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: October 31, 2008.

**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. Section 180.449 is amended by alphabetically adding a commodity to the table in paragraph (b) to read as follows:

**§ 180.449 Avermectin $B_1$ and its delta-8,9-isomer; tolerances for residues.**

* * * * *

(b) * * *

| Commodity | Parts per million | Expiration/revocation date |
|---|---|---|
| bean, lima, seed | 0.005 | 12/31/10 |
| * * * * * | | |

* * * * *

[FR Doc. E8–26876 Filed 11–12–08; 8:45 am]
**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2007–0945; FRL–8387–1]**

## MCPB; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of free and conjugated MCPB and its metabolite MCPA in or on peppermint, tops and spearmint, tops. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective November 12, 2008. Objections and requests for hearings must be received on or before January 12, 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–2007–0945. 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 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 pilot e-CFR site 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–2007–0945 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 January 12, 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–2007–0945, 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 October 24, 2007 (72 FR 60369) (FRL–8150–8), 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 7E7257) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.318 be amended by establishing a tolerance for residues of the herbicide MCPB, 4-(2-methyl-4-chlorophenoxy) butyric acid, in or on mint tops (leaves and stems) at 0.25 parts per million (ppm). That notice referenced a summary of the petition prepared by Nufarm, Inc., the registrant, on behalf of IR–4, 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 revised the commodity terms and tolerance level. EPA has also revised the tolerance expression to include combined residues of free and conjugated MCPB and its metabolite MCPA. The reasons for these changes are explained in Unit IV.C.

## 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 tolerances for combined residues of free and conjugated MCPB and its metabolite MCPA on peppermint, tops and spearmint, tops 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.

The currently available toxicological database for MCPB is limited; thus it was supplemented with data on the closely related compound, 4-(chloro-2-methylphenoxy)acetic acid (MCPA). Structurally, MCPB and MCPA differ only in that MCPB contains two additional carbon atoms. In both animal and plant metabolism studies, the data indicate that MCPB is readily converted to MCPA. Therefore, EPA has concluded that the toxicity of these compounds is similar at sub-lethal dose levels.

MCPB has low to moderate acute toxicity via the oral, dermal and inhalation routes of exposure. It is mildly to moderately irritating to the eye but is not a dermal irritant or skin sensitizer. In longer-term studies, nephrotoxicity and hepatotoxicity appear to be the most prevalent hazard concerns for MCPB, based on the effects seen throughout the MCPA database and the limited toxicity data set available for MCPB. Signs of neurotoxicity (decreased arousal, impaired coordination and gait, reduced motor activity and reduced grip strength) were also reported after MCPB or MCPA exposure. Developmental and reproduction toxicity studies conducted with MCPB and/or MCPA did not indicate an enhanced sensitivity or susceptibility of the young, as developmental effects (delayed ossifications and decreased fetal or pup body weight) occurred at the same doses eliciting toxicity in the parental animals (mortality, decreased body weight, body weight gain and food consumption and increased absolute and relative ovary weights). MCPB and MCPA have been classified as ''not likely to be carcinogenic to humans'' based on the absence of increased numbers of tumors in the rat and mouse carcinogenicity studies and no evidence of mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by MCPB and MCPA, 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 the document *4-(4-chloro-2-methylphenoxy)butanoic acid (MCPB)*; *Human-Health Risk Assessment for Proposed Section 3 New Use on Mint*, page 29 in docket ID number EPA–HQ–OPP–2007–0945.

*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 MCPB used for human risk assessment is shown in the following Table.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MCPB FOR USE IN HUMAN RISK ASSESSMENT

| Exposure/Scenario | Point of Departure and Uncertainty/Safety Factors | RfD, PAD, LOC for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Acute dietary (General population including infants and children; and females 13–50 years of age) | NOAEL = 200 milligrams/kilograms/day (mg/kg/day)<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 10x ($UF_{DB}$) | Acute RfD = 0.2 mg/kg/day<br>aPAD = 0.2 mg/kg/day | Acute neurotoxicity (MCPA), rat<br>LOAEL = 400 mg/kg/day based on gait impairment in males |
| Chronic dietary (All populations) | NOAEL= 4.4 mg/kg/day<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 10x ($UF_{DB}$) | Chronic RfD = 0.0044 mg/kg/day<br>cPAD = 0.0044 mg/kg/day | Chronic toxicity (MCPA), rat<br>LOAEL = 17.6 mg/kg/day based on liver and kidney toxicity. |
| Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months) | Dermal study<br>NOAEL = 25 mg/kg/day<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 | 21-Day dermal toxicity (MCPA), rabbit<br>NOAEL = 100<br>LOAEL = 1,000 mg/kg/day based on kidney toxicity and decreased body weight gain<br>Dermal absorption of MCPB is 4x that of MCPA. |
| Dermal long-term (> 6 months) | Oral study<br>NOAEL = 4.4 mg/kg/day (dermal absorption rate = 31%)<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 | Chronic toxicity (MCPA), rat<br>LOAEL = 17.6 mg/kg/day based on liver and kidney toxicity. |
| Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months) | Oral study<br>NOAEL= 5 mg/kg/day (inhalation absorption rate = 100%)<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 | Developmental toxicity (MCPB), rabbit<br>LOAEL = 20 mg/kg/day based on maternal mortality |
| Inhalation long-term (> 6 months) | Oralstudy NOAEL = 4.4 mg/kg/day (inhalation absorption rate = 100%)<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 | Chronic toxicity (MCPA), rat<br>LOAEL = 17.6 mg/kg/day based on liver and kidney toxicity |

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MCPB FOR USE IN HUMAN RISK ASSESSMENT—Continued

| Exposure/Scenario | Point of Departure and Uncertainty/Safety Factors | RfD, PAD, LOC for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Cancer (oral, dermal, inhalation) | Classification: Not likely to be carcinogenic to humans. | | |

$UF_A$ = extrapolation from animal to human (interspecies). $UF_H$ = potential variation in sensitivity among members of the human population (intraspecies). $UF_L$ = use of a LOAEL to extrapolate a NOAEL. $UF_S$ = use of a short-term study for long-term risk assessment. $UF_{DB}$ = to account for the absence of data or other data deficiency. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

*C. Exposure Assessment*

While the Agency has concluded that MCPB converts to MCPA in the environment, and that MCPA may be present in crops, residues of MCPA resulting from the existing use of MCPB on peas and the new use on mint are expected to be negligible, and significantly below analytical method limits of detection. These residues will not contribute significantly to the aggregate exposure to MCPA from other sources, and, therefore, EPA did not conduct an aggregate assessment combining MCPA exposures from MCPA and MCPB uses. The exposure assessments presented here are for MCPB only. A discussion of aggregate risks associated with MCPA can be found in the MCPA Reregistration Eligibility Decision (RED), available on the Office of Pesticide Programs web site at *http://www.epa.gov/oppsrrd1/REDs/mcpa_red.pdf*

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to MCPB, EPA considered exposure under the petitioned-for tolerances as well as the existing MCPB tolerance in 40 CFR 180.318 on peas, the only commodity for which a tolerance currently exists. EPA assessed dietary exposures from MCPB 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.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed that all pea and mint commodities contain tolerance-level residues and that 100 percent of pea and mint commodities are treated with MCPB.

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 in the acute exposure assessment, EPA assumed tolerance-level residues and 100 percent crop treated (PCT) for all pea and mint commodities.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA classified MCPB as ''not likely to be carcinogenic to humans.'' Therefore, an exposure assessment for evaluating cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue or PCT information in the dietary assessment for MCPB. 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 MCPB in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of MCPB. 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*.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of MCPB for acute exposures are estimated to be 54.7 parts per billion (ppb) for surface water and 2.1 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are estimated to be 13.5 ppb for surface water and 2.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 54.7 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 13.5 ppb was used to assess the contribution to drinking water.

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).

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

*D. Safety Factor for Infants and Children*

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

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology database for MCPB includes rat and rabbit developmental toxicity studies; for MCPA it includes rat and rabbit developmental toxicity studies and a 2-generation reproduction toxicity study in rats. There was no evidence of increased quantitative or qualitative susceptibility of fetuses or offspring to MCPA or MCPB exposure in any of these studies. In the developmental rat studies with MCPB and MCPA, decreased ossification and decreased fetal body weights occurred at the same dose causing maternal effects (decreased body weight gain and food consumption). No toxicity to fetuses occurred in the MCPB and MCPA rabbit developmental studies at doses resulting in maternal toxicity (mortality, decreased body weight and food consumption). In the rat reproduction study for MCPA, the only offspring toxicity was decreased weight gain while nursing, which occurred at the same dose causing maternal toxicity (increased absolute and relative ovary weights).

3. *Conclusion*. EPA has determined that the FQPA safety factor of 10X must be retained as a database uncertainty factor for MCPB acute and chronic risk assessments. This decision is based on the following findings:

i. The toxicity database for MCPB is not complete. Additional data pertaining to MCPB's potential to cause developmental neurotoxicity (DNT) or immunotoxicity are outstanding. EPA's assessment of the uncertainties arising from these data deficiencies follows:

a. *Developmental neurotoxicity:* EPA has required a developmental neurotoxicity study to be submitted because neurotoxicity was found in acute and subchronic neurotoxicity studies with MCPA in rats (decreased arousal, impaired coordination and gait, reduced motor activity, reduced grip strength), and similar signs of neurotoxicity can be expected with MCPB. The neurotoxic effects seen in the acute neurotoxicity studies were the most sensitive acute effect identified and therefore were used in calculating the aRfD for MCPB. Given these findings of neurotoxicity and sensitivity of the neurotoxic effects, EPA has concluded that it lacks reliable data to remove the FQPA 10X safety factor.

b. *Immunotoxicity:* EPA began requiring functional immunotoxicity testing (series 870.7800) of all food and non-food use pesticides on December 26, 2007. Since the requirement went into effect after this tolerance petition was submitted, these studies are not yet available for MCPB. In the absence of specific immunotoxicity studies, EPA has evaluated the available toxicity data for MCPB and MCPA regarding potential immunotoxic effects. Evidence of potential immunotoxicity was observed in subchronic 28–day oral toxicity studies in the mouse and dog with MCPA. Involution of the spleen due to lymphocytic depletion was observed in both sexes at the highest dose tested (HDT) and LOAEL of 453.7/223.9 milligrams kilogram day (mg/kg/day) male/female (M/F) in the mouse, and decreased thymus weights were seen in the dog at a dose of 30 mg/kg/day HDT. Lymphoid depletion was observed in the subchronic toxicity study in the dog at a dose of 44 mg/kg/day (HDT) of MCPB. The NOAEL in the mouse and dog for potential immunotoxic effects was 173.4/69.2 mg/kg/day M/F and 20 mg/kg/day, respectively. The NOAEL being used for calculation of the chronic reference dose (cRfD) is 4.4 mg/kg/day. The NOAEL from the mouse study (173.4/69.2 mg/kg/day (M/F)) provides the more appropriate reference for evaluating potential immunotoxic effects in humans. Unlike rodents and humans, dogs are uniquely sensitive to the toxic effects of chlorophenoxy compounds such as MCPB due to their decreased ability to excrete organic acids, and thus the effect levels in the mouse are more relevant to potential immunotoxicity in humans.

After weighing this evidence, EPA retains significant uncertainty regarding potential neurotoxic effects in infants and children but does not have such concerns for immunotoxicity. The immunotoxic effects with most relevance to humans had a NOAEL over 10X greater than the NOAEL used in establishing the cRfD. On the other hand, neurotoxic effects were the most sensitive acute effects seen in the database. Additionally, the DNT study specifically addresses potential risks to developing animals. Given these considerations, EPA has concluded that it lacks reliable data to remove the FQPA children's safety factor.

ii. There is no evidence that MCPB or MCPA results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumption's in the ground and surface water modeling used to assess exposure to MCPB in drinking water, and residential exposures are not expected. These assessments will not underestimate the exposure and risks posed by MCPB.

*E. Aggregate Risks and Determination of Safety*

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

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to MCPB will occupy 5.4% of the aPAD for infants, less than one year old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to MCPB from food and water will utilize 22% of the cPAD for infants, less than one year old, the population group receiving the greatest exposure. There are no residential uses for MCPB.

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). MCPB is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to MCPB through food and water and will not be greater than the chronic aggregate risk.

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). MCPB is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to MCPB through food and

water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population*. EPA has classified MCPB into the category ''Not Likely to be Carcinogenic to Humans''. MCPB is not expected to pose a cancer risk.

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 MCPB residues.

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (Gas chromatography/Mass Spectrometry) 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 established or proposed Codex, Canadian, or Mexican maximum residue limits (MRLs) for MCPB.

### *C. Revisions to Petitioned-For Tolerances*

IR–4 proposed a tolerance for residues of MCPB *per se* on mint tops (leaves and stems) at 0.25 ppm. EPA has determined that separate tolerances at 0.20 ppm should be established for combined residues of free and conjugated MCPB (4-(4-chloro-2-methylphenoxy)butanoic acid) and MCPA (4-chloro-2-methylphenoxy)acetic acid) on the commodities ''spearmint, tops'' and ''peppermint, tops. The commodity terms were revised to agree with the preferred commodity terms in the Agency's Food and Feed Commodity Vocabulary. EPA determined the appropriate tolerance level for mint tops based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the *Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data*. Finally, EPA revised the residues of concern to be included in the tolerance expression based on the results of plant metabolism studies.

## V. Conclusion

Therefore, tolerances are established for combined residues of free and conjugated MCPB and MCPA in or on peppermint, tops and spearmint, tops 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: October 31, 2008.

**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. Section 180.318 is amended in paragraph (a) by redesignating the existing text as paragraph (a)(1) and by adding paragraph (a)(2) to read as follows:

### 180.318 4-(2-Methyl-4-chlorophenoxy) butyric acid; tolerances for residues.

(a) *General.* (1) * * *

(2) Tolerances are established for the combined residues, free and conjugated, of the herbicide MCPB, 4-(4-chloro-2-methylphenoxy)butanoic acid, and its metabolite MCPA, (4-chloro-2-methylphenoxy)acetic acid, in or on the following food commodities:

| Commodity | Parts per million |
|---|---|
| Peppermint, tops | 0.20 |
| Spearmint, tops | 0.20 |

* * * * *

[FR Doc. E8–26875 Filed 11–10–08; 8:45 am]
**BILLING CODE 6560–50–S**

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

### 49 CFR Parts 571 and 585

**[Docket No. NHTSA–08–0168]**

**RIN 2127–AK02**

## Federal Motor Vehicle Safety Standards; Occupant Crash Protection

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** NHTSA is amending Federal Motor Vehicle Safety Standard (FMVSS) No. 208, ''Occupant crash protection,'' to update many of the child restraint systems (CRSs) listed in Appendix A of the standard. The CRSs in Appendix A are used by NHTSA to test advanced air bag suppression or low risk deployment systems, to ensure that the air bag systems pose no reasonable safety risk to infants and small children in the real world. The amendments replace the CRSs listed in Appendix A with CRSs that are more available and more representative of the CRS fleet currently on the market.

**DATES:** If you wish to petition for reconsideration of this rule, your petition must be received by December 29, 2008.

*Effective date:* The date on which this final rule amends the CFR is January 12, 2009.

This final rule adopts a one-year phase-in of the requirement to test with the child restraints in the revised Appendix A. Under the phase-in, 50 percent of vehicles manufactured on or after September 1, 2009 must be certified as meeting FMVSS No. 208 when tested with the CRSs on the revised Appendix A, and all vehicles manufactured on or after September 1, 2010 must be so certified.

**ADDRESSES:** If you wish to petition for reconsideration of this rule, you should refer in your petition to the docket number of this document and submit your petition to: Administrator, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., West Building, Washington, DC 20590.

The petition will be placed in the docket. Anyone is able to search the electronic form of all documents received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

**FOR FURTHER INFORMATION CONTACT:** Carla Cuentas, Office of Crashworthiness Standards, Light Duty Vehicle Division (telephone 202–366–4583, fax 202–493–2739). For legal issues, contact Deirdre Fujita, Office of Chief Counsel (telephone 202–366–2992, fax 202–366–3820). You may send mail to these officials at the National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building, Washington, DC 20590.

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This final rule amends FMVSS No. 208 to update the child restraint systems (CRSs) listed in Appendix A of the standard. The notice of proposed rulemaking (NPRM) preceding this final rule was published on September 25, 2007 (72 FR 54402; Docket 2007–28710).

## I. Background

FMVSS No. 208 (49 CFR 571.208) requires passenger cars and trucks, buses, and multipurpose passenger vehicles with a gross vehicle weight rating (GVWR) of 3,856 kilograms (kg) (8,500 pounds (lb)) or less and an unloaded vehicle weight of 2,495 kg (5,500 lb) or less to be equipped with seat belts and frontal air bags for the protection of vehicle occupants in crashes. While air bags have been very effective in protecting people in moderate and high speed frontal crashes, there have been instances in which they have caused serious or fatal injuries to occupants who were very close to the air bag when it deployed. On May 12, 2000, NHTSA published a final rule to require that air bags be designed to create less risk of serious air bag-induced injuries and provide improved frontal crash protection for all occupants, by means that include advanced air bag technology (''Advanced Air Bag Rule,'' 65 FR 30680, Docket No. NHTSA 00–7013). Under the Advanced Air Bag Rule, to minimize the risk to infants and small children from deploying air bags, manufacturers may suppress an air bag in the presence of a CRS or provide a low risk deployment (LRD) system.[1]

[1] The LRD option involves deployment of the air bag in the presence of a Child Restraint Air Bag Interaction (CRABI) test dummy, representing a 12-month-old child, in a rear-facing child restraint.