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

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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.

II. Background

In the **Federal Register** of October 8, 2008 (73 FR 58962) (FRL–8383-7), 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 8E7372) by Dow AgroSciences, LLC, 9330 Zionsville Rd., Indianapolis, IN 46268. 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 ADPOS at a maximum of 20% by weight in pesticide formulations. That notice referenced a summary of the petition prepared by Dow AgroSciences, LLC, the petitioner, which is available to the public in the docket, *http://www.regulations.gov*.

The Agency received only one comment in response to the notice of filing. One comment was received from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute.

This petition was submitted in response to a final rule of August 9, 2006, (71 FR 45415) (FRL–8084–1) 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 ADPOS when used as inert ingredients at a maximum of 20% by weight in pesticide formulations for pre-harvest and post-harvest use, 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 available mammalian toxicology database includes acute, subchronic repeat dose oral, reproductive/developmental screening tests, chronic rat and dog studies and mutagenicity data for four representative compounds of the C_6 to C_{16} ADPOS group. The Agency concluded that the four surrogate chemicals (CAS Reg. Nos. 147732–60–3, 39354–74–0, 119345–04–9 (alternate CAS Reg. No. 28519–02–0), and 70191-76-3) are representative of all the chemicals in the ADPOS cluster. Additionally, the Agency concluded that the currently available toxicity dataset is adequate to apply to the ADPOS inerts and to characterize these surfactants. Further, the Agency noted that there was sufficient bracketing of the range of molecular weights expected from the inerts in this grouping.

The ADPOS inerts are not acutely toxic by the oral, dermal, and inhalation routes of exposure, and are moderately irritating to the skin and eyes. Respiratory irritation is possible with mists. The ADPOS inerts, like all 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, as indicated by the acute toxicity studies for these inert materials. It is possible that some of the observed toxicity seen in the repeated studies, such as diarrhea, gastrointestinal tract effects or decreased body weight gain, can be attributed to the corrosive and irritating nature of these surfactants. The liver and possibly kidney appear to be the primary target organs. Following subchronic exposures to ADPOS inerts, the most sensitive effects include increased liver enzymes (alanine and aspartate aminotransferase), increased prothrombin time and soft/decreased feces in males and significant decreases in body weight gain in both sexes after 47–54 days of dosing at doses between 28 and 92 mg/kg/day. In comparison, in most of the other studies, no effects were observed in the range of 100 to 500

mg/kg/day, even following chronic exposures. There is some evidence of neurotoxicity in a 28–day rat study, including high-stepping gait, ataxia and salivation; however, these effects are seen at the highest dose tested (HDT). The Agency considered these effects to be the result of a high dose rather than a neurotoxic condition. No quantitative or qualitative increased susceptibility was demonstrated in the offspring in the two reproductive/developmental toxicity studies in rats following *in utero* and postnatal exposure. In one OPPTS Harmonized Guideline 870.3650 study there were no developmental effects at the HDT in the presence of maternal toxicity such as increased liver enzymes and prothrombin time. In a second OPPTS Harmonized Guideline 870.3650 study with test substance (CAS Reg. No. 147732–60–3) the developmental effects were manifested as statistically significantly decrease in body weight and clinical signs at 1,000 mg/kg which was in the presence severe maternal toxicity which manifested as mortality, clinical signs, and decrease in body weight were observed.

