

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.

#### IX. 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 6, 2006.

**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 180.1269 is added to subpart D to read as follows:

#### § 180.1269 *Bacillus mycoides* Isolate J on sugar beets: exemption from the requirement of a tolerance.

*Bacillus mycoides* isolate J is temporarily exempt from the requirement of a tolerance when used as a fungicide for control of *Cercospora* Leaf Spot (*Cercospora beticola*) on sugar beets. This temporary exemption from the requirement of a tolerance expires and is revoked on December 31, 2007. [FR Doc. E6-9282 Filed 6-13-06; 8:45 am]

**BILLING CODE** 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2006-0299; FRL-8069-6]

#### Potassium Silicate; 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 potassium silicate in or on all food commodities when applied/used as a fungicide, insecticide or miticide so long as the potassium silicate is not applied at rates exceeding 1% by weight in aqueous solution and when used in accordance with good agricultural practices. PQ Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of potassium silicate.

**DATES:** This regulation is effective June 14, 2006. Objections and requests for hearings must be received on or before August 14, 2006, 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-2006-0299. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Docket is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Carol E. Frazer, Biopesticides and

Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8810; e-mail address: [frazer.carol@epa.gov](mailto:frazer.carol@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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

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

Under section 408(g) of FFDCA, 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. 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-2006-0299 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 August 14, 2006.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2006-0299, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 telephone number for the Docket is (703) 305-5805.

## II. Background and Statutory Findings

In the **Federal Register** of July 27, 2005 (70 FR 43417) (FRL-7719-5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 5F6905) by PQ Corporation, P.O. Box 840 Valley Forge, PA 19482-0840. The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of potassium silicate. This notice included a summary of the petition prepared by the petitioner PQ Corporation. There were no comments received in response to the notice of filing.

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 exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a

reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B), 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 require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ." Additionally, section 408(b)(2)(D) of FFDCA requires that the Agency consider "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

EPA 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.

Potassium silicate is a synthetic compound that is chemically the potassium salt of silicic acid. It is produced by combining pure silica sand (SiO<sub>2</sub>) and potash (K<sub>2</sub>CO<sub>3</sub> or NaCO<sub>3</sub>). Silicic acid salts (i.e., silicates) are the most common form of silicon. For the purposes of this tolerance exemption, the Agency has relied on the extensive body of knowledge, data and/or information from the public literature as submitted by PQ Corporation and as researched by the Agency which document the similarity of silica (also known as silicon dioxide) and potassium silicate and support the conclusion that there is reasonable

certainty of no harm that will result from the use of potassium silicate as an agricultural pesticide.

Silicon dioxide (silica) has been assessed for its pesticidal uses by the Agency and it was determined that the toxicity of this compound is moderate to low and therefore, the human health risk is low and not unreasonable. Further, silicon dioxide is recognized by the Food and Drug Administration (FDA) to be a Generally-Recognized As Safe (GRAS) substance, as a food additive (21 CFR 182.90 and 182.1711).

Comprehensive reviews and risk assessments have been conducted on silicon dioxide (silica) and its related soluble silicates with regard to its toxicity to human health and have concluded that silica and its soluble silicates (potassium silicate) are low in toxicity and the primary hazard of concern is the corrosive nature of the compound. The corrosive nature of potassium silicate is not of a concern when used as a very dilute solution (less than or equal to 1%). The soluble silicates include: potassium silicate, sodium silicate and sodium metasilicate, the latter of which the Agency has exempted in diluted form from the requirement of a tolerance for use on all food commodities. Additionally, the FDA has determined that sodium silicate and potassium silicate can be used interchangeably which substantiates information in the public literature that the compounds are very similar.

The data submitted and reviewed on the end use pesticide product containing 29.1% w/w potassium silicate caused moderate to low dermal irritation and is classified as an eye irritant due to the high pH of the product. When used as a pesticide (fungicide, insecticide and miticide) the active ingredient is effective at very low concentrations (less than or equal to 1%) and thus the dilution of the active ingredient would reduce the risks to pesticide users. Labeling of such products with the appropriate protective clothing, gloves and eyewear would mitigate the risk of exposure to potassium silicate on pesticide applicators. Potassium silicate residues which may result from its use as an agricultural pesticide would be reduced by washing or processing treated commodities before their consumption; this point is supported by the water solubility of potassium silicate and the possibility of it being washed off treated surfaces by rainfall in the field. Further, potassium silicate is neutralized by stomach acid and primarily excreted in the urine.

