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).

VII. 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: September 8, 2009.

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 § 180.132 paragraph (a) is revised to read as follows:

§ 180.132 Thiram; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide thiram (tetramethyl thiuram disulfide) in or on raw agricultural commodities as follows:

Commodity	Parts per million	Expiration/revocation date
Apple	7.0	None
Banana[1]	0.80	3/31/14
Peach	7.0	None
Strawberry	7.0	None

[1] No U.S. registrations as of September 23, 2009.

* * * * *

[FR Doc. E9–22520 Filed 9–22–09; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0854; FRL–8429–7]

Meptyldinocap; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes import tolerances for combined residues of meptyldinocap, 2-(1-methylheptyl)-4,6-dinitrophenyl (2*E*)-2-butenoate and 2,4-DNOP, 2,4-dinitro-6-(1-methylheptyl)phenol expressed as meptyldinocap in or on grape. Dow AgroSciences LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 23, 2009. Objections and requests for hearings must be received on or before November 23, 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–2008–0854. 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: Mary L. Waller, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: *waller.mary @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*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0854 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 November 23, 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–2008–0854, 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. Petition for Tolerance

In the **Federal Register** of April 13, 2009 (74 FR 16866) (FRL–8396–6), 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 7E7294) by Dow AgroSciences LLC, 9330 Zionsville Rd., Indianapolis, IN 46268. The petition requested that 40 CFR part 180 be amended by establishing import tolerances for residues of the fungicide meptyldinocap, as the parent 2,4-dinitro-6-(1-methylheptyl) phenyl crotonate and the 2,4-dinitro-6-(1-methylheptyl) phenol metabolite, in or on grape; grape, juice; and grape, wine at 0.3 parts per million (ppm). That notice referenced a summary of the petition prepared by Dow AgroSciences LLC, the registrant, 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.

Based upon review of the data supporting the petition, EPA has determined that tolerances are not needed for grape, wine and grape, juice. The reason for these changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish 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.''

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 import tolerances for combined residues of meptyldinocap, 2-(1-methylheptyl)-4, 6-dinitrophenyl (2*E*)-2-butenoate and 2,4-DNOP, 2,4-dinitro-6-(1-methylheptyl)phenol expressed as meptyldinocap on grape at 0.20 ppm. 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.

Meptyldinocap is one of the six isomers found in the older fungicide dinocap (dinocap is 22% meptyldinocap and 77% remaining five isomers). Based on a comparison of the toxicological databases, EPA has determined that meptyldinocap and dinocap are toxicologically different, with meptyldinocap being less toxic. Unlike dinocap, which was teratogenic in mice and rabbits, meptyldinocap caused no developmental toxicity in any species tested. In addition, a comparison of subchronic studies in the mouse for dinocap with similar studies for meptyldinocap indicated that dinocap caused liver toxicity and death (JMPR 1998), whereas toxicity was absent with meptyldinocap following treatment for 28 days at a higher dose. Finally, the most sensitive endpoint for dinocap was ocular effects in the dog. No ocular effects were evident with meptyldinocap in a subchronic study in dogs which was extended from 90 days to 1 year specifically to determine if ocular effects were elicited.

Meptyldinocap caused no deaths following acute oral (LD_{50} >2,000 milgrams/kilograms body weight (mg/kg/bw)) or dermal (LD_{50} >5,000 (mg/kg bw)) exposures. No abnormal clinical observations were recorded following dermal exposure other than erythema/edema at the dose site at 5,000 mg/kg bw beginning on day 1 and persisting through days 4–9. Meptyldinocap is minimally irritating to the eye and slightly irritating to the skin and exhibited a skin sensitization potential under the conditions of the local lymph node assay. Short-term (90–day)

exposure of rats to meptyldinocap led to decreased body weight, body weight gain, and food consumption in both sexes at the highest dose tested (113 mg/kg bw/day). Dogs treated with low doses of meptyldinocap (approximately 4 mg/kg bw/day) for the same length of time showed evidence of hepatic toxicity, specifically as significantly increased ALT (alanine aminotransferase) and AST (aspartate aminotransferase) levels that were sustained throughout the treatment period. However, unlike the parent mixture dinocap, there was no evidence of ocular toxicity in dogs with meptyldinocap during the 90–day treatment period, or when treatment of these dogs was extended to 1 year. No adverse effects were observed in mice treated with meptyldinocap for 28 days. Meptyldinocap was tested in a number of developmental toxicity studies in several species. Unlike dinocap, which was teratogenic in mice and rabbits, meptyldinocap caused no developmental toxicity in any species tested. Meptyldinocap was negative in two *in vitro* mutagenicity studies, as well as in one *in vivo* and one *in vitro* clastogenicity assay.

Long-term toxicity studies in rodents, including carcinogenicity studies, and studies designed to assess male and female fertility were not performed with meptyldinocap. However, the hazard database for meptyldinocap, in conjunction with the dinocap hazard database, is adequate for the purposes of this action on imported grapes.

Specific information on the studies received and the nature of the adverse effects caused by meptyldinocap as well as the no-observed-adverse-effect-level and the lowest-observed-adverse-effect-level from the toxicity studies can be found at *http://www.regulations.gov* in document *Meptyldinocap (DE-126/Dinocap II): PP#7E7294. Tolerances on Fresh and Processed Imported Grapes. Human-Health Risk Assessment* at pp. 22–35 in docket ID number EPA–HQ–OPP–2008–0854.

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 meptyldinocap can be found at *http://www.regulations.gov* in document *Meptyldinocap (DE-126/DinocappII): PP# 7E7294. Tolerances on Fresh and Process Imported Grapes. Human-Health Risk Assessment* at pp. 11 in docket ID number EPA–HQ–OPP–2008–0854.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to meptyldinocap, EPA considered exposure under the petitioned-for tolerances as well as all existing dinocap tolerances in (40 CFR 180.341). EPA assessed dietary exposures from meptyldinocap in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

No such effects were identified in the toxicological studies for meptyldinocap; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the (USDA) 1994–1996 and 1998 (CSFII). As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT) for all potential sources of meptyldinocap from the proposed use on imported grapes and meptyldinocap exposure from use of dinocap on imported apples and grapes. Since 22% of technical dinocap is meptyldinocap and since the proportion of meptyldinocap in dinocap residues is unknown, the chronic analysis assumed that 100% of the dinocap residues on imported apples and grapes were meptyldinocap. Based on dinocap processing studies, the default grape juice and wine processing factors were reduced to 1. For raisin, apple juice, and dried apple, default processing factors were retained. Anticipated residue and/or PCT were not used.

iii. *Cancer*. The carcinogenic potential of meptyldinocap has not been tested. However, the parent mixture dinocap was previously classified as ''Group E, Evidence of non-carcinogenicity in humans.'' The Agency concluded that given the lack of developmental, ocular, and genetic toxicities with meptyldinocap, dinocap toxicity represents a ''worst case'' scenario relative to meptyldinocap. Therefore, the Agency concluded an exposure assessment was not necessary.

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

2. *Dietary exposure from drinking water*. There is no expectation that meptyldinocap residues would occur in surface water or ground water sources of drinking water. Meptyldinocap is proposed for use only on imported grapes, and established tolerances for dinocap are for imported grapes and apples only. The sole exposure route for the U.S. population is via food exposure. There are no registered uses of meptyldinocap or dinocap in the United States.

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).

Neither meptyldinocap nor dinocap are registered for any specific use patterns that would result in residential exposure.

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 meptyldinocap to share a common mechanism of toxicity with any other substances, and meptyldinocap does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that meptyldinocap 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 Food Quality Protection Act of 1996 (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*. There was no evidence of increased susceptibility of offspring following prenatal exposure of mice, rats, or rabbits. In both the rat and rabbit developmental toxicity studies, toxicity to offspring was not observed, whereas maternal toxicity was observed at the highest dose tested in both studies. In the non-guideline developmental toxicity studies in the mouse, meptyldinocap failed to cause either offspring or maternal toxicity in either study. One of these studies also assessed postnatal toxicity to offspring. No evidence of postnatal toxicity was observed. These results contrast with those for dinocap, which was used as a positive control in the study and caused developmental toxicity as well as adverse postnatal effects.

3. *Conclusion*. EPA has determined that an FQPA SF of 3X is necessary to protect the safety of infants and children given that the POD for estimating chronic human risk was chosen from a subchronic study. Use of a 3X SF, in the form of an uncertainty factor for subchronic-to-chronic extrapolation, with the NOAEL of 1.5 mg/kg bw/day from the 90–day toxicity study in dogs yields an effective NOAEL of 0.5 mg/kg bw/day for meptyldinocap. EPA concludes that reliable data support this FQPA SF based upon the following considerations:

i. The adjusted NOAEL for meptyldinocap is virtually identical to the NOAEL used for the (cRfD) for dinocap (0.4 mg/kg bw/day). Use of a larger SF for meptyldinocap would yield a lower point of departure than that for dinocap, which would be inappropriate, given that meptyldinocap is a significantly less toxic chemical than dinocap. Evidence showing the lower toxicity of meptyldinocap include:

Meptyldinocap is one of six isomers contained in dinocap. Toxicological studies have isolated the teratogenic isomer in dinocap, and it is not meptyldinocap.

Meptyldinocap is considered less toxic than dinocap based on the lack of developmental and ocular toxicities with meptyldinocap at approximately 5X the doses contained in dinocap.

A comparison of subchronic studies in the mouse for dinocap with similar studies for meptyldinocap indicated that dinocap caused liver toxicity and death (JMPR 1998), whereas toxicity was absent with meptyldinocap following treatment for 28 days at a higher dose.

Unlike dinocap, there is no evidence of offspring susceptibility with meptyldinocap in any of four developmental toxicity studies across three species tested. Unlike dinocap, there was no evidence of neurotoxicity or neuropathology in any of the submitted studies for meptyldinocap.

Unlike dinocap, there was no effect of treatment on mortality, clinical signs, ophthalmological examinations, or select gross or microscopic pathology in dogs treated for 1 year with meptyldinocap. The dinocap cRfD was based on a chronic study in dogs.

ii. Evidence from the meptyldinocap dog study indicates that extending exposure from subchronic to chronic would not have produced a lower NOAEL. As indicated above, the extension of the meptyldinocap dog study for an additional 9 months did not result in effects on mortality, clinical signs, ophthalmological examinations, or select gross or microscopic pathology as it did with dinocap. Moreover, while levels of serum hepatic enzymes in dogs in the meptyldinocap study were increased significantly over controls throughout the 90–day exposure period, the serum hepatic enzyme levels did not become more severe over time.

iii. Although EPA does not have toxicology studies conducted with meptyldinocap to fulfill all data requirements, EPA concludes that between the dinocap and meptyldinocap studies it has a complete database. The dinocap database was incomplete due to a lack of a developmental neurotoxicity study but such a study is not needed for meptyldinocap because there was no evidence of neurotoxicity or neuropathology in any of the submitted studies for meptyldinocap. These results contrast with those of dinocap in which minor neuropathology was noted in dogs treated with dinocap as a positive control for 90 days. EPA began requiring acute and subchronic neurotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement went into effect after the tolerance petition was submitted, these studies are not yet available for meptyldinocap. In the absence of specific neurotoxicity studies, EPA has evaluated the available toxicity data to determine whether an additional database uncertainty factor is needed to account for potential neurotoxicity. Given the lack of neurotoxicity or neuropathology in any meptyldinocap studies, EPA does not believe that conducting acute or subchronic neurotoxicity testing will result in a NOAEL less than 1.5 mg/kg/day already established for the cRfD for meptyldinocap, and an additional uncertainty factor is not needed to account for the lack of these data. Immunotoxicity testing is also required as a result of changes made to the pesticide data requirements in December of 2007. An immunotoxicity study has not been conducted with meptyldinocap. However, an *in vivo* immunotoxicity study with additional *in vitro* measurements (Smialowicz, et al., 1992) has been conducted with dinocap in mice and published in the open literature. Immune function, cellularity, organ weights, and histopathology were measured over several doses in the study. Immunotoxicity was observed at a thirtyfold higher dose than the effective NOAEL used to calculate the cRfD for meptyldinocap. Because a well conducted immunotoxicity study with dinocap was performed previously, and

since meptyldinocap is considered less toxic than dinocap, the requirement for an immunotoxicity study with meptyldinocap has been satisfied by the literature study with dinocap.

iv. There is no evidence of offspring susceptibility with meptyldinocap in any of four developmental toxicity studies across three species tested.

v. There are no residual uncertainties identified in the exposure database for meptyldinocap. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues as well as a very conservative assumption of what meptyldinocap exposure could occur from use of dinocap. No exposure to meptyldinocap in drinking water or from residential use is expected because neither meptyldinocap or dinocap is registered for use in the United States. The exposure assessment will not underestimate the exposure and risks posed by meptyldinocap.

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.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute 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, meptyldinocap 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 meptyldinocap from food will utilize 35% of the cPAD for (children 1 to 2 years old) the population group receiving the greatest exposure. There are no proposed or existing residential uses of meptyldinocap, and exposure through drinking water is not expected. Therefore, dietary risk represents the aggregate risk and does not exceed the Agency's LOC.

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).

Meptyldinocap is not registered for any use patterns that would result in residential exposure and exposure through drinking water is not expected. Therefore, the short-term aggregate risk is the sum of the risk from exposure to meptyldinocap in food which does not exceed the Agency's LOC.

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).

Meptyldinocap is not registered for any use patterns that would result in intermediate-term residential exposure and exposure through drinking water is not expected. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to meptyldinocap in food which does not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population*. Based on structural similarities and the demonstrated lower toxicity of meptyldinocap as compared to dinocap, the cancer classification of Group E—Evidence of non-carcinogenicity in humans for dinocap was extended to meptyldinocap.

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 meptyldinocap residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no currently established Codex, Canadian, or Mexican maximum residue limits for meptyldinocap on grapes. Therefore, harmonization is not an issue.

C. Revisions to Petitioned-For Tolerances

The Agency is not establishing tolerances on grape juice and wine because dinocap grape processing studies indicated that residues are reduced in juice and wine (0.15X). The Agency believes that due to structural similarities, dinocap and meptydinocap will partition in a similar manner during processing. Therefore, separate grape juice and wine tolerances are unnecessary.

V. Conclusion

Therefore, tolerances are established for combined residues of meptyldinocap, 2-(1-methylheptyl)-4,6-dinitrophenyl (2*E*)-2-butenoate and 2,4-DNOP, 2,4-dinitro-6-(1-methylheptyl)phenol expressed as meptyldinocap in or on grapes at 0.20 ppm.

VI. 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).

VII. 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: September 9, 2009.

Steven Bradbury,

Acting Director, Office of Pesticides Program.

■ 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. Section 180.648 is added to subpart C to read as follows:

§180.648 Meptyldinocap; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide meptyldinocap, 2-(1-methylheptyl)-4,6-dinitrophenyl (2E)-2-butenoate and 2,4-DNOP, 2,4-dinitro-6-(1-methylheptyl)phenol expressed as meptyldinocap in or on the following commodities:

Commodity	Parts Per Million
Grape	0.20

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. E9–22523 Filed 9–22–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0003; FRL–8436–7]

Halosulfuron-methyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of halosulfuron-methyl and its metabolites and degradates, in or on soybean, seed. Canyon Group, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 23, 2009. Objections and requests for hearings must be received on or before November 23, 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–2009–0003. 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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