There is no evidence that the ADPOS inerts are mutagenic, but there is some evidence of potential clastogenicity for a C_6 inert formulation. *In vitro* data for genotoxicity are available for the range of alkyl chains of the lower (C_6) and upper (C_{16}) compounds in this group. The Ames tests were negative for the C_6 and C_{16} inerts. The C_{16} analogue was negative in the CHO/HGPRT forward mutation assay. In chromosomal aberration tests that evaluate clastogenicity, C_6 (CAS Reg. No. 147732–60–3) was clastogenic in human lymphocytes in the absence of metabolic activation (S9), but was negative in rat lymphocytes. The registrants attributed this positive response to peroxide as an unwanted constituent, and no longer use peroxide in the ADPOS process. C_{16} was negative in both human and rat lymphocytes, although the human lymphocyte study was not acceptable. *In vivo*, there was no evidence of a cytogenetic response in rat bone marrow cells for C_{16} (CAS Reg. No. 70191–76–3) in an unacceptable study that lacked positive controls, which limits the confidence of this finding. Based on these studies and the overall weight of the evidence, the Agency concluded that the ADPOS inerts are not likely to be mutagenic. There is no evidence of carcinogenicity in the chronic/carcinogenicity rat study at does up to 500 mg/kg/day. In addition, no tumors were observed in the two year toxicity study in dogs. Based on the negative response for carcinogenicity in the carcinogenicity study in rats and two year dog study, negative response for mutagenicity, lack of any alerts in model predictions, and SAR analysis, the Agency concluded that the ADPOS inerts are not likely to be carcinogenic.

Specific information on the studies received and the nature of the adverse effects caused by ADPOS as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document ''Alkyl Diphenyl Oxide Sulfonates (JITF CST 18 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations'' pages 9-15 in docket ID number EPA–HQ–OPP–2008–0665.

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 no adverse effects are observed (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-, intermediate-, 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 ADPOS used for human health risk assessment is shown in the Table of this unit.

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

Exposure Scenerio	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assesment	Study and Toxicological Effects
Acute Dietary (General Population, including Infants and Children)	NOAEL=115 milligrams/ kilograms/day (mg/kg/day) UF_A=10x UF_H=10x FQPA SF=1x	Acute RfD=1.15 mg/kg/day aPAD=1.15 mg/kg/day	28-day oral toxicity study- rats (CAS No. 70191-76-3) LOAEL= 367 mg/kg/day, based on Post-dosing salivation (day 1 post-dose in 3/5 male and 2/5 female rats; 2-28 all rats.)

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

Exposure Scenerio	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assesment	Study and Toxicological Effects
Chronic Dietary (all populations)	NOAEL=28 mg/kg/day UF_A=10x UF_H=10x FQPA SF=1x	Chronic RfD=0.28 mg/kg/day cPAD=0.28 mg/kg/day	Reproductive/developmental-rat(CAS No. 70191-76-3) LOAEL= 92 mg/kg/day, based on increasted ALT and AST in females, increased prothrombin time and soft/decrease feces in males and significant decreased feces in males and significant decreased in body weight gain in both sexes after 47-54 days of dosing.
Short-Term (1-30 days Incidental Oral/Dermal/Inhalation)	NOAEL=115 mg/kg/day UF_A=10x UF_H=10x FQPA SF=1x	Residential/Occupational LOC for MOE=100	28-day oral toxicity study-rats(CAS No. 70191-76-3) LOAEL= 367 mg/kg/day, based on ost-dosing salvation (day 1 post-dose in 3/5 male and 2/5 female rats; days 2-28 all rats).
Intermediate and Long-Term (1-6 months/≤6months Incidental Oral/Dermal/Inhalation	NOAEL=28 mg/kg/day UF_A=10x UF_H=10x FQPA SF=1x	Residential/Occupational LOC for MOE= 100	Reproductive/developmental-rat(CAS No. 70191-76-3) LOAEL= 92 mg/kg/day, based on increasted ALT and AST in females, increased prothrombin time and soft/decreased feces in males and significant decreased feces in males and significant decreased in body weight gain in both sexes after 47-54 days of dosing.
Cancer (oral, dermal, inhalation)	Classification: no edivence of carcinogenicity in available studies		

[1]The LOAEL of 367 mg/kg/day was used from MRID 46989217 and NOAEL of 115 mg/kg/day was used from MRID 46989216 due to artifact of dose selection. Point of Departure (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

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

i. *Acute and chronic exposure.* In conducting the acute and chronic dietary exposure assessments, 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 the ADPOS inert ingredients. 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 ingredients. 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. In the case of ADPOS, EPA made a specific adjustment to the dietary exposure assessment to account for the use limitations of the amount of ADPOS that

may be in formulations (no more than 20% by weight) and assumed that the ADPOS are present at the maximum limitations rather than at equal quantities with the active ingredient. This remains a very conservative assumption because surfactants are generally used at levels far below this percentage.

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 percent 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.

ii. *Cancer*. The Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified. There is no evidence of carcinogenicity in the chronic/carcinogenicity study in rats at doe up to 500 mg/kg/day. In addition, no tumors were observed in the two year toxicity study in dogs. Based on the negative response of the carcinogenicity study in rats and two year dog study, negative response for mutagenicity, lack of any alerts in model predictions, and SAR analysis, the Agency concluded that the ADPOS inerts are not likely to be carcinogenic. Since the Agency has not identified any concerns for carcinogenicity relating to the ADPOS inerts, a cancer dietary exposure assessment was not performed.

iii. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for ADPOS. 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 ADPOS in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of ADPOS. Further information regarding EPA drinking water models used in 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 ADPOS. Modeling runs on four surrogate inert ingredients using a range of physical chemical properties that would bracket those of the ADPOS were conducted. Modeled acute drinking water values ranged from 0.001 parts per billion (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 document ''Alkyl Diphenyl Oxide Sulfonates (JITF CST 18 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations'' pages 16 and 71-73 in docket ID number EPA–HQ–OPP–2008–0665.

For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for ADPOS, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for both the acute and chronic dietary risk assessments. 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). ADPOS may be used in 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 ADPOS as inert ingredients. In this assessment, representative scenarios, based on end-use product application methods and labeled application rates, were selected.The ADPOS inerts are not added to any insecticidal products intended for pet use and are not likely to be used in personal care products. The Agency conducted an assessment to represent worst-case residential exposure by assessing ADPOS in pesticide formulations (outdoor scenarios) and ADPOS in disinfectant type uses (indoor scenarios). Based on information contained in the petition, the ADPOS inerts can be present in consumer cleaning products. Therefore, the Agency assessed the disinfectant-type products containing ADPOS using several anti-microbial scenarios to represent worst-case residential handler exposure. Standard methodologies based on the Agency's Residential SOPs were used to assess residential post application exposure to hard surfance cleaners.

Further details of this residential exposure and risk analysis can be found at *http://www.regulations.gov* in ''Alkyl Diphenyl Oxide Sulfonates (JITF CST 18 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations'' pages 20-28 and 94-110 in docket ID number EPA–HQ–OPP–2008–0665.

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 ADPOS to share a common mechanism of toxicity with any other substances, and ADPOS do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that ADPOS

do 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 toxicity database consists of two rat reproductive/developmental screening studies. There was no increased susceptibility to the offspring of rats following *in utero* or postnatal exposure in the two reproductive/developmental toxicity screening tests, In one study, there were no adverse effects to offspring, while decreased pup body weight and clinical signs were noted in the presence of maternal/parental toxicity at the limit dose of 1,000 mg/kg/day in a second study.

There are no neurotoxicity studies available for the ADPOS, however, there is some evidence of neurotoxicity in a subchronic rat study at 367 mg inert/kg/day (1,000 mg product/kg/day), including high-stepping gait, ataxia and salivation. However, since the effects noted occurred at doses significantly higher than the current points of departure for risk assessment, additional neurotoxicity data is not required.

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 ADPOS is considered adequate for assessing the risks to infants and children (the available studies are described in Unit iv.D.2.

ii. There is some evidence of neurotoxicity in a 28–day rat study, including high-stepping gait, ataxia and salivation; however, these effects are seen at the HDT. Since these effects occurred at dose levels significantly higher than the current points of departure used for regulation, the Agency determined that the points of departure selected for this risk assessment are protective of any neurotoxicity effects. Therefore, additional neurotoxicity data and other toxicity data are not required.

iii. No quantitative or qualitative increased susceptibility was demonstrated in the offspring in the two reproductive/developmental toxicity studies in rats following *in utero* and postnatal exposure.

