EPA lacks the discretionary authority to address environmental justice in this rulemaking.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 the rule in the Federal Register. A major rule cannot take effect until 60 days after it is published in the Federal Register. This action is not a “major rule” as defined by 5 U.S.C. section 804(2). This rule will be effective on August 26, 2011.

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 26, 2011. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section C, as adopted on February 8, 1993).

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 180
Carboxymethyl Guar Gum Sodium Salt and Carboxymethyl-Hydroxypropyl Guar; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of carboxymethyl guar gum sodium salt (CAS Reg. No. 39346–76–4) and carboxymethyl-hydroxypropyl guar (CAS Reg. No. 68130–15–4); when used as an inert ingredient (thicker/drift reduction agent) in pesticide formulations applied to growing crops. SciReg Inc., on behalf of Rhodia Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of carboxymethyl guar gum sodium salt and carboxymethyl-hydroxypropyl guar.

DATES: This regulation is effective July 27, 2011. Objections and requests for hearings must be received on or before September 26, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 177 (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–2011–0531 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: Alganesh Debesai, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8353; e-mail address: debesai.alganesh@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:

• 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, 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–2011–0531 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 26, 2011. 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–2011–0531, 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. Petition for Exemption

In the Federal Register of February 4, 2011 (76 FR 6467) (FRL–8858–7), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petitions (PP 0E7784) under docket ID number EPA–HQ–OPP–2010–0878 and (PP 0E7803) under docket ID number EPA–HQ–OPP–2010–1019 by SciReg Inc., on behalf of Rhodia Inc., 12733 Director’s Loop, Woodbridge VA 22192. The petitions requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of carboxymethyl guar gum sodium salt (CAS Reg. No. 39346–76–4) and carboxymethyl-hydroxypropyl guar (CAS Reg. No. 68130–15–4); when used as an inert ingredient (thicker/ drift reduction agent) in pesticide formulations applied to growing crops. Those notices referenced a summary of the petitions prepared by SciReg Inc., on behalf of Rhodia Inc., the petitioner, which is available in the docket, http://www.regulations.gov. Comments were received on both notices of filing. EPA’s response to these comments is discussed in Unit V.C.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own):

- Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth: thickeners such as carrageenan and modified cellulose: wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue and all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.”

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

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure of carboxymethyl guar gum sodium and carboxymethyl-hydroxypropyl guar including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with carboxymethyl guar gum sodium and carboxymethyl-hydroxypropyl guar follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific data, the studies reviewed and the nature of the adverse effects caused by carboxymethyl guar gum sodium and
carboxymethyl-hydroxypropyl guar as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The following provides a brief summary for the risk assessment and conclusions for the Agency’s review for the guar gums, which include carboxymethyl guar gum sodium and carboxymethyl-hydroxypropyl guar. The Agency’s full decision document for this action is available in the Agency’s electronic docket (regulations.gov) under the docket number EPA–HQ–OPP–2011–0531. Based upon the structural similarities between carboxymethyl guar gum, carboxymethyl-hydroxypropyl guar, guar gum, and hydroxypropyl guar, the risk assessment for carboxymethyl guar and carboxymethyl-hydroxypropyl guar relies upon available data on all four substances.