The components of potassium silicate are potassium and silicon. Potassium is found in the environment and is an essential element in human and plant nutrition. It is found in many fruits and vegetables consumed by humans. A common soil plant nutrient and fertilizer (as  $K_2O$ ), potassium comprises approximately 2.59% of the Earth's crust by weight. The primary source of naturally-occurring soluble potassium is from the weathering of potassium containing minerals.

Silicon is ubiquitous in the environment, the second most abundant element in the lithosphere after oxygen. A nutritional element, silica is required for proper and strong growth of mammalian bones. Silica is present naturally in all plant stems and is present in larger amounts in crops such as rice and sugar cane. It comprises approximately 31% of the Earth's crust by weight and is present as dissolved silica, amorphous silica in the solid phase (for example, silica and silica gel (FDA GRAS chemicals), and silica bound to organic matter. In the normal range of soil pH, silicic acid is the major silicate in soil water. In natural waters most dissolved silica results from weathering of silicate minerals. Research demonstrates that commercial soluble silicates rapidly degrade to molecular forms that are indistinguishable from natural dissolved silica (IUCLED, 1995). Beach sand, for example is comprised of nearly 100% silica (Crop Protection handbook, 2003). Additionally, silica is approved by the FDA for use as an anti-caking agent in food.

Potassium silicate immediately breaks down in the presence of water to the potassium and silicate ions which are indistinguishable from natural components. As stated above, potassium silicate is produced by direct fusion of precisely measured portions of pure silica sand ( $SiO_2$ ) and potash ( $K_2CO_3$ ) in a fired furnace at temperatures above 1000°C. Solutions of potassium silicate are produced by dissolving alkali silica lumps in water at elevated temperatures. Potassium silicate is classified as GRAS by FDA (21 CFR 182.90 and 21 CFR 182.1711) for limited use in canned potable water as a corrosion inhibiting agent and the EPA has exempted potassium silicate from the requirement of a tolerance when used as an inert ingredient, a surfactant, emulsifier, wetting agent, stabilizer, or inhibitor (40 CFR 180.910). Data and/or information from the public literature demonstrates a long history of safe use of fertilizers containing potassium and silica. (HERA 2005, NOSB/TAP, 2003 and the Silicon Dioxide and Silica Gel

RED EPA, 1991, Kant, T., *et al*, 2003, Savant N.K., *et al.*, 1999). Fertilizers used in the agricultural industry contain plant nutrients and micronutrients such as potassium and silicon. Potassium silicate is approved by the USDA as a fertilizer for conventional agriculture and is used on a variety of crops including rice, wheat, barley, sugar cane, melons, grapes and cucurbits (USDA/ERS, 2002, NOSB/TAP, 2003).

As mentioned above, silicon dioxide and its soluble silicates which include potassium silicate have been fully characterized and assessed by the Agency and other notable resources and it has been concluded that silicon dioxide and its related soluble silicates exhibit moderate to low toxicity, the Agency has therefore concluded there is a reasonable certainty of no harm resulting from the use of potassium silicate as an agricultural pesticide. This determination is based on information from the literature which as stated above document the similarity of silica (also known as silicon dioxide) and potassium silicate. This information combined with the fact that the components of potassium silicate (potassium and silica) are already naturally present in the stems of all plants (silica) and naturally in foods supports the Agency's conclusion that there is a reasonable certainty of no harm resulting from the use of potassium silicate as an agricultural pesticide and exposure from the use of potassium silicate as a pesticide will not add to the exposure already present from its natural occurrence, its presence in foods, in the human diet and in the environment.

#### A. Acute Toxicity

The registrant did not submit any toxicity data testing the technical grade of the active ingredient. Data waivers were requested by the registrant and granted by the Agency based on the body of extensive knowledge from the public literature and as researched by the Agency. The toxicity of the soluble silicates via oral toxicity, teratogenicity and genotoxicity were tested on the Technical Grade of the Active Ingredient (TGAI) and reported and the Agency has relied upon this information to support its decision to grant the waiver requests for these studies. Acute toxicity data were submitted using the end-use product as the test material which is approximately a 3 dilution of the technical grade of the active ingredient. Requests for data waivers were granted for additional toxicity studies described below. These data waiver requests were granted based on the findings from comprehensive

reviews and risk assessments conducted on silicon dioxide (silica) and its related soluble silicates (potassium silicate) with regard to its toxicity to human health and the conclusion that silicon dioxide and its related soluble silicates have moderate to low toxicity, and therefore, the Agency concludes that there is a reasonable certainty of no harm resulting from the use of potassium silicate. The data submitted and waivers that were granted are as follows:

Acute oral rat OPPTS Harmonized Guideline 870.1100; Master Record Identification (MRID) Number 46434903).  $LD_{50}$  = 5,000 milligrams/kilogram (mg/kg) (29.1% potassium silicate aqueous solution). The test material is classified as a Toxicity Category IV for acute oral toxicity and demonstrates that a dilution of the active ingredient to a level that is comparable to the concentration of potassium silicate in the proposed end-use product eliminates the potential of the active ingredient to cause acute toxic effects. There were no adverse effects reported at 5,000 mg/kg.

*Technical grade of the active ingredient.* A request to waive this data requirement was submitted by the registrant. The Agency has granted this data waiver based on: (1) Data from the public literature which shows soluble silicates have a moderate to low acute toxicity by the oral route (HERA 2005), (2) potassium silicate, a soluble silicate that is both chemically and toxicologically similar to silicon dioxide (silica) which has been fully characterized, assessed, and therefore determined by the Agency that silicon dioxide and its related soluble silicates pose no unreasonable adverse effects to human health when used as an agricultural pesticide and (3) potassium and silica are already present in the human diet as they are contained naturally in various crops.

Acute dermal rat OPPTS 870.1200; (MRID 4643902).  $LD_{50}$  = 5,000 mg/kg (29.1% potassium silicate aqueous solution). The test material is classified as a Toxicity Category IV for acute dermal toxicity and demonstrates that a dilution of the active ingredient to a level that is comparable to the concentration of potassium silicate in the proposed end use product will be moderately irritating to the skin.

*Technical grade of the active ingredient.* Section 158.690(c)(2)(I) states this test is not required if the test material is corrosive to skin. Therefore, this test was not required. However, this active ingredient is classified Toxicity Category I on the basis of potential dermal irritation effects.

Acute inhalation rat OPPTS 870.1300; (MRID 46434906). LC<sub>50</sub> >2.06 milligrams per liter (mg/L) (29.1% potassium silicate aqueous solution). The test material is classified as a Toxicity Category IV for acute inhalation toxicity and demonstrates that a dilution of the active ingredient to a level that is comparable to the concentration of potassium silicate in the proposed end use product will not cause acute inhalation effects at greater than 2.06 mg/L.

*Technical grade of the active ingredient.* This test is only required if the product consists of a respirable material. Since potassium silicate does not consist of a respirable material under normal conditions of use, this test is not required.

*B. Genotoxicity, Immune Response, Mutagenicity, Developmental, Oncogenicity, Subchronic and Chronic Toxicity*

The applicant requested to waive the data requirements below and submitted a summary of public literature to satisfy the data requirements for 90-day oral toxicity (OPPTS 870.3100), genotoxicity (OPPTS 870.5100; 870.5300; 870.5375), teratogenicity (OPPTS 870.3700) and immunotoxicity (OPPTS 880.3550) for the active ingredient. Potassium silicate waiver requests were submitted (MRID 46434701). As mentioned above, the Agency has determined that the data requirements were met by the submission of public literature. The public literature demonstrates that potassium silicate has low toxicity by the oral route when tested as the TGAI because potassium silicate is neutralized by stomach acid and primarily excreted in the urine. The high pH of the pesticide product may cause eye and skin irritation to humans. However, risks to humans will be reduced by dilution of the pesticide product and further mitigated by the use of protective personal equipment.

#### IV. Aggregate Exposures

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

##### A. Dietary Exposure

1. *Food.* Potassium is found in the environment and is present in the cells of humans and plants and is therefore

an essential element in human and plant nutrition. It is found in many fruits and vegetables consumed by humans. Humans require an adequate supply of potassium from consumption of foods for healthy growth and development. Humans consume daily many sources of potassium, including a variety of fruits, vegetables and beverages such as barley, bananas, plums, apricots, strawberries, oranges, apples, grapes, spinach, potatoes, carrots, celery, tomatoes, lettuce, cucumbers, milk, fruit juices, coffee, white wine and light beers, etc. The average potassium content of the above fruits and vegetables ranges from 2.4 K/kg (tomato) - 3.7 K/kg (banana).

As mentioned above, potassium is a common soil plant nutrient and fertilizer (as K<sub>2</sub>O), and comprises approximately 2.59% of the Earth's crust by weight. Silicon is a ubiquitous mineral nutrient in the environment (soil, water) and the second most abundant element in the lithosphere after oxygen. A nutritional trace element, silicon is required for proper and strong growth and development of mammalian bones. In plants, silicic acid (Si(OH)<sub>4</sub>) is rapidly absorbed. Once absorbed, silicic acid is readily circulated throughout the plant and deposited as silicon dioxide. Consequently exposure to soluble silica occurs on a daily basis and is a property of all plant products in the human diet. The concentration of silicon in vegetable plants varies greatly with cereals and grasses containing the highest concentrations (0.2-2.0%).

Good agricultural practice when using potassium silicate means it will most likely be used in aqueous solutions because application of pure potassium silicate to crops is likely to be corrosive to crops since the active ingredient is a known corrosive. When applied to food crops at concentrations not to exceed 1% by weight of potassium silicate in aqueous solution, it is highly unlikely there will be any residues of significance in or on food.

Further dilution by tank mixing with water of a pesticide product containing the active ingredient at 29% w/w of potassium silicate before application of the pesticide reduces the amount of active ingredient (to concentrations not to exceed 1% active ingredient) that will be on the crop.

Furthermore, potassium silicate breaks down in the presence of water to potassium and silicate ions, both of which occur naturally in animals and plants. Concentrations of potassium silicate as a pesticide in foliar sprays and nutrient solutions are dominated by

silicic acid, which as mentioned above, is readily absorbed by plants.

Therefore, given the use dilution of the pesticide product and other good agricultural practices as required on product labels, the likely dietary exposures to potassium silicate from the pesticidal uses are not expected to add significantly to those levels of potassium silicate already found in foods, beverages, and in drinking water as a result of conventional agriculture and its natural occurrence in the environment.

2. *Drinking water exposure.* Because potassium silicate breaks down into potassium and silicate ions in the presence of water, there will be no residues of potassium silicate in drinking water from its use as a pesticide. The Agency does not expect the resulting potassium and silicate ions resulting from this breakdown process will add significantly to the level of potassium and silica presently in the water.

Potassium and silicon dioxide are ubiquitous in the environment, and the uses of soluble silicates are widespread in dishwashing soaps, other soaps, and detergents. Potassium silicate is classified by the FDA as a GRAS substance (21 CFR 182.90 and 21 CFR 182.1711) for limited use in canned potable water as a corrosion inhibiting agent. Moreover, both potassium and silicon are already present in natural waters. The potassium (natural) content of drinking water varies greatly depending on its source and may be larger in mineral and spa waters than ordinary tap water. On average, the daily water consumption by adults supplies less than 0.1% of their potassium intake (European Fertilizer Manufacturers Association, 1997). In natural waters most dissolved silica results from weathering of silicate minerals and it has been demonstrated that commercial soluble silicates rapidly degrade to molecular forms that are indistinguishable from natural dissolved silica. Therefore, because of the levels at which potassium and silica (silicon dioxide) are already present in the water supply, the Agency does not expect that the use of potassium silicate as a pesticide will result in detectable exposures aside from what is currently in the environment.

##### B. Other Non-Occupational Exposure

1. *Dermal exposure.* Non-occupational dermal exposures to potassium silicate when used as a pesticide are expected to be negligible because it is limited to agricultural use.

2. *Inhalation exposure.* Non-occupational inhalation exposures to

potassium silicate when used as a pesticide are expected to be negligible because it is limited to agricultural use and will be used as a spray.

#### V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity.

The information available at this time indicates that potassium silicate when applied to food crops at a rate less than or equal to 1% of potassium silicate by weight in aqueous solution does not have a toxic effect. Therefore, cumulative effects from the residues of this product are not anticipated.

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

1. *U.S. population.* The Agency has determined that there is reasonable certainty that no harm will result to the U.S. population from aggregated exposure to residues of potassium silicate when used in an aqueous solution in which the potassium silicate does not exceed 29.1% by weight. This includes all anticipated dietary exposures and other exposures for which there is reliable information. The Agency arrived at this conclusion based on the anticipated low acute exposure estimates from its pesticidal use, the low mammalian toxicity in its diluted form, the widespread exposure to potassium and silica, from foods in the human diet, and the similarity both chemically and toxicologically to silicon dioxide which has already been fully characterized and assessed, and found that there is reasonable certainty of no harm that will result from the use of silicon dioxide and its related soluble silicates (potassium silicate) as an agricultural pesticide.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (MOE) for infants and children in the case of threshold effects. Margins of exposure are often referred to as uncertainty or safety factors, and are used to account for potential prenatal and postnatal toxicity and any lack of completeness of the data base. Based on available data and other information, EPA may determine that a different MOE will define a level of concern for infants and children or that a MOE approach is not appropriate. Based on all the available information the Agency reviewed on potassium silicate,

including a lack of threshold effects, the Agency concluded that potassium silicate, in its diluted form, is practically non-toxic to mammals, including infants and children. Since there are no effects of concern, the provision requiring an additional margin of safety does not apply.

#### VII. Other Considerations

##### A. Endocrine Disruptors

Based on available data, no endocrine system-related effects have been identified with consumption of potassium silicate. In addition, there is no evidence to suggest that potassium silicate functions in a manner similar to any known hormone.

##### B. Analytical Method(s)

The Agency proposes to establish an amendment to the exemption from the requirement of a tolerance without any numerical limitation for residues since it has determined that residues resulting from the pesticidal uses of potassium silicate would be so low as to be indistinguishable from the naturally occurring silicates that are ubiquitous in the environment.

##### C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels for this chemical.

#### VIII. Conclusions

Based on the toxicology data submitted, there is reasonable certainty no harm will result to the U.S. population including infants and children from aggregate exposure of residues of potassium silicate when the product is used in accordance with good agricultural practices. This includes all anticipated dietary exposures and all other exposures about which there is reliable information. As a result, EPA establishes an exemption from tolerance requirements pursuant to FFDCA 408(c) and (d) for residues of potassium silicate in or on all food commodities so long as the potassium silicate is not applied to food crops at rates that exceed 1% potassium silicate by weight in an aqueous solution.

#### IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement 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 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 section 408(d) of FFDCA, 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. The Agency hereby certifies that this rule will not have significant negative economic impact on a substantial number of small entities. 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 FFDCFA. 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.

#### X. 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: May 31, 2006.

**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 180.1268 is added to subpart D to read as follows:

#### § 180.1268 Potassium silicate; exemption from the requirement of a tolerance.

Potassium silicate is exempt from the requirement of a tolerance in or on all food commodities so long as the potassium silicate is not applied at rates exceeding 1% by weight in aqueous solution and when used in accordance with good agricultural practices.

[FR Doc. E6-8939 Filed 6-13-06; 8:45 am]

**BILLING CODE** 6560-50-S

### FEDERAL COMMUNICATIONS COMMISSION

#### 47 CFR Part 1

[WT Docket No. 05-211; FCC 06-78]

#### Commercial Spectrum Enhancement Act and Modernization of the Commission's Competitive Bidding Rules and Procedures

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Federal Communications Commission, on its own motion, clarifies certain aspects of the Implementation of the Commercial Spectrum Enhancement Act and Modernization of the Commission's Competitive Bidding Rules and Procedures. Among other things, the Commission clarifies that the expansion of the unjust enrichment payment schedule to ten years applies only to licenses granted on or after April 25, 2006. This ensures that retroactive penalties are not imposed on pre-existing designated entities.

**DATES:** Effective June 14, 2006.

#### FOR FURTHER INFORMATION CONTACT:

Brian Carter at (202) 418-0660.

**SUPPLEMENTARY INFORMATION:** This is a summary of the *Order on Reconsideration of the Second Report and Order (Order on Reconsideration)* released on June 2, 2006. The complete text of the *Order on Reconsideration* including attachments and related Commission documents is available for

public inspection and copying from 8 a.m. to 4:30 p.m. Monday through Thursday or from 8 a.m. to 11:30 a.m. on Friday at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC 20554. The *Order on Reconsideration* and related Commission documents may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc. (BCPI), Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone 202-488-5300, facsimile 202-488-5563, or you may contact BCPI at its Web site: <http://www.BCPIWEB.com>. When ordering documents from BCPI please provide the appropriate FCC document number, for example, FCC 06-78. The *Order on Reconsideration* and related documents are also available on the Internet at the Commission's Web site: <http://wireless.fcc.gov/auctions>.

#### I. Introduction

1. The Commission, on its own motion, released an Order on Reconsideration which clarifies certain aspects of the *Implementation of the Commercial Spectrum Enhancement Act and Modernization of the Commission's Competitive Bidding Rules and Procedures, Second Report and Order (Designated Entity Second Report and Order)*, 71 FR 26245, (May 4, 2006). The Commission also addresses certain procedural issues raised in filings submitted in response to the *Designated Entity Second Report and Order*.

#### II. Background

2. In the *Further Notice of Proposed Rule Making* in this proceeding (FNPRM), 71 FR 6992 (February 10, 2006), the Commission sought comment on a proposal by a commenter that the Commission restrict the award of designated entity benefits to designated entities that have material relationships with large in-region incumbent wireless service providers. The Commission asked for comment on each of the elements of this proposal, including what types of material relationships should trigger a restriction on the availability of designated entity benefits and what types of entities other than large in-region incumbent wireless service providers should be covered.

3. In the *Designated Entity Second Report and Order*, the Commission revised its Part 1 rules to include certain material relationships as factors in determining designated entity eligibility. Specifically, the Commission adopted rules to limit the award of designated entity benefits to any