iv. The Agency has concluded that an additional UF for extrapolation from subchronic toxicity study to a chronic exposure scenario would not be needed since toxicity is not expected to increase with a longer duration of exposure for the ADPOS inerts. This is because for the most sensitive endpoint, prothrombin time (PT), the clotting factor proteins evaluated by the PT test have short plasma half-lives, ranging from 4 hours for factor VII to a maximum of 96 hours for fibrinogen. The clotting factors are being continually synthesized by the liver and by 47 days of exposure would have reached steady state and further exposure is not expected to result in any further increase in prothrombin time. Therefore, the Agency concluded that the 10X interspecies and 10X intraspecies UF would be adequately protective.

v. 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 and surface water modeling used to assess exposure to ADPOS 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 ADPOS.

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-, intermediate-, 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.

In conducting this aggregate risk assessment, the Agency has incorporated the petitioner's requested use limitations of ADPOS as inert ingredients in pesticide product formulations into its exposure assessment. Specifically, the petition includes a use limitation of ADPOS at not more than 20% by weight in pesticide formulations.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, and the use limitations of not more than 20% by weight in pesticide formulations, the acute dietary exposure from food and water to ADPOS at the 95th percentile for food and drinking water is 20% of the aPAD for the U.S. population and 55% of the aPAD for children 1-2 yrs old, the population group receiving the greatest exposure.

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, and the use limitations of not more than 20% by weight in pesticide formulations, the chronic dietary exposure from food and water to ADPOS is 28% of the cPAD for the U.S. population and 90% 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).

ADPOS inerts are used as inert ingredients 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 ADPOS. Using the exposure assumptions described in this

unit, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of 490 and 530, for adult males and females respectively, for a combined high end dermal and inhalation handler exposure with a high end post application dermal exposure and an aggregate MOE of 380 for children for a combined dermal exposure with hand-to-mouth exposure. 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).

ADPOS inerts are used as inert ingredients in pesticide products that are 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 ADPOS.

Using the exposure assumptions described in this unit, EPA has concluded the combined intermediate-term food, water, and residential exposures aggregated result in aggregate MOEs of 320 and 400, for adult males and females respectively, and an aggregate MOE of 100 for children. 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 the ADPOS inerts.

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 ADPOS.

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 ADPOS 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 monoalkyl and dialkyl (C_6-C_{16}) phenoxybenzenedisulfonates and related acids, when used as inert ingredients at a maximum of 20% by weight in pesticide formulations applied to crops pre-harvest and post-harvest, or to animals.

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- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert Ingredients	Limits	Uses
*	* * * *	
Sodium monoalkyl and dialkyl (C6-C16) phenoxy benzenedisulfonates and related acids (CAS Reg. Nos. 147732-59-0, 147732-60-3, 169662-22-0, 70191-75-2, 36445-71-3, 39354-74-0, 70146-13-3, 119345-03-8, 149119-20-0, 149119-19-7, 119345-04-9, 28519-02-0, 25167-32-2, 30260-73-2, 65143-89-7, 70191-76-3)	Not to exceed 20% in pesticide formulations	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 monoalkyl and dialkyl (C6-C16) phenoxy benzenedisulfonates and related acids (CAS Reg. Nos. 147732-59-0, 147732-60-3, 169662-22-0, 70191-75-2, 36445-71-3, 39354-74-0, 70146-13-3, 119345-03-8, 149119-20-0, 149119-19-7, 119345-04-9, 28519-02-0, 25167-32-2, 30260-73-2, 65143-89-7, 70191-76-3)	Not to exceed 20% in pesticide formulations	Surfactants, related adjuvants of surfactants
*	* * * *	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0710; FRL–8425–7]

Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10, or 30 moles; 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 ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10, or 30 moles, herein referred to in this document as ethoxylated acetylenic diols, when used as inert ingredients 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 Number 19, 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 the ethoxylated acetylenic diols.

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–2008–0710. 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