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
*	* * * *	

[FR Doc. E9–17957 Filed 7–28–09; 8:45 am]
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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

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–2008–0710 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–2008–0710, 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 73640) (FRL–8390–4), 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 8E7374) by The Joint Inerts Task Force, Cluster Support Team 19 (CST 19), c/o CropLife America, 1156 15th Street, NW., Suite 400, Washington, DC 20005. 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 ingredients ethoxylated acetylenic diols. That notice referenced a summary of the petition prepared by the Joint Inerts Task Force (JITF), Cluster Support Team Number 19 (CST 19), 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) (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) (FRL–8372–7), 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 the ethoxylated acetylenic diols when used as inert ingredients 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 available mammalian toxicology database includes acute, subchronic (rat and dog) repeat dose, and reproductive toxicity studies (rat) via the oral route for a representative ethoxylated compound for the series of polyethoxylated 2,4,7,9-tetramethyl-5-decyne-4,7-diols and the proposed major unethoxylated metabolite, and mutagenicity data for the unethoxylated compound. The available toxicology data are adequate to support the requested exemption from the requirement of tolerance when used in pesticide formulations for these ethoxylated acetylenic diols. In addition to concern for the parent compounds, the Agency has identified the unethoxylated metabolite, 2,4,7,9-tetramethyl-5-decyne-4,7-diol, to be of concern. Unethoxylated and ethoxylated acetylenic diols are expected to follow a similar metabolic pathway. This would include hydrolytic or oxidative removal of the polyethoxylate chain to generate a common acetylenic diol primary metabolite and polyethoxylated moieties, which would vary in size depending on the extent of ethoxylation in the parent molecule. The primary acetylenic diol metabolite would be analogous to a related surfactant (CAS Reg. No. 126–86–3). Both the diol and polyethoxylate moieties would undergo rapid oxidative degradation and excretion likely as conjugates. The unethoxylated diol metabolite is of concern in food and water only. The Agency has concluded that the available data on the ethoxylated compound and unethoxylated metabolite (CAS Reg. Nos. 9014–85–1 and 126–86–3) are representative of the chemicals in the polyethoxylated 2,4,7,9-tetramethyl-5-decyne-4,7-diols cluster. Further, the Agency has concluded that the currently available toxicity dataset is adequate to apply to the cluster and to characterize the potential toxic effects of these surfactants.

The ethoxylated compounds are not acutely toxic by the oral, dermal and inhalation routes of exposure, but are slight to severe eye and mild skin irritants. The unethoxylated metabolite demonstrates low to medium acute toxicity by the oral and dermal routes of exposure, with the greatest concerns being eye and skin irritation. There is no evidence that the unethoxylated metabolite is mutagenic, and no increases in polyploidy or chromosome aberrations were observed in the presence and absence of metabolic activation.

There is no clear target organ identified for the ethoxylated compound or the unethoxylated metabolite, although increased liver weight (without histopathology) was a consistent finding. Following subchronic exposure to the ethoxylated compound, no specific target organ toxicity or neurotoxicity was observed in rats and dogs. In a 1–generation reproduction study, decreased pup body weights were observed at weaning following exposure to the ethoxylated and unethoxylated compounds at dose levels at and greater than the limit dose. Following subchronic exposure to the unethoxylated metabolite, compound-related neurological disturbances (convulsions and tremors) were observed in the dog. However, the concern for this finding is low based on the following considerations:

1. The clinical signs were sporadic.
2. There was no neuropathology at any dose.
3. No neurotoxic clinical signs were seen following subchronic exposures to the parent compound.
4. This endpoint is used as the point of departure in conjunction with highly conservative exposure inputs for assessing chronic dietary risks for the diol metabolite.
5. There was no evidence with either the parent or metabolite of neurotoxicity in rats, the species of choice for conducting neurotoxicity studies.

