed since the establishment of this tolerance exemption did not reveal any data that would alter the original risk conclusion for 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine in formulations applied to corn fields. Therefore, the conclusion of the final rule still applies. The initial establishment of the tolerance exemption did not include a consideration of developmental toxicity. Although no developmental toxicity study on the inert ingredient is available to the Agency at this time, a developmental toxicity study conducted on a similar compound was submitted to EPA under the Toxic Substances Control Act (TSCA) section 8(e). The results are discussed in the following section.

Special Considerations for Infants and Children: Low toxicity was the basis for the approval of 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine in the proposed rule in the Federal Register dated May 16, 1980 (45 FR 32338). A developmental toxicity study conducted on a similar compound indicated developmental sensitivity (developmental NOEL was 10 mg/kg with a LOEL of 75 mg/kg, and the maternal NOEL as 75 mg/kg with a LOEL of 175 mg/kg [the highest dose tested]). While sensitivity and effects were observed at these levels, the potential for exposure is quite limited from the use of this inert ingredient in pesticide products. The tolerance exemption is significantly limited to use only with three herbicide active ingredients and can only be applied to corn before the plants emerge from the soil. The use is further limited to no more than 0.5 pounds of the inert ingredient per acre. Therefore, exposure to residue levels of concern are not anticipated. Therefore, there is no concern, at this time, for increased sensitivity to infants and children to 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine 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 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 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine, 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 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine 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 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine and any other substances, and this material 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 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine 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:

A review of the 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 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine in herbicide formulations. 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 above.

A developmental toxicity study conducted on a similar compound indicated developmental sensitivity (developmental NOEL was 10 mg/kg with a LOEL of 75 mg/kg, and the maternal NOEL as 75 mg/kg with a LOEL of 175 mg/kg [the highest dose tested]). While sensitivity and effects were observed at these levels, the potential for exposure is quite limited from the use of this inert ingredient in pesticide products. The tolerance exemption for 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine is significantly limited to use only with three herbicide active ingredients and can only be applied to corn before the plants emerge from the soil. The use is further limited to no more than 0.5 pounds of the inert ingredient per acre. Therefore, exposure to residue levels of concern are not anticipated. Considering the significant limitations, dietary or residential exposures of concern are also not expected.

Taking into consideration the available information on 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine, 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 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine when used under 40 CFR 180.1052 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 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine (CAS Reg. No. 52836-31-4). I consider the exemption established in 40 CFR 180.1052 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: June 26, 2006

CC: Debbie Edwards, SRRD
Joe Nevola, SRRD