Inert Ingredients	Limits	Uses
* * *	* * * *	
sodium salts of N-alkyl (C8-C18)-beta-iminodipropionic acid where the C8-C18 is linear and may be saturated and/or unsaturated (CAS Reg. Nos. 3655-00-3, 61791-56-8, 14960-06-6, 26256-79-1, 90170-43-7, 91696-17-2, 97862-48-1)	Concentration in formulated end-use products not to exceed 30% by weight in pesticide formulations	Surfactants, related adjuvants of surfactants
* * *	* * * *	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0725; FRL–8426–8]

Sodium *N*-oleoyl-*N*-methyl taurine; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of sodium *N*-oleoyl-*N*-methyl taurine (MOTS), (CAS Reg. No. 137–20–2), herein referred to in this document as MOTS, when used as an inert ingredient in pesticide formulations for pre-harvest and post-harvest uses under 40 CFR 180.910, as well as for application to animals under 40 CFR 180.930. The Joint Inerts Task Force (JITF), Cluster Support Team (CST 24), submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of MOTS.

DATES: This regulation is effective July 29, 2009. Objections and requests for hearings must be received on or before September 28, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0725. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8811; e-mail address: *leifer.kerry@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guideline at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0725 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before September 28, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0725, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background

In the **Federal Register** of December 3, 2008 (73 FR 73644) (FRL–8386–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E742) by The JITF, CST 24, c/o CropLife America, 1156 15th Street, N.W., Suite 400, Washington, DC 20005. The petition was subsequently redesignated as PP 8E7423. The petition requested that 40 CFR 180.910 and 40 CFR 180.930 be amended by establishing exemptions from the requirement of a tolerance for residues of the inert ingredient MOTS. That notice referenced a summary of the petition prepared by the JITF, CST 24, the petitioner, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing..

This petition was submitted in response to a final rule of August 9, 2006, (71 FR 45415) in which the Agency revoked, under section 408(e)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA), the existing exemptions from the requirement of a tolerance for residues of certain inert ingredients because of insufficient data to make the determination of safety required by FFDCA section 408(b)(2). The expiration date for the tolerance exemptions subject to revocation was August 9, 2008, which was later extended to August 9, 2009 (73 FR 45312) to allow for data to be submitted to support the establishment of tolerance exemptions for these inert ingredients prior to the effective date of the tolerance exemption revocation.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients..

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for exemption from the requirement of a tolerance for residues of MOTS when used as an inert ingredient in pesticide formulations for pre-harvest and post-harvest uses, as well as for application to animals. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The existing toxicology database for MOTS consists of one OPPTS Harmonized Guideline 870.3650 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats and several studies in the scientific literature on acute toxicity, mutagenicity and repeat dosing exposures.

The toxicology database is adequate to support the use of MOTS as an inert ingredient in pesticide formulations. MOTS has low acute oral and dermal toxicity, is not a skin irritant or dermal sensitizer, but is a mild to moderate eye irritant. MOTS was not mutagenic in an Ames test.

In OPPTS Harmonized Guideline 870.3650 study, there was no evidence of increased susceptibility. Parental toxicity was manifested as clinical signs, decreased body weight gain and microscopic stomach lesions at 300 miligrams/kilogram/day (mg/kg/day). However, these effects were considered to be due to the corrosive nature of the test material and were not considered appropriate for risk assessment. At higher doses of 1,000 mg/kg/day, the offspring effects include increased post-implantation loss, decreased viability and decreased body weight in male and female offspring, which occurred only in the presence of parental toxicity. There was no increased susceptibility to the offspring of rats to MOTS following *in utero* and post-natal exposure in the OPPTS Harmonized Guideline 870.3650 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test. Thyroid effects were observed in the OPPTS Harmonized Guideline 870.3650 study only at the limit dose in male, but not female, rats. The increased thyroid follicular hypertrophy seen in the study is considered secondary to the enhanced liver cell metabolism also observed in males at the limit dose. Moreover, rats are known to be quantitatively more sensitive than humans in response to thyroid toxicity. Thus, regulating at a no

observed adverse effect level (NOAEL) of 300 mg/kg/day with effects seen at 1,000 mg/kg/day with a 100 fold uncertainty factor (UF_A=10X; UF_h=10X) provides an adequate margin of protection.

The Agency notes that surfactants are surface-active materials that can damage the structural integrity of cellular membranes at high dose levels. Thus, surfactants are often corrosive and irritating in concentrated solutions. It is possible that some of the observed toxicity seen in the repeated dose studies, such as microscopic stomach lesions or decreased body weight gain, can be attributed to the corrosive and irritating nature of these surfactants.

No metabolism studies were located in the literature. The registrant proposed a metabolic pathway based on analogy to accepted metabolic pathways for amide hydrolysis and fatty acid beta-oxidation. It has been proposed that the initial step involves hydrolysis of the amide linkage to generate oleic acid and sodium *N*-methyl taurine. The enzyme fatty acid amide hydrolase (FAAH) may be involved in hydrolysis, and is also a primary terminator of lipic oleoamides as well as for the *N*-acyl taurines. It is possible the anionic sulfonate, MOTS species, would be excreted in the urine or converted to a dianionic salt with glucuronic acid that is excreted. A secondary step would involve metabolism of the oleic acid by the fatty acid beta-oxidation pathway.

There is no evidence that MOTS is carcinogenic. The Agency used a qualitative structure activity relationship (SAR) database, DEREK Version 11, to determine if there were structural alerts. No structural alerts were identified. EPA has low concern that any of the postulated metabolites have greater toxicity than the parent compounds. Based on the negative response for mutagenicity, lack of any alerts in model predictions, and SAR analysis, the Agency concluded that MOTS is not likely to be carcinogenic.

Specific information on the studies received and the nature of the adverse effects caused by MOTS, as well as the NOAEL and the lowest observed adverse effect level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document *MOTS (JITF CST 24 Inert Ingredient). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide*, pages 8–12 and 47–52 in docket ID number EPA–HQ–OPP–2008–0725.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a benchmark dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for MOTS used for human health risk assessment is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MOTS FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (all populations)	An endpoint attributable to a single exposure was not seen in the database; therefore, a point of departure was not selected.		
Chronic dietary (all populations)	NOAEL= 300 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 3 mg/kg/day cPAD = 3 mg/kg/day	OPPTS Harmonized Guideline 870.3650 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in rats LOAEL = 1,000 mg/kg/day, based on thyroid histophathy in males and organ weight increases (adrenals and liver in both sexes; testes in males) Note that irritant effects seen in the forestomach of rats at 300 mg/kg/day were considered to be due to the corrosive nature of the test material and were not considered appropriate for risk assessment.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MOTS FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Incidental Oral, Dermal and Inhalation (Short-term and Intermediate-term)	NOAEL= 300 mg/kg/day Dermal absorption of 20% is considered upper end screening level; Inhalation exposure is assumed to be equivalent to oral exposureUF_A = 10x UF_H = 10x FQPA SF = 1x	Residential/Occupational LOC for MOE = 100	OPPTS Harmonized Guideline 870.3650 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in rats LOAEL = 1,000 mg/kg/day, based on thyroid histophathy in males and organ weight increases (adrenals and liver in both sexes; testes in males) Note that irritant effects seen in the forestomach of rats at 300 mg/kg/day were considered to be due to the corrosive nature of the test material and were not considered appropriate for risk assessment.
Cancer (oral, dermal, inhalation)	Classification: No animal toxicity data available for an assessment. Based on SAR analysis, MOTS is not expected to be carcinogenic.		

POD = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). PAD = population adjusted dose (a=acute, c=chronic). FQPA SF = FQPA Safety Factor. RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

C. Exposure Assessment

Very limited information is available for MOTS with respect to plant and animal metabolism or environmental degradation. The Agency relied collectively on information provided on the representative chemical structure, the submitted physicochemical EPI Suite™ data, SAR information, as well as information on other surfactants and chemicals of similar size and functionality to determine the residues of concern for this inert ingredient. The Agency has concluded that the parent compound MOTS is the residue of concern. Likely degradation in the environment would result in sodium *N*-methyl taurine and oleic acid (or shorter chain fatty acids). These compounds would likely be present in food and water at much lower concentrations than the parent compound, and since they are likely are less toxic than the parent, MOTS, are not of concern for risk assessment purposes. The Agency notes that taurine, synthesized by the liver, is important in bile acid metabolism.

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to MOTS, EPA considered exposure under the petitioned-for exemptions from the requirement of a tolerance. EPA assessed dietary exposures from MOTS in food as follows:

i. *Acute exposure.* No adverse effects attributable to a single exposure of MOTS was seen in the toxicity databases; Therefore, an acute dietary exposure assessments for MOTS is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for MOTS. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled *Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.* (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products is generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100% of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on

food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

iii. *Cancer*. The Agency used a qualitative SAR database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified. Based on the negative response for mutagenicity, the lack of any alerts in model predictions, and SAR analysis, the Agency concluded that MOTS is not likely to be carcinogenic. Since the Agency has not identified any concerns for carcinogenicity relating to MOTS, a cancer dietary exposure assessment was not performed.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for MOTS. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.*The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for MOTS in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of MOTS. Further information regarding EPA drinking water models used in the pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

A screening level drinking water analysis, based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) was performed to calculate the estimated drinking water concentrations (EDWCs) of MOTS. Modeling runs on four surrogate inert ingredients using a range of physical chemical properties that would bracket those of MOTS were conducted. Modeled acute drinking water values ranged from 0.001 ppb to 41 ppb. Modeled chronic drinking water values ranged from 0.0002 ppb to 19 ppb. Further details of this drinking water analysis can be found at *http://www.regulations.gov* in the document *MOTS (JITF CST 24 Inert Ingredient). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations*, pages 13 and 54–56 in docket ID number EPA–HQ–OPP–2008–0725.

For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for MOTS, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for chronic dietary risk assessments for the parent compounds and for the metabolites of concern. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). MOTS may be used as inert ingredients in pesticide products that are registered for specific uses that may result in both indoor and outdoor residential exposures. A screening level residential exposure and risk assessment was completed for products containing MOTS as inert ingredients. MOTS is used as a surfactant in pesticide formulations intended for use in agricultural settings as well as outdoor residential applications. Additionally, the petition indicates that this inert may also be used in household cleaners. The Agency selected representative scenarios, based on end-use product application methods and labeled application rates. The Agency conducted an assessment to represent worst-case residential exposure by assessing MOTS in pesticide formulations (outdoor scenarios) and MOTS in disinfectant-type uses (indoor scenarios). Based on information contained in the petition, MOTS can be present in consumer cleaning products. Therefore, the Agency assessed the disinfectant-type products containing MOTS using exposure scenarios used by OPP's Antimicrobials Division to represent worst-case residential handler exposure. Standard methodologies based on the Agency's Residential standard operating procedures (SOPs) were used to assess residential post application exposure to hard surface cleaners. Further details of this residential exposure and risk analysis can be found at *http://www.regulations.gov* in the memorandum entitled *JITF Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations*, (D364751, 5/7/09, Lloyd/LaMay in docket ID number EPA–HQ–OPP–2008–0710.

4. *Cumulative effects from substances with a common mechanism of toxicity*. 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.''

EPA has not found MOTS to share a common mechanism of toxicity with any other substances, and MOTS does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that MOTS does not 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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The toxicology database for MOTS consists of one OPPTS Harmonized Guideline repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats and several studies in the scientific literature on acute toxicity,

mutagenicity and repeat dosing exposures.

In the case of MOTS, there was no increased susceptibility to the offspring of rats following prenatal and postnatal exposure in the OPPTS Harmonized Guideline combined repeated dose toxicity study with the reproduction/developmental toxicity screening test. The offspring effects (increased post-implantation loss, decreased viability and decreased body weight in male and female offspring) occurred at 1,000 mg/kg/day in the presence of maternal toxicity, which was manifested as clinical signs, decreased body-weight gain, thyroid effects in male rats, and microscopic stomach lesions at doses of 300 mg/kg/day and 1,000 mg/kg/day. In an OPPTS Harmonized Guideline study, a slight decrease in body temperature was observed in males at doses of 300 and 1,000 mg/kg/day and in females at doses of 1,000 mg/kg/day. Since these decreases in body temperature were minimal, within biological variability, they were not considered to be toxicologically relevant. Therefore, the Agency concluded that there is no evidence of neurotoxicity in the database.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for MOTS is considered adequate for assessing the risks to infants and children (the available studies are described in Unit 4.D.2.

ii. No quantitative or qualitative increased susceptibility was demonstrated in the offspring in the OPPTS Harmonized Guideline combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats following *in utero* and post-natal exposure.

