

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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of

regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. 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 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 24, 2004.

James Jones,
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:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.600 is added to read as follows:

§ 180.600 Propoxycarbazone; tolerances for residues

(a) *General.* (1) Tolerances are established for combined residues of the herbicide propoxycarbazone methyl 2-[[[(4,5-dihydro-4-methyl-5-oxo-3-

propoxy-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]benzoate and its metabolite methyl 2-[[[(4,5-dihydro-3-(2-hydroxypropoxy)-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]benzoate in/ on the following raw agricultural commodities:

| Commodity | Parts per million |
|---------------------|-------------------|
| Wheat, forage | 1.5 |
| Wheat, grain | 0.02 |
| Wheat, hay | 0.15 |
| Wheat, straw | 0.05 |

(2) Tolerances are established for residues of the herbicide propoxycarbazone methyl 2-[[[(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]benzoate in/ on the following raw agricultural commodities:

| Commodity | Parts per million |
|-------------------------------|-------------------|
| Cattle, meat | 0.05 |
| Cattle, meat byproducts | 0.05 |
| Goat, meat | 0.05 |
| Goat, meat byproducts ... | 0.05 |
| Horse, meat | 0.05 |
| Horse, meat byproducts | 0.05 |
| Milk | 0.004 |
| Sheep, meat | 0.05 |
| Sheep, meat byproducts | 0.05 |

(b) *Section 18 emergency exemptions.*

[Reserved]

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

(d) *Indirect or inadvertent residues.*

[Reserved]

[FR Doc. 04-15210 Filed 7-6-04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0190; FRL-7364-4]

Sulfuric Acid; 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 sulfuric acid (CAS Reg. No. 7664-93-9) when used as an inert ingredient. Magna Bon Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This

regulation eliminates the need to establish a maximum permissible level for residues of sulfuric acid.

DATES: This regulation is effective July 7, 2004. Objections and requests for hearings must be received on or before September 7, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket ID number OPP-2004-0190. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8380; e-mail address: gandhi.bipin@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 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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 Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. Background and Statutory Findings

In the **Federal Register** of August 21, 2002 (67 FR 54203) (FRL-7194-7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170), announcing the filing of a pesticide tolerance petition (PP 2E6476) by Magna Bon Corporation, 1531 NW 25th Drive, Okeechobee, FL 34972. This notice included a summary of the petition prepared by the petitioner Magna Bon Corporation.

The petitioner requested to amend 40 CFR 180.1001(c) newly redesignated as 180.910 by amending an existing exemption from the requirement of a tolerance for sulfuric acid (see 40 CFR 180.910). As currently established, sulfuric acid as an inert ingredient in formulated pesticide products can be applied to crops pre-harvest and post-harvest with a limitation of 0.1% in the pesticide formulation when used as a pH control agent. The petitioner requested to increase the limitation to 10% and to include a new use as a chelating agent. The petitioner requested the establishment of an exemption from the requirement of a tolerance in plants and plants products, meat, milk, poultry, eggs, fish, shellfish, and irrigated crops when it results from the use of sulfuric acid as an inert ingredient in a pesticide product used in irrigation conveyance systems and lakes, ponds, reservoirs, or bodies of water in which fish or shellfish are cultivated. Two comments were received in response to the notice of filing. See Unit IX.

Section 408(c)(2)(A)(i) of the 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(c)(2)(A)(ii) 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), 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), which 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 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. The nature of the toxic effects caused by sulfuric acid are discussed in this unit.

In formulating a pesticide product, an acidic chemical such as sulfuric acid serves a specific purpose, that of a neutralizing agent or a pH adjuster. During the manufacture of a pesticide product (or, in fact, many industrial chemicals), it may be necessary to adjust the pH of the product. An acid functions as a neutralizing agent when the hydrogen ion (H⁺) combines with the hydroxy (OH⁻) in a basic solution to form a molecule of water. Small amounts of the hydrogen ion would be added to the solution to lower the pH until a neutral pH is reached. After the pH adjustment is performed and the neutralization reaction occurs, sulfuric acid is no longer present. The reaction

products that are then present are the sulfate (II) negatively charged ion and water.

