

US EPA ARCHIVE DOCUMENT



DATE: June 14, 2006

ACTION MEMORANDUM

SUBJECT: Inert Reassessments: Four Exemptions from the Requirement of a Tolerance for Aluminum Isopropoxide (CAS Reg. No. 555-31-7) and Aluminum Secondary Butoxide (CAS Reg. No. 2269-22-9)

FROM: Pauline Wagner, Chief *Pauline Wagner 6/14/06*
Inert Ingredient Assessment Branch
Registration Division (7505P)

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

I. FQPA REASSESSMENT ACTION

Action: Reassessment of four inert ingredient exemptions from the requirement of a tolerance. Current exemptions are to be maintained.

Chemical: Aluminum Isopropoxide and Aluminum Secondary Butoxide

| Table 1. CFR and CAS Registry Numbers and Names | | | | |
|---|-----------------------------|---------------------------------------|--------|---|
| 40 CFR | Inert Ingredients | CAS Reg. No. and Names | Limits | Uses (Pesticidal) |
| 180.1091 | Aluminum isopropoxide | 555-31-7 2-Propanol, aluminum salt | None | Stabilizers in formulations of the insecticide amitraz [<i>N</i> -(2,4-dimethylphenyl)- <i>N</i> -[[2,4-dimethylphenyl]imino]- <i>N</i> -methylmethanimidamide] applied to growing crops or animals. |
| | Aluminum secondary butoxide | 2269-22-9 2-Butanol, aluminum salt | | |

Use Summary: Aluminum isopropylate is used to make aluminum soaps, paints, waterproofing finishes for textiles, and other chemicals. It is used as a dehydrating agent, a viscosity adjustor for varnishes, an intermediate for pharmaceuticals, and as an antitranspirant in cosmetics. Other than

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the inert ingredient use in pesticide formulation, no information on industrial or consumer-uses of aluminum secondary butoxide was found. Aluminum isopropylate and aluminum secondary butoxide are both used as stabilizers in formulations with the insecticide amitraz [*N*-(2,4-dimethylphenyl)-*N*-[[2,4-dimethylphenyl]imino]-*N*-methylmethanimidamide] applied to growing crops or animals.

FQPA Safety Finding: In the Federal Register of September 1, 1988, (53 FR 34508), EPA issued a final rule establishing an exemption from the requirement of a tolerance for aluminum isopropylate and aluminum secondary butoxide when used as inert ingredients (stabilizers) in formulations of the insecticide amitraz applied to growing crops or animals. The Agency concluded that, “when used in accordance with good agricultural practices these ingredients are useful and do not pose a hazard to humans or the environment.” 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 aluminum isopropylate and aluminum secondary butoxide under 40 CFR 180.1091. 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: The basis for the approval of aluminum isopropylate and aluminum secondary butoxide was given in the proposed rule in the Federal Register dated July 13, 1988 (53 FR 26450): “1. The data submitted in the request and other relevant materials have been evaluated. The environmental fate data considered in support of the proposed exemption from the requirement of a tolerance include a hydrolysis study of a mixture of aluminum isopropoxide and aluminum secondary butoxide. This study determined that the mixture is completely hydrolyzed. The hydrolysis products were determined to be isopropanol, secondary butanol, and aluminum hydroxide. Hydrolysis was judged to be complete after 25 seconds. 2. Each of the three hydrolysis products noted above are cleared as pesticide inert ingredients and food additives under the following sections of 40 CFR and 21 CFR...” This fate property of the chemicals essentially reduces the potential of exposure to below a level of concern. Based on this information, there is no concern, at this time, for increased sensitivity to infants and children to aluminum isopropylate and aluminum secondary butoxide 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 FFDCIA 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 aluminum isopropylate and aluminum secondary butoxide, 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 aluminum isopropylate and aluminum secondary butoxide 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 aluminum isopropylate and aluminum secondary butoxide 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 aluminum isopropylate and aluminum secondary butoxide 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: Taking into consideration the available information on aluminum isopropylate and aluminum secondary butoxide, there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure when considering exposure through dietary exposure and all other non-occupational sources for which there is reliable information. Therefore, it is recommended that the four exemptions from the requirement of a tolerance established for residues of aluminum isopropylate and aluminum secondary butoxide when used as stabilizers in formulation with amitraz for use on growing crops and animals under 40 CFR 180.1091 can be considered reassessed as safe under section 408(q) of the FFDCA.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the four exemptions from the requirement of a tolerance for the inert ingredients aluminum isopropoxide (CAS Reg. No. 555-31-7) and aluminum secondary butoxide (CAS Reg. No. 2269-22-9). I consider the four exemptions established in 40 CFR 180.1091 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 19, 2006*

CC: Debbie Edwards, SRRD
Joe Nevola, SRRD