iii. Although there is some evidence of thyroid toxicity in the OPPTS Harmonized Guideline study, this occurred in males at the highest dose tested (HDT) and males are known to be the more sensitive sex for thyroid effects. Rats are also known to be more senstitive to these effects than humans. Additionally, the increased thyroid follicular hypertrophy is considered secondary to the enhanced liver cell metabolism observed in males at the HDT. Regulating at a NOAEL of 300 mg/kg/day with effects seen at 1,000 mg/kg/day with a 100 fold uncertainty factor (UF_A= 10X; UF_H= 10X) provides an adequate margin of protection.

iv. There is no indication that MOTS is a neurotoxic chemical in the database and thus there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

v. While there is no chronic toxicity data, the Agency has concluded that an additional uncertainty factor is not needed for the use of a subchronic study for a chronic exposure assessment considering the lack of any alerts in model predictions, as well as, the highly conservative nature of the exposure assessment. The conservative point of departure selected along with the standard UF factor of 100X to account for inter- and intra-species variablitiy is considered health protective.

vi. There are no residual uncertainties identified in the exposure databases. The food and drinking water assessment is not likely to underestimate exposure to any subpopulation, including those comprised of infants and children. The food exposure assessments are considered to be highly conservative as they are based on the use of the highest tolerance level from the surrogate pesticides for every food and 100 PCT is assumed for all crops. EPA also made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to MOTS in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by MOTS.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. There was no hazard attributable to a single exposure seen in the toxicity database for MOTS. Therefore, MOTS is not expected to pose an acute risk.

2. *Chronic risk*. A chronic aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for chronic exposure, the chronic dietary exposure from food and water to MOTS is 6% of the cPAD for the U.S. population and 21% of the cPAD for children 1–2 yrs old, the most highly exposed population subgroup.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

MOTS is used as an inert ingredient in pesticide products that are currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to MOTS. Using the exposure assumptions described in this unit, EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in aggregate MOEs of 240, for both adult males and females, respectively. Adult residential exposure combines high end dermal and inhalation handler exposure with a high end post application dermal exposure. EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 360 for children. Children's residential exposure combines outdoor and indoor dermal and hand-to-mouth exposures. As the level of concern is for MOEs that are lower than 100, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

MOTS is currently registered for uses that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to MOTS. Using the exposure assumptions described in this unit, EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in aggregate MOEs of 1,500 for both adult males and females, respectively. Adult residential exposure includes high end post application dermal exposure from contact with treated lawns. EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of

410 for children. Children's residential exposure combines outdoor dermal and hand-to-mouth exposures. As the level of concern is for MOEs that are lower than 100, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population*. The Agency has not identified any concerns for carcinogenicity relating to MOTS.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to residues of MOTS.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

The Agency is not aware of any country requiring a tolerance for MOTS nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

VI. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of sodium *N*-Oleoyl-*N*-methyl taurine, when used as inert ingredients applied to crops pre-harvest and post-harvest, or to animals under 40 CFR 180.910 and 40 CFR 180.930.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 21, 2009.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§180.910 Inert ingredients used pre-harvest and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert Ingredients	Limits	Uses
* * * * *	* *	
Sodium *N*-oleoyl- *N*-methyl taurine (CAS Reg. No. 137–20–2)		Surfactants, related adjuvants of surfactants
* * * * *	* *	

3. In §180.930, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert Ingredients	Limits	Uses
* * * * * * *		
Sodium *N*-oleoyl-*N*-methyl taurine (CAS Reg. No. 137–20–2)		Surfactants, related adjuvants of surfactants
* * * * * * *		

[FR Doc. E9–17960 Filed 7–28–09; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0665; FRL–8421–7]

Sodium monoalkyl and dialkyl (C_6-C_{16}) phenoxybenzenedisulfonates and related acids; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of Sodium monoalkyl and dialkyl (C_6-C_{16}) phenoxybenzenedisulfonates and related acids, often known as the ''alkyldiphenyl oxide sulfnates'', herein referred to in this document as ADPOS, when used as inert ingredients at a maximum of 20% by weight in pesticide formulations for pre-harvest and post-harvest use under 40 CFR 180.910, as well as for application to animals under 40 CFR 180.930. Dow AgroSciences, LLC, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ADPOS.

DATES: This regulation is effective July 29, 2009. Objections and requests for hearings must be received on or before September 28, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0665. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8811; e-mail address: *leifer.kerry@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0665 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before September 28, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0665, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.