BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0874; FRL-9904-57]

Dimethyl esters of glutaric acid (i.e., dimethyl glutarate), succinic acid (i.e., dimethyl succinate), and adipic acid (i.e., dimethyl adipate); 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 dimethyl esters of glutaric acid (i.e., dimethyl glutarate), succinic acid (i.e., dimethyl succinate), and adipic acid (i.e., dimethyl adipate), herein referred to as DMEGSA, when used as inert ingredients (as solvents/co-solvents) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. SciReg, Inc., on behalf of Rhodia, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of DMEGSA**.**

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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: The docket for this action, identified by docket identification (ID)

number EPA-HQ-OPP-2012-0874, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

• Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 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-2012-0874 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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 (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0874, by one of the following

methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Petition for Exemption

In the **Federal Register** of January, 16, 2013 (78 FR 3377) (FRL-9375-4), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (IN-10520) by SciReg Inc. 12733 Director's Loop, Woodbridge, VA 22192, on behalf of Rhodia Inc., CN 7500, 8 Cedar Brook Drive, Cranbury NJ, 08512-7500. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of dimethyl esters of glutaric acid (i.e., dimethyl glutarate, CAS Reg. No. 1119-40-0), succinic acid (i.e., dimethyl succinate, CAS Reg. No. 106-65-0), and adipic acid (i.e., dimethyl adipate, CAS Reg. No. 627-93-0) when used as an inert ingredient as solvents/co-solvents in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. That document referenced a summary of the petition prepared by on SciReg

Inc., on behalf of Rhodia, Inc., the petitioner, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

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(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for 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 establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), 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 DMEGSA including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with DMEGSA follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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. Specific information on the studies received and the nature of the adverse effects caused by DMEGSA as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Acute toxicity studies demonstrate low acute oral and dermal toxicity (Office of Chemical Safety and Pollution Prevention (OCSPP) 870.1100 and 870.1200, respectively) with minimal eye irritation (OCSPP 870.2400) and no dermal irritation (OCSPP 870.2500). Results from a dermal sensitization study were negative (OCSPP 870.2600).

The repeat dose database contains oral, dermal, and inhalation studies. Due to their prevalence in commercial paint strippers, polishes, and lacquer thinners, the majority of the studies were conducted via inhalation, the most expected route of exposure from non-pesticidal uses.

Animals in a 14-day oral dietary study showed reduced weight gain and food consumption at 1,684 mg/kg/day (LOAEL) but showed no adverse effects at 842 mg/kg/day (NOAEL). Animals in a one month oral gavage study showed no adverse effects at the limit dose of 1,000 mg/kg/day. In addition, a 14-day dermal study was conducted and although mild skin irritation was noted in rats at doses equal to and greater than 100 mg/kg/day, the effects were reversible and no systemic effects were observed at any dose tested up to the limit dose of 1,000 mg/kg/day.

To support the safety finding as it relates to oral exposure, oral studies on the metabolites were also evaluated. Available repeat dose oral studies on the metabolites include a 13-week study on succinic acid, two 90-day studies on glutaric acid and a two year study on adipic acid. Succinic acid was shown to cause decreased body weight gain in rats at and above 2,500 mg/kg/day. Glutaric acid also caused a decrease in body weight gain in both rats and dogs at 1,000 and 750 mg/kg/day, respectively. Similarly, adipic acid was seen to cause decreased body weight gain and food consumption in rats at 2,250 mg/kg/day. The results of these studies indicate that the metabolites of DMEGSA are of low toxicity via the oral route of exposure.

