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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DATE: June 20, 2006

ACTION MEMORANDUM

SUBJECT: Inert Reassessments: Two Exemptions from the Requirement of a Tolerance for *N*-(*n*-dodecyl)-2-pyrrolidone (CAS Reg. No. 2687-96-9) and *N*-(*n*-octyl)-2-pyrrolidone (CAS Reg. No. 2687-94-7)

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 two inert ingredient exemptions from the requirement of a tolerance. Current exemptions are to be maintained.

Chemicals: *N*-(*n*-dodecyl)-2-pyrrolidone and *N*-(*n*-octyl)-2-pyrrolidone

Table 1. CFR and CAS Registry Numbers and Names

40 CFR	Inert Ingredients	Limits	Uses (Pesticidal)	CAS Reg. No. and Names
180.1130	*N*-(*n*-dodecyl)-2-pyrrolidone	Cotton	Solvents in cotton defoliant formulations containing thidiazuron and diuron as active ingredients.	2687-96-9 2-Pyrrolidinone, 1-dodecyl-
	N-(*n*-octyl)-2-pyrrolidone			2687-94-7 2-Pyrrolidinone, 1-octyl-

Use Summary: *N*-(*n*-octyl)-2-pyrrolidone is used in electronics and agrochemicals. It is used as a solvent in industrial chemicals, or as a chemical intermediate. *N*-(*n*-dodecyl)-2-pyrrolidone and *N*-(*n*-octyl)-2-pyrrolidone are used as inert ingredients (solvents) in cotton defoliants containing thidiazuron and diuron as active ingredients. There were no industrial or consumer uses found for *N*-(*n*-dodecyl)-2-pyrrolidone.

Background: In the Federal Register of June 22, 1994 (59 FR 32083), EPA issued a final rule establishing two exemptions from the requirement of a tolerance for *N*-(*n*-dodecyl)-2-pyrrolidone and *N*-(*n*-octyl)-2-pyrrolidone when used as inert ingredients (solvents) in cotton defoliant pesticide formulations containing thidiazuron and diuron as active ingredients. The Agency concluded in the final rule that, based on the available information "these ingredients are useful and a tolerance is not necessary to protect the public health." 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 *N*-(*n*-dodecyl)-2-pyrrolidone and *N*-(*n*-octyl)-2-pyrrolidone in cotton defoliant 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 below.

Special Considerations for Infants and Children: In the final rule, "A developmental toxicity study in the rat using *N*-(*n*-octyl)-2-pyrrolidone with a maternal NOAEL of 50 mg/kg and a developmental NOAEL of 200 mg/kg. At the developmental LOAEL of 800 mg/kg there was altered growth and an increased incidence of wavy ribs." Based on the available information, there is no concern, at this time, for increased sensitivity to infants and children to *N*-(*n*-dodecyl)-2-pyrrolidone and *N*-(*n*-octyl)-2-pyrrolidone when used as inert ingredients 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 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 *N*-(*n*-dodecyl)-2-pyrrolidone and *N*-(*n*-octyl)-2-pyrrolidone, 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 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 *N*-(*n*-dodecyl)-2-pyrrolidone and *N*-(*n*-octyl)-2-pyrrolidone and any other substances, and these materials do not appear to produce toxic metabolites produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that *N*-(*n*-dodecyl)-2-pyrrolidone and *N*-(*n*-octyl)-2-pyrrolidone 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: Low subchronic oral toxicity, no mutagenicity, and low developmental toxicity were the basis for approval of *N*-(*n*-dodecyl)-2-pyrrolidone and *N*-(*n*-octyl)-2-pyrrolidone as inert ingredients (solvents) in cotton defoliant formulations containing thidiazuron and diuron as active ingredients. Based on the available information, there is no increased sensitivity to infants and children. The two tolerance exemptions for *N*-(*n*-dodecyl)-2-pyrrolidone and *N*-(*n*-octyl)-2-pyrrolidone are limited to use only with two herbicide active ingredients and further limited to use on cotton only. Considering the low toxicity and use limitations of these two chemicals, dietary or residential exposures of concern are not expected.

Taking into consideration the available information on *N*-(*n*-dodecyl)-2-pyrrolidone and *N*-(*n*-octyl)-2-pyrrolidone, 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 two exemptions from the requirement of a tolerance established for residues of *N*-(*n*-dodecyl)-2-pyrrolidone and *N*-(*n*-octyl)-2-pyrrolidone when used under 40 CFR 180.1130 can be considered reassessed as safe under section 408(q) of the FFDCA.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the two exemptions from the requirement of a tolerance for the inert ingredients *N*-(*n*-dodecyl)-2-pyrrolidone (CAS Reg. No. 2687-96-9) and *N*-(*n*-octyl)-2-pyrrolidone (CAS Reg. No. 2687-94-7). I consider the two exemptions established in 40 CFR 180.1130 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 26, 2006

CC: Debbie Edwards, SRRD
Joe Nevola, SRRD