For each . . . | Complying with the requirement to . . . | You must demonstrate continuous compliance by . . .
---|---|---
| a. After you have demonstrated compliance for two consecutive tests, you may reduce the frequency of subsequent performance tests to annually. If the results of any subsequent annual performance test indicate the stationary RICE is not in compliance with the CO or formaldehyde emission limitation, or you deviate from any of your operating limitations, you must resume semiannual performance tests. | | iv. Maintaining the 4-hour rolling averages within the operating limitations for the operating parameters established during the performance test. |
(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 6, 2008 (73 FR 6964) (FRL–8350–9), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 7E7241) by Landis International, on behalf of Whitmire Micro-Gen, 3185 Madison Highway, P.O. Box 5126, Valdosta, GA 31603–5126, under docket ID number EPA–HQ–OPP–2008–0040. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of potassium benzoate (Cas No. 582–25–2) when used as an inert ingredient (preservative) in pesticide formulations applied pre- and post-harvest. In the Federal Register of June 4, 2008 (73 FR 31862) (FRL–8365–3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 8E7333) by Landis International, on behalf of Whitmire Micro-Gen, 3185 Madison Highway, P.O. Box 5126, Valdosta, GA 31603–5126, under docket ID number EPA–HQ–OPP–2008–0059. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of potassium benzoate (Cas No. 582–25–2) when used as an inert ingredient (preservative) in pesticide formulations applied to animals. Both notices referenced a summary of the petition prepared by Landis International, on behalf of Whitmire Micro-Gen, the petitioner, which is available in the docket, http://www.regulations.gov. Two comments were received in the docket for PP 7E7241, however they are unrelated to potassium benzoate and the Agency believes they were placed in this docket in error by the commenters. There were no comments received in response to the notice of filing for PP 8E7333.

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 polymeric surfactants and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as diatomaceous earth; thickeners such as acids; carriers such as clay and hydrocarbons; surfactants such as Solvents such as alcohols and pesticidal efficacy of their own): Inert ingredients are all ingredients in 408(c)(2)(A) of FFDCA, and the factors considered by EPA in reviewing 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 potassium benzoate including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with potassium benzoate 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. Potassium benzoate is an approved food preservative, similar in structure and reactivity to the more widely used sodium benzoate. Both are classified by the U.S. Food and Drug Administration (FDA) as Generally Recognized as Safe (GRAS). In conducting this assessment, toxicity data on potassium benzoate and the surrogate chemicals sodium benzoate and benzoic acid were used. Both potassium benzoate and sodium benzoate are salts of benzoic acid. Because all benzoates, in particular benzoic acid and sodium benzoate, react similarly to potassium benzoate, they were used as surrogates in the development of this profile.

Available data show that the acute toxicity of potassium benzoate is negligible, having an oral median lethal dose (LD₅₀) of >10,000 milligrams per kilogram body weight (mg/kg/bw). Acute dermal and inhalation toxicity is low as indicated by the >2,000 mg/kg/bw LD₅₀ and >12.2 milligrams per liter (mg/L) median lethal concentration (LC₅₀) of benzoic acid. Sodium benzoate was not irritating to the skin and induced only slight eye irritation in rabbits. Sodium benzoate and benzoic acid were non-sensitizing in animal tests but showed a very low incidence of sensitization in humans patch tested. Both sodium benzoate and benzoic acid are known to induce non-immunogenic contact reactions, and that is the likely explanation for the low positive response.

Subacute, subchronic and chronic toxicity data also indicate that potassium benzoate should be relatively nontoxic. Available oral and dermal studies had a no-observed-adverse-effect-level (NOAEL) ≥2,000 mg/kg/bw and the inhalation studies had a NOAEL >25 milligrams per cubic meter (mg/m³). Sodium benzoate was not
carcinogenic in a lifetime mouse feeding study and there is no indication that potassium benzoate should be neurotoxic. Genotoxicity studies indicate the benzoates are not mutagenic; however chromosomal aberration studies gave ambiguous results. Benzoic acid did not induce reproductive toxicity in a 4-generation study. In the human body under normal physiological conditions, potassium benzoate changes from the ionized form to the undissociated benzoic acid. Benzoic acid and its salts are rapidly absorbed by mammals, conjugated with glycine, and rapidly excreted in the urine as hippuric acid. There is no reported accumulation of benzoate in the body. However, the ability to conjugate benzoic acid depends upon adequate liver function and nutritional supply of glycine.

All data indicates that potassium benzoate is relatively non-toxic as are the other benzoates. No toxicity would be expected from potassium benzoate when used at low concentrations in pesticides.

No developmental toxicity studies are available in the database. However, no systemic toxicity was observed at doses up to 750 mg/kg/day, the highest dose tested (HDT), in a 4-generation reproductive study with benzoic acid. In addition, no systemic toxicity was observed in the laboratory animals at doses >2,000 mg/kg/day of potassium benzoate and benzoates indicating relatively low hazard potential.


B. Toxicological Points of Departure/Levels of Concern

Subacute, subchronic and chronic toxicity data indicate that potassium benzoate is relatively nontoxic. Available oral and dermal toxicity studies had a NOAEL greater than or equal to 2,000 mg/kg/day and the inhalation study had a NOAEL greater than 25 mg/m³. Sodium benzoate was not shown to be carcinogenic and there is no indication that potassium benzoate will be neurotoxic. Studies also indicate that benzoates are not mutagenic and benzoic acid did not induce reproductive toxicity in a 4-generation study. Since no toxicity was observed at high doses, quantitative risk assessment is deemed unnecessary.

C. Exposure Assessment

No hazard was identified for the acute and chronic dietary assessment (food and drinking water), or for the short, intermediate, and long term residential assessments; therefore no aggregate risk assessments were performed. Available toxicological studies indicate lack of systemic toxicity at doses up to 2,000 mg/kg/day. Therefore, no quantitative dietary or occupational and residential risk assessment was conducted.

1. Dietary exposure from food and feed uses and drinking water. In evaluating dietary exposure to potassium benzoate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. Since toxicity was seen only at doses greater than 2,000 mg/kg/day for potassium benzoate, a quantitative exposure assessment for potassium benzoate was not conducted. Any possible dietary exposure to potassium benzoate from its use as an inert ingredient in pesticide products would be through consumption of food to which pesticide products containing it have been applied and possibly through drinking water (from runoff). Metabolism data indicates that potassium benzoate would be rapidly absorbed, metabolized, and excreted.

2. From non-dietary exposure. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Potassium benzoate is used in pharmaceuticals and cosmetics. It can also be used in nonfood use pesticide products. Considering the low toxicity of potassium benzoate, residues of concern are not anticipated from residential exposures (inhalation and dermal) and therefore a quantitative aggregate risk assessment was not performed.

3. 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 and/or other substances that have a common mechanism of toxicity.”

EPA has not found potassium benzoate to share a common mechanism of toxicity with any other substances, and potassium benzoate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that potassium benzoate 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 Web site at [http://www.epa.gov/pesticides/cumulative](http://www.epa.gov/pesticides/cumulative).

D. Safety Factor for Infants and Children

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.

No developmental toxicity studies are available in the database. However, no systemic toxicity was observed at doses up to 750 mg/kg/day in a 4-generation reproductive study with benzoic acid. In addition, no systemic toxicity was observed in the laboratory animals at high doses >2,000 mg/kg/day of potassium benzoate and benzoates indicating relatively low hazard potential. There was no evidence of clinical signs of neurotoxicity, therefore, a developmental neurotoxicity study is not required. In addition, no evidence of immunotoxicity is available in the database, therefore, an immunotoxicity study is not required. In terms of hazard, there are low concerns and low residual uncertainties regarding prenatal and/or postnatal toxicity. Based on this information, there is no concern at this time for increased sensitivity to infants and children to potassium benzoate when used as an inert ingredient in pesticide formulations and a safety factor analysis has not been used to assess risk. For the same reason, EPA has determined that an additional safety factor is not needed to protect the safety of infants and children.
E. Aggregate Risks and Determination of Safety

Given the lack of concern for hazard posed by potassium benzoate, EPA concludes that there are no dietary or aggregate dietary/non-dietary risks of concern as a result of exposure to potassium benzoate in food and water or from residential exposure. Residues of concern are not anticipated for dietary exposure (food and drinking water) or for residential exposure (dermal and inhalation) from the use of potassium benzoate as an inert ingredient in pesticide products. As discussed in this unit, EPA expects aggregate exposure to potassium benzoate to pose no appreciable dietary risk given that the data show a lack of any systemic toxicity at doses up to 2,000 mg/kg/day and a lack of any apparent developmental effects. Taking into consideration all available information on potassium benzoate, 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 potassium benzoate under reasonably foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.910 for residues of potassium benzoate when used as an inert ingredient in pesticide formulations applied pre- and post-harvest and under 40 CFR 180.930 for residues of potassium benzoate when used as an inert ingredient in pesticide formulations applied to animals, 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 establishing an exemption from the requirement of a tolerance without any numerical limitation.

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 a MRL for potassium benzoate.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 and 40 CFR 180.930 for potassium benzoate when used as an inert ingredient (preservative) in pesticide formulations applied pre- and post-harvest and applied to animals.

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 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 26355, 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) (Pub. L. 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: February 25, 2011.

Daniel J. Rosenblatt,
Acting 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:

2. In § 180.910, the table is amended by adding alphabetically the following inert ingredients to read as follows:
§ 180.910 Inert ingredients used pre-harvest and post-harvest; exemptions from the requirement of a tolerance.

<table>
<thead>
<tr>
<th>Inert ingredients</th>
<th>Limits</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium benzoate (as No. 582–25–2).</td>
<td>none preservative</td>
<td>active</td>
</tr>
</tbody>
</table>

3. In § 180.930, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

<table>
<thead>
<tr>
<th>Inert ingredients</th>
<th>Limits</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium benzoate (as No. 582–25–2).</td>
<td>none preservative</td>
<td>active</td>
</tr>
</tbody>
</table>

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 180

Fomesafen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fomesafen in or on pepper (bell and non-bell), potato, and tomato. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 9, 2011. Objections and requests for hearings must be received on or before May 9, 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–2010–0122. 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 file an 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–2010–0122 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 May 9, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.23(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–2010–0122, 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. Summary of Petitioned-for Tolerance