The majority of the repeat dose and reproductive/developmental studies conducted on dibasic esters (DBE, CAS Reg. No. 95481-62-2- a chemical mixture of approximately 55-75% dimethyl glutarate, 15-27% dimethyl succinate, and 10-25% dimethyl adipate) and/or the individual chemicals are via the inhalation route of exposure. The available database includes three 90-day inhalation studies in rats, one conducted with DMEGSA and two with DBE. In the first study rats were exposed to DMS and DMA at doses of 0 or 0.4 mg/L and DMG at doses of 0, 0.01, 0.05, or 0.4 mg/L. Degeneration of the olfactory epithelium was observed for all chemicals at and above 0.05 mg/L with the severity of the local effect being dose dependent. Exposed animals also showed microscopic alterations in the liver (males) and lung (females). The hormonal changes observed in these studies with DMS, DMA, and DMG were: An increase in sperm counts (2/3 studies), a decrease in testosterone levels (1/3 studies), and a decrease in leutenizing hormone levels (1/3 studies) in males and a decrease in estradiol levels in females (1/3 studies). The significance of these findings is unclear because the

decrease in male hormone levels should result in a decrease in sperm counts, yet the opposite effect was observed. The single study showing changes in estradiol was not observed in the other two studies. Furthermore, there were no functional parameters such as estrous cycle and sperm motility or morphology affected. In addition, a reproductive study was conducted with DBE and there were no effects on fertility, viability of pups at birth, and the ability of the mothers to lactate.

Two other 90-day rat studies (OCSPP 870.3465), tested DBE and again, degeneration of the olfactory epithelium was noted at all doses tested (0.02-1.0 mg/L). In both studies decreases in liver weight were observed but no histopathological findings were evident. Similarly, when rats were exposed to 1 mg/L DBE slight increases in relative heart and testes weights in males and a slight decrease in absolute spleen weight in females were observed. These slight organ weight changes were not accompanied by any histopathological changes and are therefore, considered of minimal biological significance. No other significant effects were observed.

Repeat dose inhalation studies have demonstrated the chemicals potential to affect the olfactory mucosa in the nasal passage of rats. These local effects are believed to be related to the hydrolysis of DMEGSA by carboxylesterases located in the nasal/olfactory epithelium to the dicarboxylic acid metabolites. These effects on the olfactory epithelium are expected to be of much lower impact in humans due to major anatomical and physiological differences between rats and humans. See Unit VI.B for further discussion.

Depressed pup weights were observed in a one-generation reproduction inhalation toxicity study with DBE at 1.0 mg/L but were only seen in the presence of maternal toxicity. Two developmental inhalation toxicity studies (OCSPP 870.3700) were

conducted, one testing DBE on rats and with DMG on rabbits. In both studies no developmental effects were observed at doses up to and including 1.0 mg/L. Similarly, no adverse developmental effects were observed in oral studies on the metabolites glutaric acid (rat and rabbit) and adipic acid (rat and mice) at doses up to and including 1,300 mg/kg/day.

An Ames test conducted with DBE was negative; however, a chromosome aberration study conducted with DBE was positive at high concentrations in the presence of S9 metabolic activation (negative without S9 activation) in lymphocytes from female donors. This result is not consistent with what is known about the hydrolysis products of the methyl esters. Methanol is not clastogenic or genotoxic. Glutaric acid, succinic acid, and adipic acid are all endogenous and not considered to be clastogenic or genotoxic; a chromosome aberration study conducted with adipic acid was negative. As such, it is possible that, in the presence of S9 metabolic activation, the esters were hydrolyzed and the acids released, affecting the pH, making it more acidic. This is known to cause false positive effects in cytogenicity assays. Therefore, an *in vivo* genotoxicity assay on somatic cells was performed. A bone marrow micronucleus assay was performed in mice following a single inhalatory nose-only exposure to DBE for six hours. There were no statistically significant differences in the proportion of micronucleated polychromatic erythrocytes between mice of all groups including controls at any sampling time up to 72 hours following exposure up to a very high concentration of 19 mg/L, illustrating the absence of clastogenicity of the test substance *in vivo*. In addition, a rat micronucleus study conducted with DMG was negative.

No neuropathological changes or effects on the functional observation battery parameters were reported in any of the studies. The agency does not believe DMEGSA will be neurotoxic. Chronic/carcinogenicity studies could not be identified for DMEGSA. A DEREK evaluation for DMG and DMS was conducted and did not show any special alerts. In addition, carcinogenicity studies were conducted with adipic acid and monosodium succinate in rats and no carcinogenic effects were observed. Therefore, the agency does not expect DMEGSA to be carcinogenic in humans.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). 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 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.

Various inhalation studies with DMEGSA show local effects (likely a result of irritation at the point of contact in the nasal region) as well as some changes in hormone levels that, although consistently observed, are not considered to be toxicologically significant. The effects on the olfactory epithelium are expected to be of much lower impact in humans due to major physiological differences between rats and humans (e.g., rats have a larger surface of nasal epithelium and different air flow and breathing pattern (e.g., rats are obligate nose breathers) and greater carboxylesterase activity in nasal/olfactory epithelium than do humans) so the local exposure will be significantly lower in humans. In vitro experiments with human nasal tissue homogenates suggest that DBE metabolism in human nasal tissue is 100 to 1000 times less active than rat nasal tissue. Therefore, humans are expected to be much less sensitive. In the absence of other systemic toxicity along with the expected decrease in sensitivity of humans to olfactory responses, EPA concluded that these effects were not sufficiently adverse to be used as an endpoint for risk assessment.

As noted in Unit VI. A. above, exposed animals in repeat dose inhalation studies showed microscopic organ changes and hormonal changes in studies with DMS, DMA, and DMG. The significance of these findings is unclear because for example, the decrease in male hormone levels should result in a decrease in sperm counts, yet the opposite effect was observed. The single study showing changes in estradiol was not observed in the other two studies. Furthermore, there were no functional parameters such as estrous cycle and sperm motility or morphology affected. In addition, a reproductive study was conducted with DBE and there were no effects on fertility, viability of pups at

birth, and the ability of the mothers to lactate. For these reasons the point of departure for the risk assessment for chronic oral routes of exposure was from the 14-day oral toxicity study in rats. The NOAEL was 842 mg/kg/day and the LOAEL was 1684 mg/kg/day based on reduced weight gain and food consumption. A 1000 fold uncertainty factor was used for the chronic exposure (10X interspecies extrapolation, 10X for intraspecies variability and 10X FQPA safety factor)).

The dermal study did not result in an endpoint of concern. Adverse local olfactory effects were observed in inhalation toxicity studies; however, due to anatomical and physiological difference between study animals and humans, the effects are likely to be less severe in humans and subsequently of minimal toxicological concern. No systemic endpoint of concern was identified in the available inhalation toxicity studies; therefore, quantification of inhalation risk is not necessary.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to DMEGSA, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from DMEGSA in food as follows:

Because no acute endpoint of concern was identified, a quantitative acute dietary exposure assessment is unnecessary. In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM– FCIDTM, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What we eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008.

The Inert Dietary Exposure Evaluation Model (I-DEEM) is a highly conservative model with the assumption 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 between the active and inert ingredient (if any) 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 model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has tolerance-level residues. 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.

2. *Dietary exposure from drinking water*. For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for DMEGSA, 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 parent compound. 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., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

The majority of the current pesticidal uses (e.g., use in paints and wood products)

of DMEGSA are for industrial and commercial settings; however, DMEGSA are approved for use in textiles, as paper coatings, and in and around homes and landscapes. There are no approved antimicrobial uses of DMEGSA. Neither the dermal nor inhalation studies resulted in an endpoint of concern; therefore, there was no need to quantify dermal or inhalation exposure. Since there is potential for use of this chemical in and around homes, residential exposure was evaluated using agency approved models to estimate high end post-application oral exposures to children from treated lawns. The residential and aggregate level of concern (LOC) is for margins of exposure (MOE) that are less than 1000 and is based on 10X interspecies extrapolation, 10X for intraspecies variability, and 10X FQPA safety factor.

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 DMEGSA to share a common mechanism of toxicity with any other substances, and DMEGSA does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that DMEGSA does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. No evidence of increased susceptibility was seen in the available developmental and reproductive toxicity studies for DMEGSA and its metabolites. Depressed pup weights were observed in a one-generation reproduction inhalation toxicity study with DBE at 1.0 mg/L but were only seen in the presence of maternal toxicity. Two developmental inhalation toxicity studies were conducted, one testing DBE on rats and with DMG on rabbits. In both studies no developmental effects were observed at doses up to and including 1.0 mg/L; while maternal toxicity was observed at doses of 0.3 mg/L and above. Similarly, no adverse developmental effects were observed in oral studies on the metabolites glutaric acid (rat and rabbit) and adipic acid (rat and mice) at doses up to and including 1,300 mg/kg/day.