Alternatively, it might be necessary to have a pesticide product maintain an acidic pH; thus, the sulfuric acid would be added during the manufacturing process to deliberately lower the pH, which would mean an excess of the hydrogen ion. Such products are not likely to be sold to the residential market.

As a chemical class, acids are significantly different from many of the chemicals regulated as inert ingredients in pesticide products. First, acids are highly corrosive. Due to this property, toxicity testing can only be performed on very diluted solutions. Therefore, toxicity studies performed with undiluted (concentrated) sulfuric acid are not available. Second, acids are highly reactive, and therefore are not expected to be persistent in the food supply, the environment, or in water resources. Sulfuric acid would be expected to dissociate and immediately react with both plant and animal materials.

Chemically, an acid, is a substance that when dissolved in water yields hydrogen (H^{+1}) ion. The increase of the concentration of the H^{+1} ion reduces the pH. It is the hydrogen ion that is highly reactive, thus displaying the corrosive characteristic. The consequences of acute exposure to acids

are well understood; they are corrosive to the eyes, the skin, and the respiratory tract. The hazard of any acidic chemical derives directly from and is due to these irritation and acidic effects.

Sulfuric acid is a strong acid. It is also a commonly used chemical. It has been used for years, and therefore, there is a significant body of existing publicly-available information.

- Solutions of sulfuric acid greater than 10% are severely corrosive by all routes of exposure.
- Solutions of sulfuric acid of less than 10% are strong irritants.
- There is sufficient evidence that occupational exposure to strong-inorganic-acid mists containing sulfuric acid is carcinogenic (International Agency for Research on Cancer).
- There were no significant developmental or reproductive effects in mice or rabbits exposed to 20 mg/m³ sulfuric acid aerosols 7 hours per day on gestation days 6 to 15 (Agency for Toxic Substances and Disease (ATSDR)).

Previously, the Agency reviewed several acute toxicity studies conducted with sulfuric acid. The following information on the acute toxicity of sulfuric acid was extracted from the 1993 Mineral Acid RED (Reregistration Eligibility Decision Document):

- The oral lethal dose (LD)₅₀ is 350 mg/kg, Toxicity Category II.
- The dermal LD₅₀ is > 2,000 mg/kg, Toxicity Category III.

- Sulfuric acid is Toxicity Category I for eye and dermal irritation.

No other toxicological data were required based on the use patterns at the time of the issuance of the RED, and considering the corrosiveness shown in the acute studies for dermal and eye irritation. More recently, the Office of Pesticide Programs at the Environmental Protection Agency, as part of the tolerance reassessment process, completed its tolerance reassessment review of sulfuric acid with particular emphasis on the role of sulfuric acid in pesticide products.

The National Institute of Occupational Safety and Health (NIOSH) Immediately Dangerous to Life or Health (IDLH) Documentation and the International Chemical Safety Card for sulfuric acid indicate that it is a colorless, oily, odorless liquid. The IDLH is 15 mg/m³. The Threshold Limit Value (TLV) is 1 mg/m³ (TWA). Sulfuric acid reacts violently with water. It is corrosive to the skin and the respiratory tract, and on ingestion.

Sulfuric acid is considered to be a strong acid. The following acids have been approved by the Food and Drug Administration (FDA) for direct use in the food supply. In fact, FDA has determined that the following substances are Generally Recognized as Safe (GRAS) when used as direct food additives.

| Chemical | FDA GRAS Citation | GRAS Use Pattern |
|-------------------|-------------------|---|
| Sulfuric acid | 21 CFR 184.1095 | pH control agent, processing aid |
| Hydrochloric acid | 21 CFR 182.1057 | neutralizing agent (no limitations specified) |
| Phosphoric acid | 21 CFR 182.1073 | (no limitations specified) |

Sulfuric acid is also cleared under 21 CFR 178.1010 for use in food-contact surface sanitizing solutions.