There was evidence of increased susceptibility following pre- and post-natal exposures to rats for 1–generation where decreases in body weights of the offspring were seen at high doses (1,000 or 2,000 milligrams/kilogram/day (mg/kg/day)) that did not cause any parental/systemic toxicity. It should be noted that the offspring effects were seen at and above the limit dose. Similarly, following exposure to the unethoxylated compound, there was a decrease in pup body weight at dose levels of 1,000 and 2,000 mg/kg/day, whereas the parental animals displayed body-weight effects only at the 2,000 mg/kg/day dose level. Based on the fact that the effect (decreased body weight) was observed only at the limit dose and above and there is a clear NOAEL, there is no residual concern for this finding.

There are no chronic toxicity studies available for this series of nonionic surfactants. The Agency used a qualitative structure activity relationship (SAR) database, DEREK Version 11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts were identified. Based on the negative response for mutagenicity, the fact that no specific target organs have been identified in the rat and dog subchronic studies at the limit dose, the lack of any alerts in model predictions, and SAR analysis, the Agency concluded that the ethoxylated acetylenic diol inerts or their unethoxylated diol metabolite are not likely to be carcinogenic.

Specific information on the studies received and the nature of the adverse effects caused by ethoxylated acetylenic diols or the unethoxylated diol metabolite 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 ''Ethoxylated Acetylenic Diols (JITF CST 19 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 10–15 and pages 50–57 in docket ID number EPA–HQ–OPP–2008–0710.

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-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 ethoxylated acetylenic diols used for human health risk assessment is shown in Table 1 of this unit.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ETHOXYLATED ACETYLENIC DIOLS 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) Parent and Diol Metabolite	No appropriate endpoints were identified for acute dietary risk assessment.		
Chronic dietary (all populations) Parent Compound	NOAEL= 500 mg inert/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 5 mg/kg/daycPAD = 5 mg/kg/day	1–generation reproduction/subchronic oral toxicity study - rat (CAS Reg. No. 9014–85–1) Offspring LOAEL = 1,000 mg/kg/day, based on decreased pup body weight (11% lower than control) at weaning (only time assessed); BW decreased 21–22% lower than control at 2,000 mg/dg/day.
Chronic Dietary (all populations) Diol Metabolite	NOAEL = 200 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 2 mg/kg/daycPAD = 2 mg/kg/day	Subchronic oral toxicity study - dog (CAS Reg. No. 126–86–3) LOAEL = 250 mg/kg/day, based on sporadic compound-related neurological disturbances (convulsions and tremors; time of occurrence unknown)
Incidental Oral Short- and Intermediate Term Dermal and Inhalation (All Durations) Parent Compound	NOAEL= 500 mg/kg/day UF_A = 10 x UF_H = 10 x FQPA SF = 1x (20% Dermal absorption; inhalation and oral toxicity assumed equivalent)	Residential/Occupational LOC for MOE = 100	1–generation reproduction/subchronic oral toxicity study - rat (CAS Reg. No. 9014–85–1) Offspring LOAEL = 1,000 mg/kg/day, based on decreased pup body weight (11% lower than control) at weaning (only time assessed); BW decreased 21–22% lower than control at 2,000 mg/kg/day.
Cancer (oral, dermal, inhalation) Parent and Diol Metabolite	Classification: No animal toxicitydata available for an assessment. Based on SAR analysis, the ethoxylated acetylenic diols and the diol metabolite are not expected to be carcinogenic.		

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 the ethoxylated acetylenic diols and the unethoxylated diol metabolite, EPA considered exposure under the petitioned-for exemptions from the requirement of a tolerance. EPA assessed dietary exposures from ethoxylated acetylenic diols in food as follows:

i. *Acute exposure.* No adverse effects attributable to a single exposure of ether the parent ethoxylated acetylenic diol inerts or the unethoxylated diol metabolite were seen in the toxicity databases; Therefore, acute dietary risk assessments for the parent compound and the unethoxylated diol metabolite are not necessary.