3. *Conclusion*. EPA concludes that the FQPA safety factor of 10X for DMEGSA should be retained because of the need to extrapolate from a subchronic study for a chronic risk assessment. In making this determination, EPA considered the following factors:

i. The toxicity database for DMEGSA and their metabolites includes several

subchronic and chronic studies, several developmental and reproductive toxicity studies, and mutagenicity studies. No chronic studies are available on DBEs; however, chronic toxicity studies on metabolites are available to characterize long term toxicity potential of DBEs.

ii. Increased incidence of delayed renal papillary development and decreased pup weights were observed in reproductive/developmental inhalation toxicity studies at 1000 mg/m^3; however, these effects were only observed in the presence of depressed maternal body weight. In addition, there were no systemic effects seen in oral studies at doses up to and including the limit dose of 1000 mg/kg/day indicating no evidence of increased susceptibility.

iii. There is no indication that DMEGSA are neurotoxic chemicals. Although no neurotoxicity studies are available in the database, no clinical signs of neurotoxicity were observed in the available subchronic and chronic studies. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

vi. The dietary food exposure assessment utilizes proposed tolerance level or higher residues and 100% CT information for all commodities. By using these screening-level assessments, chronic exposures/risks will not be underestimated.

Based on the absence of reproductive and developmental toxicity for DMEGSA in inhalation studies at maternally toxic doses, the high developmental NOAEL for glutaric acid, and the lack of neurotoxicity, there is no concern for increased sensitivity to infants and children to DMEGSA when used as an inert ingredients in pesticide formulations. However, due to the lack of a chronic oral toxicity study the 10X FQPA safety factor has

been retained to protect infants and children.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer 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 appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, DMEGSA is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to DMEGSA from food and water will utilize 83.9 % of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no current or proposed residential uses for DMEGSA at this time. Based on the explanation in this unit, regarding residential use patterns, chronic residential exposure to residues of DMEGSA is not expected.

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). A short-term adverse effect was identified; however, DMEGSA is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in short-term residential exposure. They

may, however, be used in the future as an inert ingredient in pesticide products that are 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 DMEGSA.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential oral exposures result in aggregate MOEs for children of 1450 for hand-to-mouth exposure to treated lawns. Because EPA's level of concern for DMEGSA is a MOE of 1000 or below, 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).

An intermediate-term adverse effect was identified; however, DMEGSA is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in intermediate-term residential exposure. They may, however, be used in the future pesticide products that are registered for use**s** 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 oral exposures to DMEGSA.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs for children of 1500 for hand-to-mouth exposure to treated lawns. Because EPA's level of concern for DMEGSA is a MOE of

1000 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in available studies of the metabolites of the subject chemicals and a DEREK assessment of DMEGSA which revealed no alerts, DMEGSA is not expected to pose a cancer risk to humans.

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 DMEGSA residues.

V. Other Considerations

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.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180. 910 for dimethyl glutarate (CAS Reg. No. 1119-40-0), dimethyl succinate (CAS Reg. No. 106-65-0), and dimethyl adipate (CAS Reg. No. 627-93-0) when used as inert ingredients (solvent/co-solvent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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) (2 U.S.C. 1501 *et seq.*).

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) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: December 23, 2013.

Lois Rossi,
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, alphabetically add the following inert ingredient(s) to the table to read as follows:

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

*** * * * ***

Inert ingredients	**Limits**	**Uses**
* * *	* *	* *
Dimethyl adipate (CAS no. 627-93-0)	None	Solvent/co-solvent
* * *	* *	* *
Dimethyl glutarate (CAS no. 1119-40-0)	None	Solvent/co-solvent
* * *	* *	* *
Dimethyl succinate (CAS no. 106-65-0)	None	Solvent/co-solvent
* * *	* *	* *

[FR Doc. 2013-31582 Filed 01/03/2014 at 8:45 am; Publication Date: 01/06/2014]