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

OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

August 2, 2006

ACTION MEMORANDUM

SUBJECT: Reassessment of One Exemption from the Requirement of a Tolerance for Sodium α-olefinsulfonate (sodium C_{14}-C_{16})

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

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

I. FQPA REASSESSMENT ACTION

Action: Reassessment of one inert ingredient exemption from the requirement of a tolerance as listed in Table 1 below. Current exemption is to be maintained.

Table 1. Tolerance Exemption Expression

40 CFR	Inert Ingredient	Limits	Uses	CAS Reg. No. and Names
180.910[a]	Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) (Olefin sulfonate)[b]	None	Surfactants, related adjuvants of surfactants	68439-57-6 Sulfonic acids, C14-16-alkane hydroxy and C14-16-alkene, sodium salts

[a]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 (RACs) after harvest.
[b]Molecular Formula: $C_{14-16}H_{27-31}SO_3Na$

Use Summary: Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) is used in cosmetics as a surfactant-cleansing agent (Nair 1998). It is also used as an inert ingredient surfactant or related adjuvant of surfactants in pesticide formulations used on growing crops or RACs.

List Reclassification Determination: Because EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to these chemicals when used as an inert ingredient in pesticide formulations,

the List Classification for Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) will be changed 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 sodium α-olefinsulfonate (sodium C_{14}-C_{16}), as well as the List Classification Determination described above. I consider the one exemption established in 40 CFR 180.910 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

August 2, 2006

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 α-Olefinsulfonate (Sodium C_{14}-C_{16})

FROM: Tracy Ward
Inert Ingredient Assessment Branch
Registration Division (7505P)

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

BACKGROUND

Attached is the science assessment for sodium α-olefinsulfonate (sodium C_{14}-C_{16}) (olefin sulfonate). This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profile, environmental fate, and ecotoxicity of the sodium α-olefinsulfonate (sodium C_{14}-C_{16}). The purpose of this document is to reassess the one exemption from the requirement of a tolerance for residues of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) when used as an inert ingredient in pesticide formulations as required under the Food Quality Protection Act (FQPA).

EXECUTIVE SUMMARY

This document evaluates the tolerance exemption for sodium α-olefinsulfonate (sodium C_{14}-C_{16}) for use as an inert ingredient in pesticide formulations applied to growing crops or raw agricultural commodities after harvest under 40 CFR 180.910.

Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) is an anionic surfactant. It is widely used as a detergent in cleaning products and shampoos. It is also an olefin sulfonate, which is "a mixture of long-chain sulfonate salts prepared by sulfonation of alpha-olefins of various carbon chain lengths" (Nair 1998).

For sodium α-olefinsulfonate (sodium C_{14}-C_{16}), acute oral toxicity ranges from 1.3 to 2.4 g/kg in rats, and 2.5 to 4.3 g/kg in mice. Sensitization observed in animal studies was attributed to low level gamma sultone residues (sultones have been demonstrated to produce sensitization). Mild ocular irritation was observed at 5% concentrations in

rabbits. In chronic repeat dose toxicity studies, sodium α-olefinsulfonate (sodium C_{14}-C_{16}) did not produce adverse effects in rats at levels upto 0.5% (5000 ppm) of the diet. In developmental studies, developmental effects were only seen at at maternally toxic doses of 300 mg/kg/day or greater. Reliable genotoxicity assays were overall negative and oral and dermal studies were negative for carcinogenicity.

Dietary (food and drinking water) exposures of concern are not anticipated for sodium α-olefinsulfonate (sodium C_{14}-C_{16}) considering their ready biodegradation in the environment. Residential exposures (dermal and inhalation) from the use of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) as an inert ingredient in pesticide formulations may occur, but considering the episodic-type uses (not chronic), combined with the low acute and chronic toxicity of the chemical, exposures of concern are not expected.

Taking into consideration all available information on sodium α-olefinsulfonate (sodium C_{14}-C_{16}), EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to sodium α-olefinsulfonate (sodium C_{14}-C_{16}) when used as an inert ingredient in pesticide products when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Overall, exposure due to the inert ingredient use of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) is expected to result in human exposure below any dose level that would produce an adverse effect. Therefore, it is recommended that the exemption from the requirement of a tolerance established for residues of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) can be considered reassessed as safe under section 408(q) of FFDCA.

Based on the results of laboratory toxicity testing, the ready biodegradability of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) in the environment, effects of concern to nontarget aquatic organisms resulting from the use of these substances as inert ingredients in pesticide formulations would occur only at extremely high use rates of sodium α-olefinsulfonate (sodium C_{14}-C_{16}). Acute effects to nontarget terrestrial animals, based on the rodent acute toxicity data, are unlikely. However, based on available developmental toxicity data, effects to nontarget terrestrial animals cannot be ruled out.