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 the ethoxylated acetylenic diol inert ingredients or the unethoxylated diol metabolite. 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 ethoxylated acetylenic diols, a conservative screening level chronic dietary (food and water) assessment was conducted for both the parent ethoxylated acetylenic diol inerts and for the 2,4,7,9-tetramethyl-5-decyne-4,7-diol metabolite.

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.

iii. *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. Based on the negative response for mutagenicity, the fact that no specific target organs have been identified in the rat and dog subchronic studies at the limit dose, the lack of any alerts in model predictions, and SAR analysis, the Agency concluded that the ethoxylated acetylenic diol inerts or their unethoxylated diol metabolite are not likely to be carcinogenic. Since the Agency has not identified any concerns for carcinogenicity relating to the ethoxylated acetylenic diol inerts or their unethoxylated diol metabolite, 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 the ethoxylated acetylenic diols or their unethoxylated diol metabolite. 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 the ethoxylated acetylenic diols and unethoxylated diol metabolite in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of the ethoxylated acetylenic diols and unethoxylated diol metabolite. 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 the ethoxylated acetylenic diols and unethoxylated diol metabolite. Modeling runs on four surrogate inert ingredients using a range of physical chemical properties that would bracket those of the the ethoxylated acetylenic diols and unethoxylated diol metabolite 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 ''Ethoxylated Acetylenic Diols (JITF CST 19 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide'', at pages 15–16 and 59–61 in docket ID number EPA–HQ–OPP–2008–0710.

For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for the ethoxylated acetylenic diols and unethoxylated diol metabolite, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for the parent compounds and for the metabolite 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). The ethoxylated acetylenic diols 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. The ethoxylated acetylenic diol inerts are used in pesticide formulations that may be used around the home. In addition, these inerts may be used in pesticide products applied to pets as dust formulations and aerosol sprays intended for flea control on carpeted surfaces and bedding. Lastly, these inert surfactants may be present in home cleaning products. The ethoxylated acetylenic diols inerts do not have utility in personal care products. A screening level residential exposure and risk assessment was completed for products containing ethoxylated acetylenic diols as inert ingredients. In

this assessment, representative scenarios, based on end-use product application methods and labeled application rates, were selected. The Agency conducted an assessment to represent worst-case residential exposure by assessing ethoxylated acetylenic diols in pesticide formulations (Outdoor Scenarios); ethoxylated acetylenic diols in disinfectant-type uses; (Indoor Scenarios) and ethoxylated acetylenic diols in pet products; (Pet Product Scenarios). 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 ethoxylated acetylenic diols to share a common mechanism of toxicity with any other substances, and ethoxylated acetylenic diols do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that ethoxylated acetylenic diols 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 a 1–generation reproductive toxicity study on the ethoxylated compound and a 1–generation reproductive toxicity study on the unethoxylated compound.

The Agency performed a Degree of Concern Analysis because the rat reproduction studies provided evidence of increased susceptibility in the offspring relative to the parents. The purpose of the Degree of Concern analysis was:

i. To determine the level of concern for the effects observed when considered in the context of all available toxicity data; and

ii. Identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment.

In the case of the ethoxylated acetylenic diols and unethoxylated diol metabolite, there was evidence of increased susceptibility in the 1–generation reproduction toxicity studies in rats. Although there is some increased susceptibility in the rat reproductive toxicity studies (where the offspring NOAEL of 500 mg/kg/day was lower than the paternal NOAELs of 1,000 and 2,000 mg/kg/day), the effects (decreased body weight) were observed only at the limit and twice the limit dose. The dose-response for this effect has been adequately characterized, and the NOAEL selected as a point of departure for the chronic dietary, dermal and inhalation risk assessment is protective of the adverse offspring effects. Thus, there are no residual concerns.

There was some evidence of clinical signs indicative of neurotoxicity following subchronic exposures to the diol metabolite in dogs. However, the concern for this finding is low based on the following considerations:

a. The clinical signs were sporadic;

b. There was no neuropathology at any dose;

c. No neurotoxic clinical signs were seen following subchronic exposures to the parent compound;

d. This endpoint is used as the point of departure in conjunction with highly conservative exposure inputs for assessing chronic dietary risks for the diol metabolite; and

e. There was no evidence with either the parent or metabolite of neurotoxicity in rats, the species of choice for conducting neurotoxicity studies. Therefore, additional neurotoxicity data, including developmental neurotoxicity studies are 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 the ethoxylated acetylenic diols and unethoxylated diol metabolite is considered adequate for assessing the risks to infants and children (the available studies are described in Unit IV.D.2.).

ii. There are no concerns or residual uncertainties concerning pre- and postnatal toxicity for the reasons given in this Unit.

iii. No additional neurotoxicity data are required.

iv. While there is no chronic toxicity study, the Agency has concluded that based on the very conservative exposure assessment and the fact that the toxicity endpoint is also very conservative (effects were only seen at and above the limit dose), the 10X interspecies and 10X intraspecies uncertainty factor would be adequately protective, and no additional uncertainty factor is needed for extrapolating from subchronic to chronic exposure.

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 the ethoxylated acetylenic diols or their diol metabolite 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 the ethoxylated acetylenic diols.

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.

The Agency has conducted aggregate risk assessments to support the proposed uses of the ethoxylated acetylenic diols as inert ingredients in pesticide formulations. As noted previously, the ethoxylated acetylenic diols assessment includes not only parent compounds, but also 2,4,7,9-tetramethyl-5-decyne-4,7-diol. The Agency notes that concern for this degradate is for residues in food and water only. Additionally, the Agency has selected endpoints and doses for risk assessment separately for the parent compound and diol metabolite. Therefore, separate parent compound and diol metabolite aggregate risk assessments are appropriate. The aggregate risk assessment for the diol metabolite includes residues in food and water only.

1. *Acute risk*. There was no hazard attributable to a single dietary exposure seen in the toxicity database for the parent ethoxylated acetylenic diols or the unethoxylated diol metabolite. Therefore, the parent ethoxylated acetylenic diols or the unethoxylated diol metabolite are 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 the parent ethoxylated acetylenic diol is 4% of the cPAD for the U.S. population and 13% of the cPAD for children 1–2 yrs old, the most highly exposed population subgroup. The chronic dietary (food and water) exposure for the unethoxylated diol metabolite resulted in a risk estimate of 10% of the cPAD for the U.S. population and 31% of the cPAD for children 1–2 yrs old, the most highly exposured 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).

Ethoxylated acetylenic diol 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 the ethoxylated acetylenic diols. 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 670, for both adult males and females, respectively. Adult residential exposure combines high end dermal and inhalation handler exposure from indoor hand wiping with a high end post application dermal exposure from contact with treated lawns. EPA has concluded the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 600 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). As the LOC 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).

Ethoxylated acetylenic diol 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 ethoxylated acetylenic diols. 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 2,500 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 690 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). As the LOC 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 parent ethoxylated acetylenic diol inerts or the degradate of concern.

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 the ethoxylated acetylenic diol inerts.

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 the ethoxylated acetylenic diol inerts 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 Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10, or 30 moles, when used as inert ingredients 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-harvest and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert Ingredients	Limits	Uses
* * *	* *	* *
Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10 or 30 moles (CAS Reg. No. 9014–85–1)	.....	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
* * *	* *	* *
Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10 or 30 moles (CAS Reg. No. 9014–85–1)	.....	Surfactants, related adjuvants of surfactants
* * *	* *	* *

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[FR Doc. E9–17958 Filed 7–28–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0556; FRL–8420–6]

Fenpyroximate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of fenpyroximate in or on raw agricultural commodities (RAC): Vegetables, fruiting, group 8 at 0.20 ppm; okra at 0.20 ppm; melon subgroup 9A at 0.10 ppm; and cucumber at 0.10 ppm. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

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