In 1975 FDA published an assessment entitled "Evaluation of the Health Aspects of Sulfuric Acid and Sulfates as Food Ingredients." "Sulfates are natural constituents of foods and normal products of sulfur metabolism in animals. It is evident that the toxic manifestations following oral administration of the sulfates considered in this report appear only at levels that are many times greater than those to which man is exposed in his daily diet." It was concluded that: "There is no evidence in the available information on sulfuric acid that demonstrates or suggests that reasonable grounds to suspect, a hazard to public when they are used at levels that are

now current or that might reasonably be expected in future."

IV. Conclusions of the Human Health Assessment

Sulfuric acid in its concentrated form is highly corrosive. Due to this property, toxicity testing can only be performed on dilute concentrations or on neutralized forms of the acid such as a salt. The consequences of acute exposure to sulfuric acid are well-understood. According to NIOSH and ATSDR, "Concentrated sulfuric acid has an extremely irritant, corrosive, and destructive action on all living matter including human tissues, not by virtue of its acidity (in concentrated form it is only slightly ionized) but because of its affinity for water. The affinity is so strong that it will remove the elements of water from even anhydrous organic

matter such as carbohydrates, resulting in charring or carbonization with the liberation of heat. In sulfuric acid splashing accidents, the heat liberated by dilution of the concentrated acid with water used to flush the affected areas, can add thermal burn to chemical injury of the body." Thus sulfuric acid "can burn and char the skin. It is even more rapidly injurious to the mucous membranes, and exceedingly dangerous to the eyes. Dilute sulfuric acid, while it does not possess this charring property, irritates the skin and mucous membranes by virtue of its acidity and can cause dermatitis."

Exposure to a mist of sulfuric acid can cause irritant effects on the mucous membranes and chemical corrosive effects upon the teeth. Strong inorganic acid mists containing sulfuric acid are listed as known human carcinogens.

However, exposure to sulfuric acid in pesticide products as an inert ingredient would be in the role of a pH adjuster, that is, a liquid form, not a mist. As an inert ingredient small amounts of sulfuric acid are incorporated in a pesticide product to lower the pH. After the pH adjustment is performed, the sulfuric acid would be neutralized, and therefore no longer present. It is recognized that sulfuric acid must be used and applied according to good manufacturing or good agricultural practices.

There are no available information on sulfuric acid indicative of a human health hazard from the ingestion of food directly treated with sulfuric acid. In fact, sulfuric acid would not be present in consumed foods. The small amounts of acids that might be added to a food during processing react rapidly with a food substance. Thus, the exposure is actually to sulfate residues.

The sulfate residues (resulting from the use of sulfuric acid) are of minimal toxicity. In fact, calcium, sodium, magnesium, and potassium sulfates have been classified as List 4A, chemical substances of minimal risk. Various sulfate chemicals have uses as direct food additives. The human body metabolizes sulfate through well-understood pathways. It is a necessary human nutrient. There are no significant adverse effects, to the general public or any population subgroup from consumption of residues of sulfuric acid (actually the neutralized form which is the sulfate ion in solution) resulting from pesticide product uses.

V. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 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.* During the manufacture of a pesticide product, it is very possible that sulfuric acid (when used as an inert ingredient) could be used to adjust the pH of the pesticide product. Sulfuric acid is highly reactive. Adjusting the pH creates a chemical reaction known as neutralization, in which the acidic characteristics of the sulfuric acid disappear. At this point the sulfate ion is in solution in the pesticide product. The amount of the sulfate ion in the solution from the neutralization reaction

would be equivalent to the amount of sulfuric acid used.

Sulfuric acid can also be used as an active ingredient when used as a herbicide in the production of garlic and onions and as a potato vine desiccant, prior to harvest, to make harvesting less difficult. There is no reasonable expectation that residues of sulfuric acid would be present in the harvested commodity.