I. Introduction

This report provides a qualitative assessment for the sodium α-olefinsulfonate (sodium C_{14}-C_{16}), a pesticide inert ingredient which has an exemption from the requirement of a tolerance when used as a surfactant or related adjuvant of surfactants in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910.

II. Use Information

A. Pesticide Uses

The tolerance exemption expression for sodium α-olefinsulfonate (sodium C_{14}-C_{16}) is provided in Table 1 below.

Table 1. Tolerance Exemption Expression

40 CFR	Inert Ingredient	Limits	Uses	CAS Reg. No. and Names
180.910[a]	Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) (Olefin sulfonate)[b]	None	Surfactants, related adjuvants of surfactants	68439-57-6 Sulfonic acids, C14-16-alkane hydroxy and C14-16-alkene, sodium salts

[a]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.
[b]Molecular Formula: $C_{14\text{-}16}H_{27\text{-}31}SO_3Na$

B. Other Uses

Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) is used in cosmetics as a surfactant-cleansing agent (Nair 1998).

III. Hazard Assessment

A. Hazard Profile

The main sources of hazard information for this reassessment are published peer-reviewed references for toxicity data on sodium α-olefinsulfonate (sodium C_{14}-C_{16}).

Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) is an anionic surfactant. It is widely used as a detergent in cleaning products and shampoos. It is also an olefin sulfonate, which is "a mixture of long-chain sulfonate salts prepared by sulfonation of alpha-olefins of various carbon chain lengths. " (Nair 1998).

For sodium α-olefinsulfonate (sodium C_{14}-C_{16}), acute oral toxicity ranges from 1.3 to 2.4 g/kg in rats, and 2.5 to 4.3 g/kg in mice. Sensitization observed in animal studies was attributed to low level gamma sultone residues (sultones have been demonstrated to produce sensitization). Mild ocular irritation was observed at 5% concentrations in rabbits. In chronic repeat dose toxicity studies, sodium α-olefinsulfonate (sodium C_{14}-C_{16}) did not produce adverse effects in rats at levels upto 0.5% (5000 ppm) of the diet. In developmental studies, developmental effects were only seen at at maternally toxic doses of 300 mg/kg/day or greater. Reliable genotoxicity assays were overall negative and oral and dermal studies were negative for carcinogenicity.

B. Toxicological Data

Acute Toxicity

Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) has low acute oral toxicity in mice and rats (Table 3). Dermal sensitization observed in animals studies was attributed to low level gamma sultone residues (sultones have been demonstrated to produce sensitization). Mild ocular irritation occurred in rabbits exposed to 5% concentrations of sodium α-olefinsulfonate (sodium C_{14}-C_{16}), while moderate ocular irritation occurred at concentrations of 10% and above (Nair 1998).

Table 3. Acute Toxicity Data for Sodium α-olefinsulfonate (sodium C_{14}-C_{16})

Parameter	Toxicity Value	Reference
Oral LD_{50}, rat	1.3 - 2.4 g/kg	Nair 1998
Oral LD_{50}, mice	2.5 - 4.3 g/kg	Nair 1998
Eye Irritation, rabbits	Mild irritation @ 5%	Nair 1998
Eye Irritation, rabbits	Moderate irritation @ 10%	Nair 1998

Subchronic Toxicity

In subchronic toxicity studies in rats, no consistent effects were observed at concentrations of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) between 0.5 and 1.0 g/kg/day (Nair 1998).

Chronic Toxicity

In a long-term toxicity study, sodium α-olefinsulfonate (sodium C_{14}-C_{16}) was fed to rats at concentrations of 1000, 2500, or 5000 ppm over a two-year period (Hunter and Benson 1976). There were no adverse clinical effects and no effect on survival observed. Body-weight gain was marginally lower in both males and females at the 5000 ppm dose level in the second trimester of the study, and food intake was also marginally lower in females in the first year at this dose level. For the remainder of the study, body-weight change and food consumption were similar for treated and control animals. There were no adverse effects to the rats' eyes, blood, and urine and no treatment-related changes in macroscopic pathology or organ weights. There was no treatment-related histopathological toxicity or tumors observed.

Sodium α-olefinsulfonate (sodium C_{14}-C_{16}), "when fed for 2 years to rats at relatively high levels (0.5% of the diet) produced no adverse effects on any parameter measured" (Hunter and Benson 1976).

Neurotoxicity

No published neurotoxicity studies were identified, however, no neurotoxic effects were observed from the available data for α-olefinsulfonate (sodium C_{14}-C_{16}).

Mutagenicity

Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) tested negative for mutagenicity in all but one assay in a battery of genotoxicity tests (Yam et al 1984). Sodium α-olefin-sulfonate (sodium C_{14}-C_{16}) was positive in a rat host-mediated Salmonella/microsome assay with *Salmonella typhimurium* strain TA 1530. However, it was negative for mutagenicity in a plate-incorporation assay with strains TA 1534 and TA 1530 (Little 1977 and 1981, as cited in Yam et al 1984).

Carcinogenicity

Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) was negative for carcinogenicity in oral and dermal animal studies (Nair 1998).

Developmental and Reproductive Toxicity

Fetal abnormalities were observed only at maternally toxic doses in developmental studies of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) on rats, mice and rabbits (Palmer, Readshaw and Neuff 1974). Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) was administered by gavage during gestation days (GD) 6 to 15 in rats and mice, and GD 6 to 18 in rabbits at doses of 0.2, 2, 300, or 600 mg/kg/day.

From the available studies, rats were the least sensitive to sodium α-olefinsulfonate (sodium C_{14}-C_{16}) while mortality was observed in rabbits (16/16) and mice (6/20) at the highest dose tested (600 mg/kg/day). No adverse effects in dams or pups were observed in rats at any dose tested. At 300 mg/kg/day 1/13 rabbits died with no deaths in mice but 6/20 demonstrated total litter loss. In rabbit and mice dams, a slight initial retardation of weight gain was observed at 0.2 and 2 mg/kg/day.

In rabbit pups, litter parameters in sodium α-olefinsulfonate (sodium C_{14}-C_{16}) - treated animals at the two lowest dosages (0.2 and 2 mg/kg/day) were comparable to controls. A statistically insignificant lower mean pup weight was observed in rabbits at 300 mg/kg/day, and embryonic mortality and litter size also were not affected. However, statistically significant minor skeletal anomalies and extra ribs were observed in pups at the maternally toxic dose of 300 mg/kg/day.

Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) did not affect litter size or embryonic mortality in mice at concentrations of 0.2 and 2 mg/kg/day. However, higher fetal loss (which reduced litter size) and cleft palates were observed in mice at the maternally toxic doses of 300 and 600 mg/kg/day. A lower mean pup weight and a significantly higher incidence of retarded ossification of the occipitals were observed in mice treated with the highest dose only (600 mg/kg/day).

B. Metabolism and Pharmacokinetics

Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) are poorly absorbed through normal skin, but significantly absorbed through damaged skin (Nair 1998).

C. Special Considerations for Infants and Children

The database for the sodium α-olefinsulfonate (sodium C_{14}-C_{16}) is sufficient for assessing the potential developmental effects of this chemical. Skeletal anomalies, cleft palate, reduced pup weight, and fetal loss were observed in rabbits and mice only at the observed maternally toxic doses of 300 and 600 mg/kg/day. No adverse body weight or skeletal anomalies were observed at 0.2 or 2.0 mg/kg/day in pups of rats, rabbits, and mice. Although the lowest dose at which no observable adverse effects were demonstrated was 2.0 mg/kg/day, the dosing scheme and reduced toxicity at 300 mg/kg/day suggest the dose level at which no effects may be demonstrated in pups is much greater than 2.0 mg/kg/day. Therefore, there is no concern at this time for increased sensitivity to infants and children from sodium α-olefinsulfonate (sodium C_{14}-C_{16}). For the same reason, a safety factor analysis has not been used to assess the risk and, therefore, the additional tenfold safety factor for the protection of infants and children is also unnecessary.

IV. Environmental Fate Characterization and Drinking Water Considerations

Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) is readily biodegradable in the environment and is both soluble and stable in water (Little 1994).

V. Exposure Assessment

Dietary (food and drinking water) exposures of concern are not anticipated for sodium α-olefinsulfonate (sodium C_{14}-C_{16}) considering their ready biodegradation in the environment. Residential exposures (dermal and inhalation) from the use of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) as an inert ingredient in pesticide formulations may occur, but considering the episodic-type uses (not chronic), combined with the low acute and chronic toxicity of the chemical, exposures of concern are not expected.

VI. Aggregate Exposures

In examining aggregate exposure, the Federal Food, Drug, and Cosmetic Act (FFCDA) 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 sodium α-olefinsulfonate (sodium C_{14}-C_{16}), a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given the exposure via these pathways is orders of magnitude less than the effects observed in the available repeated dose studies.

VII. Cumulative Exposure

Section 408(b)(2)(D)(v) of 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 sodium α-olefinsulfonate (sodium C_{14}-C_{16}) and any other substances, and this chemical does not appear to produce toxic metabolites produced by other substances. For the purposes of these tolerance actions, therefore, EPA has not assumed that sodium α-olefinsulfonate (sodium C_{14}-C_{16}) 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/.