Acute oral toxicity studies conducted with guar, hydroxypropyl guar, and carboxymethyl guar resulted in oral LD₅₀ values ranging from 7,060 milligrams per kilogram of body weight (mg/kg bw) to 17,800 mg/kg bw. Dermal irritation studies conducted with guar, hydroxypropyl guar, and carboxymethyl guar resulted in no irritation to slight irritation. Eye irritation studies conducted with guar, hydroxypropyl guar, and carboxymethyl-hydroxypropyl guar demonstrated a range of results from non-irritation to severe irritation. Results of skin sensitization and mutagenicity studies conducted with guar gum, hydroxypropyl guar, and carboxymethyl-hydroxypropyl guar were all negative. There are three 90-day toxicity studies available for guar gums. In one study, the LOAEL of guar gum in a diet was 1% (equivalent to 580 mg/kg/day) based on effects on body weight gains, and dose related decrease in kidney weights. The NOAEL was not established in this study. In the second study, no effects were observed in male rats at doses up to 6% (equivalent to 3,000 mg/kg/day). In the third study in rats, decreased in body weight gains, decreased in food efficiency, increased in blood urea nitrogen and thyroid toxicity (males only) were observed at a dietary concentration of 2 and 5%. The NOAEL in this study was 1% (equivalent to 500 mg/kg/day). No adverse effects were reported in dogs that were fed 0, 1, 5, or 10% (approximately 0, 250, 1,250, or 2,500 mg/kg/day) of a precooked mixture of guar and carob bean for 30 weeks. No effects were observed in monkeys that were fed 1 gram (equal to 10 mg/kg/day) of guar flour for 2 months. Teratogenicity studies with guar gum in mice, rats, and hamsters did not indicate that guar gum is a teratogen; in mice at doses up to 800 mg/kg/day, in rats up to 900 mg/kg/day and in hamsters up to 600 mg/kg/day. Male and female Osborne-Mendel rats were fed guar gum at 0, 1, 2, 4, 7, 5, or 15% (approximately 0, 500, 1,000, 2,000, 3,750 or 7,500 mg/kg/day) in the diet for 13 weeks before mating, during mating, and throughout gestation. No effects on parental fertility, fetal development, sex distribution, and no malformations of the pups were observed. The NOAEL for parental and reproductive toxicity is 7,500 mg/kg/day. No evidence of carcinogenicity was found in male and female F344 rats and B6C3F1 mice administered diets containing 25,000 or 50,000 ppm (approximately 3,570 or 7,140 mg/kg/day) guar gum for 103 weeks. A reduction in the mean body weight of the higher dose females and of the feed consumption was observed, as compared with the controls. No compound-related clinical signs of adverse effects on survival were observed. There was no increase in the incidence of tumors that could be related to the test substance. Subchronic, reproductive and developmental, and carcinogenicity studies with guar gum showed no long term, reproductive/developmental, or carcinogenic effects. Overall, a low toxicity profile is expected with both carboxymethyl guar and carboxymethyl-hydroxypropyl guar because of low likelihood of absorption via any route of exposure due to their high molecular weights.

B. Toxicological Points of Departure/Levels of Concern

Majority of the available studies suggest that high levels of guar were well tolerated by laboratory animals. In the two 90-day toxicity studies, the body weight gains appears to be depressed at 500 mg/kg/day dose levels and above, however, generally the food consumption was not affected, indicating low food conversion efficiency. In a third 90-day toxicity study in rats, no effect on body weight was observed at doses up to 3,000 mg/kg/day. No effect on the body weights were observed in the reproduction study in rats at doses up to 7,500 mg/kg/day. In the carcinogenicity studies in mice and rats by National Toxicology Program (NTP) (1982), no adverse effects were observed at doses up to 3,570 mg/kg/day. Based on their high molecular weights, these two chemicals are not expected to be significantly absorbed via oral, dermal and inhalation routes of exposure. This is further supported by the animal toxicity studies where no significant effects were observed in a carcinogenicity studies in mice and rats and reproduction study in rats at doses up to and including 3,500 mg/kg/day. Based on the above weight of evidence, no endpoint of concern was identified, therefore, the Agency has determined that a qualitative assessment for all pathways of human exposure to both carboxymethyl guar and carboxymethyl-hydroxypropyl guar (food, drinking water, and residential) is appropriate.

C. Aggregate Exposure

In examining aggregate exposure, the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408 directs EPA to consider available information concerning exposures from the pesticide residues in food and all other nonoccupational sources, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and outdoor uses). There are no residential uses proposed at this time. No quantification of aggregate exposure was performed because no end point of concern was identified in the available toxicity studies.

1. Dietary and non-dietary exposure. Carboxymethyl guar and carboxymethyl-hydroxypropyl guar are slightly modified forms of guar gum, a natural polymer which is an affirmed GRAS substance of low toxicity. Carboxymethyl guar and carboxymethyl-hydroxypropyl guar are also structurally similar to hydroxypropyl guar, another slightly modified form of guar gum. EPA reassessed the tolerance exemption for hydroxypropyl guar in 2005 and concluded that there is a reasonable certainty of no harm to any population subgroup that will result from aggregate exposure to hydroxypropyl guar when considering dietary exposure and all other nonoccupational sources of pesticide exposure for which there is reliable information. Based on their close structural relationship to guar gum and hydroxypropyl guar, as well as their high molecular weights and likelihood of low absorption via any route of exposure, both carboxymethyl guar and carboxymethyl-hydroxypropyl guar can also be considered to be low toxicity substances with a reasonable certainty of no harm from dietary exposure and all other nonoccupational sources of exposure. 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.”

Carboxymethyl guar and carboxymethyl-hydroxypropyl guar are slightly modified form of guar gum, a natural polymer that has been affirmed as generally recognized as safe (GRAS) substance of low toxicity. Carboxymethyl guar and carboxymethyl-hydroxypropyl guar are also structurally similar to hydroxypropyl guar, another slightly modified form of guar gum. They all have same toxicity pattern but the exact mode of action is not known. Therefore, cumulative risk assessment was not conducted. 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 Web site at http://www.epa.gov/pesticides/cumulative.

D. Safety Factor for Infants and Children

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 (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.

Carboxymethyl guar and carboxymethyl-hydroxypropyl guar are slight modified forms of guar gum, a natural polymer which is an affirmed GRAS substance of low toxicity. Carboxymethyl guar and carboxymethyl-hydroxypropyl guar gum are also structurally similar to hydroxypropyl guar, another slightly modified form guar gum. According to EPA’s 2005 tolerance exemption reassessment document for hydroxypropyl guar, it was concluded that hydroxypropyl guar is a high molecular weight polymer that is devoid of reactive functional groups and which is not absorbed by any route of human exposure. Also teratogenicity studies with guar gum in mice, rats, and hamsters did not indicate that guar gum is a teratogen; in mice at doses up to 800 mg/kg/day, in rat up to 900 mg/kg/day and in hamsters up to 600 mg/kg/day. In addition, no effects on parental fertility, fetal development, sex distribution, and no malformations of the pups were observed at doses up to 7,500 mg/kg/day in the one generation reproduction study in rats. Based on the structural similarities to guar gum and hydroxypropyl guar, as well as their high molecular weights and low likelihood of absorption via any route of exposure, carboxymethyl guar and carboxymethyl-hydroxypropyl guar are unlikely to elicit a toxic response in infants and children when used as an inert ingredient in pesticide products. Available toxicity studies confirm this belief and indicate low toxicity; therefore, the Agency did not use a safety factor analysis for assessing risk and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

EPA expects aggregate exposure to carboxymethyl guar gum sodium salt and carboxymethyl-hydroxypropyl guar residues to pose no appreciable risk to human health given that they both are a polymer with high molecular weight that are devoid of reactive functional groups and which are not absorbed by any route of human exposure. Taking into consideration all available information on carboxymethyl guar gum sodium salt and carboxymethyl-hydroxypropyl guar, EPA has determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to carboxymethyl guar gum sodium salt and carboxymethyl-hydroxypropyl guar under reasonably foreseeable circumstances. Therefore, the establishment of an exemption from a tolerance under 40 CFR 180.920 for residues of carboxymethyl guar gum sodium salt and carboxymethyl-hydroxypropyl guar when used as an inert ingredient in pesticide formulations applied to growing crops under 40 CFR 180.920 is safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residue of carboxymethyl guar gum sodium salt and carboxymethyl-hydroxypropyl guar in or on any food commodities.

B. 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 an MRL for carboxymethyl guar gum sodium salt and carboxymethyl-hydroxypropyl guar.

C. Response to Comments

Two comments, one for each notice of filing were received from private citizens who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency understands the commenter’s concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for carboxymethyl guar gum sodium salt (CAS Reg. No. 39346–76–4) and carboxymethyl-hydroxypropyl guar (CAS Reg. No. 68130–15–4); when used as an inert ingredient (thicker/thick drift reduction agent) in pesticide formulations applied to growing crops under 40 CFR 180.920.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and
SUMMARY: This regulation establishes tolerances for residues of chlorantraniliprole in or on multiple commodities which are identified and discussed later in this document. This regulation additionally amends previously established tolerances in or on multiple commodities and deletes tolerances in or on several commodities that will be superceded by inclusion in crop group tolerances. E.I. du Pont de Nemours and Company, DuPont Crop Protection, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 27, 2011. Objections and requests for hearings must be received on or before September 26, 2011, 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–2010–0888. 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,