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).

XI. 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: June 30, 2010.

Martha Monell,
Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

§180.1296 Terpene Constituents α-terpinene, d-limonene and p-cymene, of the Extract of Chenopodium ambrosioides near ambrosioides as Synthetically Manufactured; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of the biochemical pesticide Terpene Constituents α-terpinene, d-limonene and p-cymene, of the Extract of Chenopodium ambrosioides near ambrosioides as Synthetically Manufactured when used as an insecticide/acaricide in or on all food commodities.

SUPPLEMENTARY 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:

• 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 provides 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 Get Electronic Access to Other Related Information?


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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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–2007–1187 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 September 7, 2010. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2007-1187, by one of the following methods:

- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the Federal Register of February 13, 2008 (73 FR 38312) (FRL–8349–2), 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 tolerance petition (PP 7F7296) by Repar Corporation, 8070 Georgia Avenue, Suite 209, Silver Spring, MD 20910. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of homobrassinolide. This notice referenced a summary of the petition prepared by the petitioner, Repar Corporation, which is available in the docket, http://www.regulations.gov. Comments were received on the notice of filing. EPA’s response to these comments is discussed in Unit VII.C.

Section 408(c)(2)(A)(ii) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(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. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require 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....” Additionally, section 408(b)(2)(D) of FFDCA requires that EPA consider “available information concerning the cumulative effects of a particular pesticide’s residues and other substances that have a common mechanism of toxicity.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information 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.

A. Overview of Homobrassinolide

The active ingredient, homobrassinolide, is a plant growth regulator that is a synthesized homologue of brassinolide, a naturally occurring brassinosteroid. Brassinosteroids are a group of steroidal plant hormones that were discovered in 1973, when it was shown that pollen from rapeseed (Brassica napus) could promote stem elongation and cell division and that the biologically active molecule was a steroid. Brassinosteroids are ubiquitously distributed in the plant kingdom. Since their discovery, over 70 brassinosteroids have been isolated from plants. The occurrence of these steroids has been demonstrated in various plant parts, such as pollen, flower buds, fruit seeds, vascular cambium, leaves, shoots, and roots. Studies on higher plants suggest that these steroids play a critical role in a range of developmental processes (i.e., stem elongation, root growth, floral initiation, etc.).

B. Biochemical Pesticide Human Health Assessment Data Requirements

1. Acute Toxicity. Tier I acute toxicity studies showed that homobrassinolide is a Toxicity Category IV (low toxicity) compound via oral and inhalation routes of exposure and a Toxicity Category III (slightly toxic) compound for dermal and eye exposures. Moreover, homobrassinolide is neither a skin irritant nor a dermal sensitizer. Given the results of these studies, no additional toxicity (i.e., Tiers II or III) or residue data are required to support food uses of this biochemical active ingredient.

i. The acute oral median lethal doses (LD₅₀) for homobrassinolide in rats and mice were greater than 5,000 milligrams per kilogram (mg/kg) and confirmed negligible toxicity through oral exposure (Master Record Identification Numbers [MRID Nos.] 47185118 and 47208903). Homobrassinolide is classified as Toxicity Category IV for acute oral toxicity.

ii. The acute dermal median lethal dose (LD₅₀) for homobrassinolide in rats was over 2,000 mg/kg, which confirmed low dermal toxicity (Master Record Identification Number [MRID No.] 47185120). Homobrassinolide is classified as Toxicity Category III for acute dermal toxicity.

iii. The acute inhalation median lethal concentration (LC₅₀) was greater than 2.26 milligrams per liter (mg/L) in rats and showed practically no inhalation toxicity or irritation (MRID No. 47185121). Homobrassinolide is classified as Toxicity Category IV for acute inhalation toxicity.

iv. An acute eye study showed that exposure to homobrassinolide will cause temporary mild eye irritation (MRID No. 47185122). As such, EPA has determined that homobrassinolide is Toxicity Category III for acute eye irritation. Acute dermal irritation and skin sensitization studies showed that homobrassinolide is non-irritating and not a sensitizer to the skin (MRID Nos. 47185123 and 47185124). EPA has determined that homobrassinolide is Toxicity Category IV for both dermal irritation and dermal sensitization.
These acute toxicity studies, submitted to support the registration of one manufacturing-use product containing homobrassinolide, confirm a low toxicity profile.

2. Subchronic Toxicity. i. The submitted 90–day oral toxicity (MRID No. 47208906) study showed that test animals did not exhibit any clinical signs of toxicity that were statistically different from untreated controls. There were no significant changes in organ weights (e.g., thymus and spleen) or differential white blood cell counts of the treated animals during the 90–day study period, which would indicate potential interference with normal immune function. The 90–day oral feeding no observable effect level (NOEL) for Homobrassinolide Technical was 1,000 milligrams per kilogram per day. Based on the review of these data, EPA concluded that no subchronic oral toxicity is expected to occur when this compound is used in accordance with good agricultural practices.

ii. Submission of 90–day dermal toxicity data was waived by EPA (MRID No. 47185136) for primarily two reasons. First, dermal metabolism of homobrassinolide is not expected to differ from its oral metabolism. Acute guideline studies demonstrated that homobrassinolide has a low dermal toxicity (LD₅₀ >2,000 mg/kg), was not a dermal irritant, and was not a dermal sensitizer. In addition, prolonged human dermal exposure is remote as brassinosteroids are readily metabolized by plants to inactive forms and, therefore, the application of homobrassinolide to crop plants as a plant growth stimulant is unlikely to increase levels of brassinosteroids in the treated plants. Brassinosteroids are present in all plants, resulting in ubiquitous exposure to humans and other organisms though the food chain without causing harm.

iii. Submission of 90–day inhalation toxicity data was also waived. The acute inhalation toxicity study demonstrates homobrassinolide’s lack of toxicity (Toxicity Category IV) and there is no anticipated repeated inhalation exposure under the conditions of product use at a concentration that could be toxic (MRID No. 47185137).