FDA has determined that sulfuric acid is generally recognized as safe as a direct food additive. Sulfuric acid can be used as a component of a food-contact surface sanitizing solution. Given the highly reactive nature of sulfuric acid, the actual exposure would be to sulfate residues. Thus, the public is not directly exposed to sulfuric acid in its food supply.

2. *Drinking water.* Sulfuric acid is not expected to be persistent in the environment. Instead it is expected to dissociate, react with organic or inorganic materials, and complex with ionic substrates. Releasing low levels of sulfuric acid would not normally be expected to adversely affect water resources. Sulfates form the basis of many rocks and minerals which are naturally occurring materials.

B. Other Non-Occupational Exposure

As a group mineral acids, including sulfuric acid constitute a group of chemicals with many industrial uses. However, considering the reactivity and corrosivity of these acids, there are few uses of even diluted solutions of strong acids in and around the home. As stated previously the actual exposure is to sulfate. Several sulfate chemicals (sodium, calcium, magnesium, and potassium) have been classified as List 4A chemicals, that is chemicals of minimal risk.

VI. Cumulative Effects

Section 408(b)(2)(D)(v) of the 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." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to sulfuric acid and any other substances, and sulfuric acid does not appear to produce toxic metabolites produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that sulfuric acid has 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative>.

VII. Children's Safety Factor

Due to its reactive nature, sulfuric acid used in pesticide products will not carryover to the food supply. Residues of sulfuric acid in the form of sulfate pose minimal risk and therefore a safety factor analysis has not been used to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VIII. Determination of Safety for U.S. Population, Infants and Children

The toxicity of sulfuric acid derives from the irritation and caustic effects. However, the actual exposure in the food supply is to the sulfate ion. The human body metabolizes sulfate through well-understood pathways. Based on the information in this preamble and considering the use patterns of pesticide products, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of sulfuric acid. Accordingly, EPA finds that exempting non-aerosol uses of sulfuric acid from the requirement of a tolerance with a limitation of not exceeding 10% of the formulated product will be safe.

IX. Other Considerations

A. Endocrine Disruptors

There is no available evidence that sulfuric acid is an endocrine disrupter.

B. Analytical Method

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.

C. Existing Tolerance Exemptions

Sulfuric acid is exempt from the requirement of a tolerance under 40 CFR 180.910 (formerly 40 CFR 180.1001(c)) when used as an inert ingredient as a pH adjuster in pesticide formulations applied to growing crops and to raw agricultural commodities after harvest at concentrations not to exceed 0.1%. This exemption is being amended in today's final rule.

Sulfuric acid is also exempt from the requirement of a tolerance under 40 CFR 180.1019 as an active ingredient, a herbicide, in the production of garlic and onions and as a potato vine desiccant in the production of potatoes. This text is not being changed.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance exemption for sulfuric acid.

E. Public Comments

Two comments were received in response to the Notice of Filing. A private citizen who works for the United States Geological Survey (USGS) contacted the Agency using his USGS e-mail address account. He stated that sulfuric acid can be harmful to teeth and gum at 0.3% concentration. The Merck Index from 1960 was quoted as the source of his information.

The Agency is well-aware of the fact that sulfuric acid is a strong acid. The effects of sulfuric acid are well studied. Sulfuric acid has been assessed by other governmental agencies, including NIOSH and ATSDR.

The Agency believes that the commenter misinterpreted the intent of the tolerance exemption proposed. The 10% limitation is for the pesticide products that would be marketed for application to crops. The Agency has never suggested that 10% of the food supply would be sulfuric acid. As is explained in Unit III., it is not possible for significant amounts of sulfuric acid to be present in the food supply.

A comment was also received asking about the use of sulfuric acid as a chelating agent. The Agency contacted the petitioner to provide additional information regarding sulfuric acid's use as a chelating agent. The petitioner did not provide additional information but informed the Agency on November 6, 2002, that the petitioner wished to withdraw the request for the use of sulfuric acid as a chelating agent.

X. Conclusion

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm to the general population including infants and children from aggregate exposure to residues of sulfuric acid (CAS Reg. No. 7664-93-9). EPA finds that exempting sulfuric acid from the requirements of a tolerance will be safe.

Therefore, the exemption from the requirement of a tolerance for residues of sulfuric acid not to exceed 10% of the pesticide formulation (non-aerosol formulations only) is established.

XI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2004-0190 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 on or before September 7, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing

Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564-6255.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2004-0190, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not

include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since

tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as

specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XIII. 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 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 21, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, in the table, the entry for sulfuric acid is revised to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

| Inert Ingredient | Limits | Uses |
|---|--|------------------|
| Sulfuric acid (CAS Reg. No. 7664-93-9). | Not to exceed 10% of the pesticide formulation; non-aerosol formulations only. | pH Control agent |

■ 3. Section 180.1019 is revised to read as follows.

§ 180.1019 Sulfuric acid; exemption from the requirement of a tolerance.

(a) Residues of sulfuric acid are exempted from the requirement of a tolerance when used in accordance with good agricultural practice when used as a herbicide in the production of garlic and onions, and as a potato vine dessicant in the production of potatoes.

(b) Residues of sulfuric acid are exempted from the requirement of a tolerance in meat, milk, poultry, eggs, fish, shellfish, and irrigated crops when it results from the use of sulfuric acid as an inert ingredient in a pesticide product used in irrigation conveyance systems and lakes, ponds, reservoirs, or bodies of water in which fish or shellfish are cultivated. The sulfuric acid is not to exceed 10% of the pesticide formulation (non-aerosol formulations only).

[FR Doc. 04-15352 Filed 7-6-04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[OPPT-2003-0075; FRL-7332-3]

RIN 2070-AC61

TSCA Inventory Update Rule Corrections

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to make several minor corrections to the Inventory Update Rule (IUR) reporting regulations. First, EPA is relocating the non-isolated intermediate definition to properly place it in the section of the regulation associated with both the IUR and the compilation of the TSCA Inventory. Second, the Agency is correcting the low current interest partial exemption chemical list by removing a chemical that is improperly identified and was mistakenly placed on the list. Third, EPA is correcting the percent production volume associated with the chemical substance's physical form(s) reporting requirement by removing the requirement that the sum of the percent production volumes be no more than 100%. Fourth, EPA is correcting overlapping site ranges in the number of sites code table. Fifth, EPA is correcting a misprint in a paragraph reference. Sixth, EPA is updating the

procedure to obtain the reporting documents.

DATES: This direct final rule is effective on September 7, 2004, without further notice, unless EPA receives adverse comment by August 6, 2004. If, however, EPA receives adverse comment, EPA will publish a **Federal Register** document to withdraw the specific correction(s) for which the adverse comment was made before the effective date of the direct final rule. The remaining corrections will become effective on September 7, 2004.

ADDRESSES: Submit your comments, identified by docket identification (ID) number OPPT-2003-0075, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov/>. Follow the on-line instructions for submitting comments.
- *Agency Website:* <http://www.epa.gov/edocket/>. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

- *E-mail:* oppt.ncic@epa.gov.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID number OPPT-2003-0075. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number OPPT-2003-0075. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at <http://www.epa.gov/edocket/>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, [regulations.gov](http://www.epa.gov/edocket/), or e-mail. The EPA EDOCKET and the [regulations.gov](http://www.regulations.gov) websites are "anonymous access" systems, which means EPA will not

know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL-7181-7).

Docket: All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket/>. Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the OPPT Docket, EPA Docket Center, EPA West, Rm. B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566-1744, and the telephone number for the OPPT Docket, which is located in the EPA Docket Center, is (202) 566-0280.

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Susan Sharkey, Project Manager, Economics, Exposure and Technology Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania