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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

July 12, 2006

ACTION MEMORANDUM

SUBJECT: Inert Reassessments: One Exemption from the Requirement of a Tolerance for Sodium Molybdate (CAS Reg. No. 7631-95-0)

FROM: Pauline Wagner, Chief *Pauline Wagner 7/12/06*
Inert Ingredient Assessment Branch

TO: Lois A. Rossi, Director
Registration Division

I. FQPA REASSESSMENT ACTION

Action: Reassessment of one inert ingredient exemption from the requirement of a tolerance. Current exemption is to be maintained.

Chemical: Sodium molybdate

CFR Citation, CAS Registry Numbers and CAS Index Name for Sodium Molybdate				
40 CFR	Inert Ingredient	Limits	Uses (Pesticidal)	CAS Reg. No. and CAS Index Name
180.920*	Sodium molybdate	None	Plant nutrient	7631-95-0** (Molybdic acid, disodium salt)

*Residues listed in 40 CFR 180.920 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 only.

** Sodium molybdate is commonly available in the dihydrate form as sodium molybdate dihydrate (CAS Reg. No. 10102-40-6). For the purposes of this tolerance exemption expression, CAS Reg. No. 10102-40-6 is considered equivalent to CAS Reg. No. 7631-95-0 for describing sodium molybdate.

Use Summary: Sodium molybdate is a soluble sodium salt form of molybdenum, a naturally-occurring element that is present in the earth's crust and in soils at background concentrations of 1-2 mg/kg. Molybdenum is an essential trace element for virtually all life forms. Sodium

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molybdate is used in plant fertilizers as a micronutrient and is also utilized in coatings as a colorant and corrosion inhibitor.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the one exemption from the requirement of a tolerance for the inert ingredient sodium molybdate. I consider the one exemption established in 40 CFR 180.920 for sodium molybdate 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: 

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD



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MEMORANDUM

SUBJECT: Reassessment of One Exemption from the Requirement of a Tolerance for Sodium Molybdate (CAS Reg. No.7631-95-0)

FROM: Bipin Gandhi 
Inert Ingredient Assessment Branch
Registration Division (7505P)

and

Kerry Leifer 
Inert Ingredient Assessment Branch
Registration Division (7505P)

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

Background

Attached is the science assessment for sodium molybdate (CAS Reg. No. 7631-95-0). This chemical has an exemption from the requirement of a tolerance under 40 CFR 180.920, as listed in Table 1. This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profile, environmental fate, and ecotoxicity of sodium molybdate. The purpose of this document is to reassess the one existing exemption from the requirement of a tolerance for residues of sodium molybdate when used as an inert ingredient (plant nutrient) in pesticide formulations as required under the Food Quality Protection Act (FQPA).

Executive Summary

This assessment evaluates sodium molybdate, an inert ingredient for which one exemption from the requirement of a tolerance exists when used as an inert ingredient (plant nutrient) in pesticide formulations applied to growing crops only under §40 CFR 180.920.

Sodium molybdate is a soluble sodium salt form of molybdenum, a naturally-occurring element that is present in the earth's crust and in soils at background concentrations of 1-2 mg/kg. Molybdenum is an essential trace element for virtually all life forms. Sodium molybdate is used as a micronutrient in fertilizers and as a component of coatings in addition to its use as a pesticide inert ingredient.

→ Molybdenum (in all forms, including sodium molybdate) has undergone extensive evaluations based upon its significant role as a human micronutrient. The most widely recognized authoritative source of information on nutrient levels for healthy people has been the National Academy of Sciences (NAS) Recommended Dietary Allowances (RDAs). As part of its evaluation of molybdenum, the NAS has concluded ~~that concludes~~ that molybdenum appears to be a low toxicity compound in humans.

The NAS concluded that molybdenum (including sodium molybdate) appears to be a low toxicity substance in humans. The exposures to molybdenum resulting from the use of sodium molybdate as plant nutrient in pesticide formulations would be less than the natural background levels of molybdenum and far less than the Tolerable Upper Intake Level of 2 mg/day established by NAS as a safe level of molybdenum exposure.

Taking into consideration the available information on sodium molybdate, 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 sodium molybdate when used on growing crops only under 40 CFR 180.920 can be considered reassessed as safe under section 408(q) of the FFDCA.

I. Introduction

This report provides a qualitative assessment for sodium molybdate, an inert ingredient which has one exemption from the requirement of a tolerance when used as a plant nutrient in pesticide formulations applied to growing crops only under 40 CFR 180.920.

Sodium molybdate is a soluble sodium salt form of molybdenum, a naturally-occurring element that is present in the earth's crust and in soils at background concentrations of 1-2 mg/kg. Molybdenum is an essential trace element for virtually all life forms. It functions as a cofactor for a number of enzymes that catalyze important chemical transformations in the global carbon, nitrogen, and sulfur cycles (Wuebbens et al., 2001).

II. Use Information

A. Pesticide Uses

The one tolerance exemption expression for sodium molybdate is presented in Table 1.

40 CFR	Inert Ingredient	Limits	Uses (Pesticidal)	CAS Reg. No. and CAS Index Name
180.920*	Sodium molybdate	None	Plant nutrient	7631-95-0** (Molybdic acid, disodium salt)

*Residues listed in 40 CFR 180.920 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 only.

** Sodium molybdate is commonly available in the dihydrate form as sodium molybdate dihydrate (CAS Reg. No. 10102-40-6). For the purposes of this tolerance exemption expression, CAS Reg. No. 10102-40-6 is considered equivalent to CAS Reg. No. 7631-95-0 for describing sodium molybdate.

B. Other Uses

Molybdenum (in the form of molybdenum oxides) is mined primarily for use in metal alloys. The annual U.S. mining production of molybdenum is estimated to be over 90 million lbs. (IMOA, 2006). Water soluble forms of molybdenum oxides, such as sodium molybdate are used commercially in plant fertilizers as micronutrients and in coatings as colorants and corrosion inhibitors. (HSDB, 2006).

III. Physical and Chemical Properties

Some physical and chemical characteristics of sodium molybdate, along with its structure and molecular formula, are given in Table 2.

Table 2. Physical and Chemical Properties of Sodium Molybdate

Parameter	Value	Reference
Structure	$ \begin{array}{c} \text{O} \\ \\ \text{O} = \text{Mo} - \text{O}^- \\ \\ \text{O}^- \end{array} \begin{array}{l} \text{Na}^+ \\ \\ \text{Na}^+ \end{array} $	ChemIDPlus 2004
CAS Reg. No.	7631-95-0 (anhydrous form) 10102-40-6 (dihydrate form)	ChemIDPlus 2004
Molecular formula	Na ₂ MoO ₄	
Molecular Weight	223.98	IMOA 2006

Parameter	Value	Reference
Physical State	Colorless crystals or white powder	IMOA 2006
Melting Point	687 °C	
Boiling Point	N/A	
Density	N/A	
Water Solubility	67 gm/100 cc (25° C)	
Octanol-water partition coefficient (Log P)	-4.33*	EPISuite 2004
Henry's Law Constant	2.926×10^{-27} atm-m ³ /mole*	
Vapor Pressure	1.08×10^{-20} mm Hg*	

*Estimated using U.S. EPA's modeling software, EPISuite 2004, available at <http://www.epa.gov/opptintr/exposure/docs/EPISuitedl.htm>

IV. Hazard Assessment

Molybdenum (in all forms, including sodium molybdate) has undergone extensive evaluations based upon its significant role as a human micronutrient. The most widely recognized authoritative source of information on nutrient levels for healthy people has been the National Academy of Sciences (NAS) Recommended Dietary Allowances (RDAs). The first RDAs were issued in 1941. Since 1994 the NAS Institute of Medicine's (IOM) Food and Nutrition Board has developed an expanded approach to developing dietary reference standards. This approach, the Dietary Reference Intakes (DRIs), provides a set of four nutrient-based reference values designed to replace the Recommended Dietary Allowances (RDAs) in the United States and the Recommended Nutrient Intakes (RNIs) in Canada. These reference values include Estimated Average Requirement (EAR), Recommended Dietary Allowance (RDA), Adequate Intake (AI), and Tolerable Upper Intake Level (UL) ¹.

Dietary Reference Intakes for molybdenum were issued by the National Academy of Sciences in 2000 (IOM/NAS, 2000).

A. **Hazard Profile**

Molybdenum has been shown to act as a cofactor for a limited number of enzymes in humans: sulfite oxidase, which is believed to be most important for health, xanthine oxidase, and aldehyde oxidase. In all mammalian molybdoenzymes, functional molybdenum is present as an organic component called molybdopterin (Rajagopalan, 1988). These enzymes are involved in catabolism of sulfur amino acids and heterocyclic compounds, including purines and pyridines. Molybdenum deficiencies may result in severe neurological abnormalities and death. (IOM/NAS, 2000).

The Tolerable Upper Intake Level (UL) for adults is set at 2 mg/day of molybdenum, a level based on impaired reproduction and growth in animals. (IOM/NAS, 2000)

¹ Tolerable Upper Intake Level (UL): the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the risk of adverse effects increases.

C. Toxicological Data

The National Academy of Sciences evaluated the available toxicity data on molybdenum and concluded that molybdenum appears to be a low toxicity compound in humans. The NAS hazard identification of molybdenum identified the most definitive toxicological indices as reproductive effects in rats, and stated, “[T]he administration of supplemental dietary molybdenum was associated with a prolonged estrus cycle, decreased gestational weight gain of the pups, and several adverse effects on embryogenesis in female Sprague-Dawley rats (Fungwe et al., 1990). These effects were not observed at 0.9 mg/kg/day, but were observed at doses of 1.6 mg/kg/day.”

The NAS further noted that “there is no evidence that molybdenum causes cancer in humans or animals.”

D. Special Considerations for Infants and Children

The rat reproductive study utilized by the NAS in its selection of a Tolerable Upper Intake Level for molybdenum demonstrated no reproductive effects in the absence of maternal toxicity so there is no concern, at this time, for increased sensitivity to infants and children to sodium molybdate when used as an inert ingredient in pesticide formulations. Based on this information and the NAS conclusions as to the effects of molybdenum exposure to infants and children, the additional tenfold safety factor for the protection of infants and children may be removed.

V. Environmental Fate Characterization and Drinking Water Considerations

Molybdenum is found in the soil at concentrations of 1-2 mg/kg and has been detected in surface waters at concentrations from 2 -200 µg/L (EPA, 1979). A drinking water maximum contaminant level goal (MCLG) of 40 µg/L (<http://www.epa.gov/safewater/standard/setting.html>) has been established by EPA’s Office of Water as being protective of human health. While sodium molybdate is very water soluble and unlikely to bind to soils or sediments, based on the very low concentrations of sodium molybdate in pesticide formulations as a plant nutrient (typically at levels less than 0.01%) and use rates of pesticide products containing sodium molybdate, it is very unlikely that sodium molybdate would be present in drinking water at levels approaching the MCLG as a result of its use as a pesticide inert ingredient.

VI. Exposure Assessment

The tolerance exemption for sodium molybdate limits its use to a plant nutrient in pesticide formulations applied to growing crops only. Exposures to sodium molybdate as a pesticide inert ingredient may occur through the diet (drinking water and food), but would be at levels below that of background molybdenum, which is also naturally found in legumes, grains, and nuts (IOM/NAS, 2000). Residential exposures (inhalation and dermal) of concern to sodium

molybdate are not expected given the low concentrations of sodium molybdate in pesticides as described in unit V. above.

VII. Aggregate Exposure

In examining aggregate exposure, the FFDCFA 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 sodium molybdate, 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 this chemical as an inert ingredient (plant nutrient) in pesticide formulations applied to growing crops only.

VIII. Cumulative Exposure

Section 408(b)(2)(D)(v) of the FFDCFA 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 sodium molybdate and any other substances, and this material does not appear to produce toxic metabolites produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that sodium molybdate 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

The NAS concluded that molybdenum (including sodium molybdate) appears to be a low toxicity substance in humans. The exposures to molybdenum resulting from the use of sodium molybdate as plant nutrient in pesticide formulations would be less than the natural background levels of molybdenum and far less than the Tolerable Upper Intake Level of 2 mg/day established by NAS as a safe level of molybdenum exposure.

Taking into consideration the available information on sodium molybdate, 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 sodium molybdate when used on growing

crops only under 40 CFR 180.920 can be considered reassessed as safe under section 408(q) of the FFDCA.

X. Ecotoxicity and Ecological Risk Characterization

Sodium molydate is slightly toxic to practically nontoxic to fish and aquatic invertebrates, based on numerous studies found in EPA's Ecotox database (<http://mountain.epa.gov/ecotox>). In toxicity studies with water fleas (*Daphnia magna*) the 96 hr LC50's were greater than 1000 mg/L. The 96 hr LC50 in rainbow trout (*Oncorhynchus mykiss*) was 1320 mg/L.

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