



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

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC
SUBSTANCES

March 24, 2006

ACTION MEMORANDUM

SUBJECT: Inert Reassessment – Ammonium Carbamate (CAS Reg. No. 1111-78-0)

FROM: Pauline Wagner, Chief *Pauline Wagner 3/27/06*
Inert Ingredient Assessment Branch

TO: Lois A. Rossi, Director
Registration Division

I. FQPA REASSESSMENT ACTION

Action: Reassessment of one exemption from the requirement of a tolerance for ammonium carbamate. The reassessment decision is to maintain “as-is” the one exemption from the requirement of a tolerance under 40 CFR 180.910.

Chemical: Ammonium carbamate

CFR Citation				CAS Reg. No. 9CI Name
40 CFR §	Inert Ingredients	Limits	Uses	
180.910*	Ammonium carbamate	(none)	Synergist in aluminum phosphide formulations	1111-78-0 Carbamic acid, monoammonium salt

*Residues listed in 40 CFR 180.910 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 or to raw agricultural commodities after harvest.

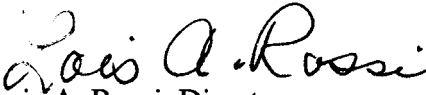
Use Summary: Ammonium carbamate is approved for use as an inert ingredient in aluminum phosphide pesticide formulations. Aluminum phosphide is used as a fumigant to control insects and rodents in sealed containers and structures where raw agricultural commodities and processed foods are stored. Ammonium carbamate is used in the aluminum phosphide formulation to reduce the potential fire hazard of the phosphine. In order to suppress the flammability (self-ignition) of the phosphine, the ammonium carbamate liberates ammonia and carbon dioxide to dilute the hydrogen

phosphide formed by the hydrolysis reaction. The ammonia also serves as a warning agent.

List Reclassification Determination: The current List Classification for ammonium carbamate is 3. Because EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to ammonium carbamate when used as an inert ingredient in aluminum phosphide pesticide formulations, the List Classification for ammonium carbamate will change from List 3 to List 4B.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the exemption from the requirement of a tolerance for the inert ingredient ammonium carbamate, CAS Reg. No. 1111-78-0 and with the List reclassification determination, as described above. I consider the one exemption established in 40 CFR part 180.910 [formerly 40 CFR 180.1001(c)], 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: 3/29/06

CC: Debbie Edwards, SRRD
Joe Nevola, SRRD



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March 24, 2006

MEMORANDUM

SUBJECT: Reassessment of One Exemption from the Requirement of a Tolerance
For Ammonium Carbamate (CAS Reg. No. 1111-78-0)

FROM: Keri Grinstead *Keri Grinstead*
Inert Ingredient Assessment Branch (IIAB)
Registration Division (7505C)

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

Background

Attached is the science assessment for ammonium carbamate. Ammonium carbamate has one exemption from the requirement of a tolerance under 40 CFR 180.910 for use in aluminum phosphide formulations only. This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profile, environmental fate, and ecotoxicity of ammonium carbamate. The purpose of this document is to reassess the existing exemption from the requirement of a tolerance for residues of ammonium carbamate when used as an inert ingredient in pesticide formulations as required under the Food Quality Protection Act (FQPA).

Executive Summary

This report evaluates the existing exemption from the requirement of a tolerance for ammonium carbamate (CAS Reg. No. 1111-78-0) under 40 CFR 180.910 when used as an inert ingredient in aluminum phosphide pesticide formulations. The use of ammonium carbamate as an inert ingredient in these pesticide products is as a fire suppressor and/or warning agent. The food use of aluminum phosphide pesticide products is as a fumigant of raw agricultural commodities, animal feeds, and processed food commodities in sealed containers or structures for insect control. The other uses of ammonium carbamate are as an ammoniating agent and as an intermediate in the production of urea, a component of chemical fertilizers.

There are no available applicable toxicity data for ammonium carbamate; however, because the use of ammonium carbamate is restricted for use only as an inert ingredient in pesticide formulations (fumigants) containing aluminum phosphide as the

active ingredient, the use pattern/restrictions and exposure assessment for aluminum phosphide were used in this assessment to characterize the use and potential hazard of ammonium carbamate. The Agency's Reregistration Eligibility Decision (RED) for Aluminum and Magnesium Phosphide (USEPA 1998) and Phosphine Fumigant Labeling Questions and Answers (USEPA 2005), as well as publicly available information on fumigation, were used as the basis for this assessment.

The use of aluminum phosphide fumigant formulations is severely restricted because of the inhalation toxicity of the phosphine released by the aluminum phosphide. There is a required aeration period after fumigation and contact of the aluminum phosphide formulations (or any of their unreacted residues) with any processed food or food/feed commodities used directly as food is explicitly not permitted. There are no available applicable toxicity data for ammonium carbamate; however, based on the rapid degradation of ammonium carbamate to the gases ammonia and carbon dioxide and the significant use restrictions of aluminum phosphide pesticide products, dietary exposures (from food or drinking water) are not expected. There are no residential food uses of aluminum phosphide pesticide products; therefore, residential exposures to ammonium carbamate are also not anticipated. Additionally, based on this information, ammonium carbamate is not expected to bioaccumulate in the environment and does not pose an ecological hazard to non-target pests from its use as an inert ingredient in food-use aluminum phosphide pesticide products.

Taking into consideration all available information on ammonium carbamate, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to ammonium carbamate when used as an inert ingredient in food-use aluminum phosphide pesticide formulations 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 ammonium carbamate, as listed in Table 2, can be considered reassessed as safe under section 408(q) of the FFDCFA.

I. Introduction

This report provides a qualitative assessment for ammonium carbamate, an inert ingredient used as a synergist in aluminum phosphide pesticide formulations. Ammonium carbamate has one exemption from the requirement of a tolerance under 40 CFR 180.910. Synonyms of ammonium carbamate include: ammonium aminofornate and carbamic acid, monoammonium salt.

A. Physical and Chemical Properties

Table 1. Physical and Chemical Properties of Ammonium Carbamate

Parameter	Value	Source
log P (octanol-water)	-3.670 (Estimated)	ChemID ¹

Parameter	Value	Source
Atmospheric OH Rate Constant	2.70E-12 cm ³ /molecule-sec at 25° C (Estimated)	ChemID
Structure	<p>The image shows three chemical structures: carbamic acid (H₂N-C(=O)-OH), an ammonium ion (NH₄⁺), and a water molecule (H₂O).</p>	ChemID

¹ChemIDplus Advanced on TOXNET (<http://www.toxnet.nlm.nih.gov/index.html>)

B. Pesticide Uses

The exemption from the requirement of a tolerance for ammonium carbamate is provided in Table 1 below.

Table 2. Pesticide Uses

CFR Citation				CAS Reg. No. 9CI Name
40 CFR §	Inert Ingredients	Limits	Uses	
180.910*	Ammonium carbamate	(none)	Synergist in aluminum phosphide formulations	1111-78-0 Carbamic acid, monoammonium salt

*Residues listed in 40 CFR 180.910 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 or to raw agricultural commodities after harvest.

C. Other Uses

Ammonium carbamate is used as an ammoniating agent and as an intermediate in the synthesis of urea, a component of artificial fertilizer.

II. Hazard Profile

There are no available applicable toxicity data for ammonium carbamate; however, since the use of ammonium carbamate is restricted for use only as an inert ingredient in pesticide formulations (fumigants) containing aluminum phosphide as the active ingredient, the use pattern/restrictions and exposure assessment for the active ingredient aluminum phosphide were used to characterize the use and potential hazard of ammonium carbamate. The Agency's Reregistration Eligibility Decision (RED) for Aluminum and Magnesium Phosphide (USEPA 1998) and Phosphine Fumigant Labeling Questions and Answers (USEPA 2005), as well as publicly available information on fumigation were used as the basis for this assessment.

III. Pesticide Use Characterization

Ammonium carbamate is restricted for use as an inert ingredient in aluminum phosphide pesticide formulations only. The food uses of aluminum phosphide are as a fumigant of raw agricultural commodities, animal feeds, and processed food commodities in sealed containers or structures for insect control (USEPA 1998).

“Fumigation is the act of introducing a pesticide into an enclosed space in such a manner that it disperses quickly and acts in a gaseous state on the target organism. Pesticides formulated as fumigants have physical characteristics which cause them to occupy all air spaces within an enclosed area and to penetrate commodities within these areas” (USEPA 2005).

According to the United States Department of Agriculture (USDA) Federal Grain Inspection Service’s Fumigation Handbook (USDA 1993) “aluminum phosphide formulations are composed of approximately 55% aluminum phosphide and 45% inert ingredients, such as ammonium carbamate, ammonium bicarbonate, urea, and paraffin. Aluminum phosphide is manufactured in pellet, tablet, and granular formulations.” “Pellets or tablets are often placed in moisture permeable enclosures to retain the residual dust. The granules are placed in moisture permeable envelopes, sachets, or bags which may in turn be placed in cloth strips, blankets or belts.” “Aluminum phosphide reacts with moisture in the air to produce phosphine (hydrogen phosphide) which is highly toxic to all forms of animal and human life.”

Ammonium carbamate is used in the aluminum phosphide formulation to reduce the potential fire hazard of the phosphine. In order to suppress the flammability (self-ignition) of the phosphine, the ammonium carbamate liberates ammonia and carbon dioxide to dilute the hydrogen phosphide formed by the hydrolysis reaction. The ammonia also serves as a warning agent.

In 1998 the Agency developed a Reregistration Eligibility Decision (RED) for aluminum phosphide (USEPA 1998). Pesticide products containing aluminum phosphide are for use only in sealed containers or structures. The following excerpts from the RED summarize the use/labeling restrictions of aluminum phosphide formulations.

“Commodities which can be directly consumed as food must not be contaminated by direct contact with aluminum and magnesium phosphide. Fumigation of these items requires the registered product be placed in trays fastened to a support within the area to be fumigated or the use of sachets, belts or blankets.” “To ensure that phosphine residues will not exceed the established tolerances, fumigated commodities (except tobacco) should be aerated for 48 hours prior to making them available to consumers. This aeration entails the venting of the structure that has been fumigated to slowly reduce the level of phosphine gas in the structure/commodity.” Aluminum phosphide is “not to be directly mixed with foods, feed, and raw agricultural products which may be directly used as foods. All labels must include the restriction, ‘Under no

conditions shall food, feed, and/or raw agricultural products which may be used directly as foods come into contact with aluminum or magnesium phosphide.” “Residue data reflecting registered post-harvest treatments of stored raw agricultural and processed commodities indicate that, with adequate aeration or further processing after treatment, residues of phosphine dissipate to nondetectable levels.” “Label restrictions have also been established specifying that under no conditions should the formulations containing aluminum phosphide be used so that they or their unreacted residues come in contact with any processed food.”

IV. Exposure Assessment

Ammonium carbamate is approved for use only as an inert ingredient in aluminum phosphide pesticide formulations. Its liberation of ammonia and carbon dioxide is used to suppress the flammability of the phosphine released by the active ingredient. The ammonia also serves as a warning agent. As described in the RED, the food uses of aluminum phosphide are as a fumigant of raw agricultural commodities, animal feeds, and processed food commodities in sealed containers or structures for insect control. The use of these fumigants is severely restricted because of the inhalation toxicity of the phosphine gas released by the aluminum phosphide. Dietary exposures (from food and drinking water) to ammonium carbamate from consumption of agricultural commodities or processed food treated with aluminum phosphide pesticide products are not anticipated because of the rapid degradation of ammonium carbamate to ammonia and carbon dioxide gases and the significant use pattern restrictions of aluminum phosphide pesticide products. There are no residential food uses of aluminum phosphide pesticide formulations, therefore, residential exposures (dermal or inhalation) are also not expected.

V. Environmental Fate Characterization/Drinking Water Considerations

According to the RED (USEPA 1998), “The Agency has determined through a qualitative risk assessment the use patterns associated with aluminum and magnesium phosphide are not expected to impact water resources through labeled uses. In light of this finding, the Agency believes that aluminum and magnesium phosphide use will not impact ground water or surface water resources, and therefore, is not expected to lead to exposure to humans through drinking water.” Ammonium carbamate is expected to decompose/degrade rapidly in the environment to the gases ammonia and carbon dioxide. Ammonium carbamate does not present a surface water concern because the chemical is not applied to the soil surface and would not be expected to runoff in surface water. The use sites of pesticide products containing ammonium carbamate are restricted to sealed containers and structures. Based on all of this information, there is no expected potential for exposures to ammonium carbamate via drinking water or for bioaccumulation in the environment from the use of ammonium carbamate as an inert ingredient in aluminum phosphide pesticide formulations.

Special Consideration for Infants and Children

Ammonium carbamate is approved for use only as an inert ingredient in aluminum phosphide pesticide formulations. Dietary (from food and drinking water) and residential (dermal and inhalation) exposures to ammonium carbamate when used as an inert ingredient in aluminum phosphide pesticide products are not anticipated because of the significant use restrictions of food-use aluminum phosphide pesticide products and the rapid degradation of the ammonium carbamate to the gases ammonia and carbon dioxide.

Based on this information, there is no concern, at this time, for increased sensitivity to infants and children to ammonium carbamate when used as an inert ingredient in aluminum phosphide 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, FFDCIA 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 ammonium carbamate, 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 the use of ammonium carbamate as an inert ingredient in aluminum phosphide pesticide formulations.

Cumulative Exposure

Section 408(b)(2)(D)(v) of the FFDCIA 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 safety finding as to ammonium carbamate and any other substances, and ammonium carbamate does not appear to produce toxic metabolites produced by other substances. For the purpose of this tolerance action, therefore, EPA has not assumed that ammonium carbamate 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/>.

IX. Human Health Risk Characterization

Ammonium carbamate is only permitted for use as an inert ingredient in aluminum phosphide pesticide formulations. The Agency characterizes the use and exposure of the active ingredient aluminum phosphide in its RED for Aluminum and Magnesium Phosphide (EPA 1998). The use of these fumigant formulations is severely restricted because of the inhalation toxicity of the phosphine released by the aluminum phosphide. There is a required aeration period after fumigation and contact of the aluminum phosphide formulations (or any of their unreacted residues) with any processed food or food/feed commodities used directly as food is explicitly not permitted. There are no available applicable toxicity data for ammonium carbamate; however, based on the rapid degradation of ammonium carbamate to the gases ammonia and carbon dioxide and the significant use restrictions of products containing this inert ingredient, dietary exposures (from food or drinking water) are not expected. There are no residential food uses of aluminum phosphide pesticide products, therefore, residential exposures to ammonium carbamate are also not anticipated.

Taking into consideration all available information, EPA has determined there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to ammonium carbamate when used as an inert ingredient in aluminum phosphide pesticide formulations 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 current exemption from the requirement of a tolerance established for residues of ammonium carbamate be maintained and considered reassessed as safe under section 408(q) of the FFDCA.

X. Ecotoxicity and Ecological Risk Characterization

In a 96 hour static study, ammonium carbamate's LC₅₀ was determined to be 37 ppm classifying it as slightly toxic to fish. Ammonium carbamate is expected to degrade rapidly in the environment and is at no risk for contaminating ground or surface waters with proper use of aluminum phosphide products containing it as an inert ingredient. Therefore, ammonium carbamate is not expected to pose a significant ecological risk to nontarget organisms from its use as an inert ingredient in aluminum phosphide pesticide formulations.

References:

Bond, E.J., FAO Plant Production and Protection Paper 54, Food and Agriculture Organization (FAO) of the United Nations, Manual of Fumigation for Insect Control – Chemicals Used as Fumigants – Phosphine, 1984 (reprinted 1989)
<http://www.fao.org/docprep/X5042E/x5042E0a.htm>.

Tiongson, R., “Fumigation for the Control of Insect Pests in Storage,” Towards Integrated Commodity and Pest Management in Grain Storage, A Training Manual for Application in Humid Tropical Storage Systems, Food and Agriculture Organization, May 1992, <http://www.fao.org/docrep/x5048E/x5048E0q.htm>.

USDA 1993. Fumigation Handbook, United States Department of Agriculture, Federal Grain and Inspection Service, 10-28-1993. <http://151.121.3.117/reference-library/handbooks/fumigation/fumhb.pdf>.

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USEPA 2005. Phosphine Fumigant Labeling Questions and Answers, May 27, 2005, United States Environmental Protection Agency, http://www.epa.gov/oppsrrd1/reregistration/alphosphide/fumigation_qa.pdf.