VIII. Human Health Risk Characterization

Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) is an anionic surfactant. It is widely used as a detergent in cleaning products and shampoos. It is also an olefin sulfonate, which are "a mixture of long-chain sulfonate salts prepared by sulfonation of alpha-olefins of various carbon chain lengths. In the manufacture of these ingredients, delta and gamma sultones may be produced" (Nair 1998).

For sodium α-olefinsulfonate (sodium C_{14}-C_{16}), acute oral toxicity ranges from 1.3 to 2.4 g/kg in rats, and 2.5 to 4.3 g/kg in mice. Sensitization observed in animal studies was attributed to low level gamma sultone residues (sultones have been demonstrated to produce sensitization). Mild ocular irritation was observed at 5% concentrations in rabbits. In chronic repeat dose toxicity studies, sodium α-olefinsulfonate (sodium C_{14}-C_{16}) did not produce adverse effects in rats at levels upto 0.5% (5000 ppm) of the diet. In developmental studies, developmental effects were only seen at at maternally toxic doses of 300 mg/kg/day or greater. Reliable genotoxicity assays were overall negative and oral and dermal studies were negative for carcinogenicity.

Dietary (food and drinking water) exposures of concern are not anticipated for sodium α-olefinsulfonate (sodium C_{14}-C_{16}) considering their ready biodegradation in the environment. Residential exposures (dermal and inhalation) from the use of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) as an inert ingredient in pesticide formulations may occur, but considering the episodic-type uses (not chronic), combined with the low acute and chronic toxicity of the chemical, exposures of concern are not expected.

Taking into consideration all available information on sodium α-olefinsulfonate (sodium C_{14}-C_{16}), EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to sodium α-olefinsulfonate (sodium C_{14}-C_{16}) when used as an inert ingredient in pesticide products when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Overall, exposure due to the inert ingredient use of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) is expected to result in human exposure below any dose level that would produce an adverse effect. Therefore, it is recommended that the exemption from the requirement of a tolerance established for residues of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) can be considered reassessed as safe under section 408(q) of FFDCA.

IX. Ecotoxicity and Ecological Risk Characterization

Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) is moderately toxic to aquatic invertebrates, based on a study found in EPA's Ecotox database (http://mountain.epa.gov/ecotox). In a toxicity study with water fleas (*Ceriodaphnia dubia*), the lowest reported 48-hr EC_{50} was 4.53 mg/L.

Based on the results of laboratory toxicity testing, the ready biodegradability of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) in the environment, effects of concern to nontarget aquatic organisms resulting from the use of these substances as inert ingredients in pesticide formulations would occur only at extremely high use rates of sodium α-olefinsulfonate (sodium C_{14}-C_{16}). Application of approximately 4-5 pounds of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) per acre may exceed the acute level of concern (LOC) for endangered aquatic species and application of 40-50 pounds sodium α-olefinsulfonate (sodium C_{14}-C_{16}) per acre would exceed the non-listed aquatic species acute LOC. Based on the available aquatic toxicity data and ready biodegradation of sodium α-olefinsulfonate (sodium C_{14}-C_{16}) in the environment, chronic effects to aquatic species are less likely to occur. Acute effects to nontarget terrestrial animals, based on the rodent acute toxicity data, are unlikely. However, based on available developmental data, effects to nontarget terrestrial animals cannot be ruled out.

REFERENCES:

CAS (Chemical Abstracts Service) 2006. STN on the Web. http://stnweb.cas.org/ Last updated: July 1, 2006.

ChemIDPlus 2004. ChemIDPlus. National Library of Medicine. National Institute of Health. Last Updated: September 9, 2004.

EPA (U.S. Environmental Protection Agency). 2004. Estimation Programs Interface (EPI) Suite™, Version 3.12. U.S. Environmental Protection Agency, Washington, DC

Hunter, B. and H.G. Benson. 1976. Long-term toxicity of the surfactant α-olefin sulphonate (AOS) in the rat. Toxicology 5: 359-370.

Palmer, A.K., Readshaw. M.A., and Neuff, A.M. 1975. Assessment of the teratogenic potential of surfactants. Part II-AOS. Toxicology 3(1): 107-113.

Nair, B. 1998. Final report on the safety assessment of sodium alpha-olefin sulfonates. International Journal of Toxicology 17(5): 39-65.

Yam, J., et al. 1984. Surfactants: A survey of short-term genotoxicity testing. Food Chemistry and Toxicology 22(9): 761-769.