3. Developmental Toxicity and Mutagenicity. Based on in vivo studies using oral applications of homobrassinolide, the active ingredient did not have the potential to induce chromosome aberrations in mice treated up to a single oral dose of 2,000 mg/kg body weight. The active ingredient did not have micronucleus induction potential in mice after two days of oral dosing up to a level of 2,000 mg/kg body weight. Thus, homobrassinolide is non-mutagenic to mice (MRID No. 47208905). In vitro studies demonstrated that treatment with 100 and 1,000 mg/kg body weight of homobrassinolide did not result in mortality or overt signs of toxicity for pregnant rats during the observation period. Body weight changes in the groups of test substance treated dams were statistically similar to controls and no significant changes were observed in the weights of ovary and fetuses. The test further showed that there were no significant changes in the uterine weights, as well as, no test related recurrent visceral and skeletal malformations when compared to controls. Based on these findings it appears that homobrassinolide is non-teratogenic to Wistar rats at the dose levels of 100 and 1000 mg/kg of bodyweight (MRID No. 47185132).

As a result of the findings in these studies, EPA concludes that homobrassinolide is not mutagenic or genotoxic.

C. References


IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. Food. The primary route of homobrassinolide exposure to the general population is expected to be through consumption of food. Dietary exposure to homobrassinolide from application/use as a plant growth regulator is expected to be minimal, assuming use consistent with the labeling and use of good agricultural practices. The approved label allows a maximum application rate of 20 grams of active ingredient per acre per application. In addition, homobrassinolide is present in all plants, resulting in ubiquitous exposure to humans and other organisms through the food chain without causing harm.

The endogenous levels of brassinosteroids are in parts per million or parts per billion (e.g., brassinosteroid levels in pollen have been measured at 200 parts per billion). The 20 grams per acre of homobrassinolide from application/use as a plant growth regulator is not expected to increase natural levels of brassinosteroids in treated plants. This is because the homobrassinolide applied/used as a crop plant will be metabolized as the plant grows.

2. Drinking water exposure. No significant drinking water exposure or residues are expected to result from the use of homobrassinolide as a plant growth regulator. The active ingredient is intended for use as a foliar application on food commodities and is not to be applied directly to water. If used in accordance with EPA-approved labeling and good agricultural practices, homobrassinolide is not likely to accumulate in drinking water. Furthermore, it is doubtful that homobrassinolide concentrations in water would exceed levels that are currently ubiquitous to plants. Although fate information is not available on homobrassinolide, the compound is not soluble in water (water solubility 3.18%), and the log Pow = 3.96 suggests both moderate binding to soil and a low probability of ground water contamination. Overall, drinking water exposure to residues of homobrassinolide is expected to be minimal.

B. Other Non-Occupational Exposure

The potential for non-dietary exposure of the general population, including infants and children, is limited based on the use patterns of homobrassinolide. Non-dietary exposures would not be expected to pose any quantifiable risk to the general population.

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

VI. Determination of Safety for the United States Population, Infants, and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold 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 unless EPA determines that a different margin of safety will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessments either directly or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

Based on the results of the toxicological data discussed in Unit III., as well as all other available information, EPA concludes that there is a reasonable certainty that no harm will result to the United States population, including infants and children, from aggregate exposure to the residues of homobrassinolide. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion based on the low level of toxicity of the compound, the minimal exposure from application/use of homobrassinolide as a plant growth regulator, the ubiquitous nature of brassinosteroids in the plant kingdom, and the already widespread exposure to these plant steroids without any reported adverse effects on human health. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply in this instance.

VII. Other Considerations

A. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for homobrassinolide.

B. Response to Comments

A notice of receipt of the application for registration of a pesticide product containing homobrassinolide (a new active ingredient) was published in the Federal Register and opened a 30–day comment period (73 FR 8312, February 13, 2008). Two comments were received following this publication, but neither comment was related to the registration of homobrassinolide as a new active ingredient (i.e., both referenced a pesticide product apparently associated with another active ingredient) nor provided any substantive basis, such as data or other available information, supporting their respective positions or calling into question any of EPA’s risk assessments.

VIII. Conclusions

The Agency concludes that there is a reasonable certainty that no harm will result to the United States population, including infants and children, from aggregate exposure to residues of homobrassinolide applied/used as a plant growth regulator in accordance with good agricultural practices.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption 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 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 exemption 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).

X. 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: June 14, 2010.

Steven Bradbury,
Director, 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:


2. Section 180.1297 is added to subpart D to read as follows:

§180.1297 Homobrassinolide; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of homobrassinolide in or on all food commodities when applied/used as a plant growth regulator in accordance with good agricultural practices.

Dated: June 14, 2010.

Steven Bradbury,
Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows: