

number of small entities because: this rule is about the correctional management of offenders committed to the custody of the Attorney General or the Director of the Bureau of Prisons, and its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995

This rule will not cause State, local and tribal governments, or the private sector, to spend \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. We do not need to take action under the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 28 CFR Part 523

Prisoners.

Harley G. Lappin,

Director, Bureau of Prisons.

Under the rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director, Bureau of Prisons, we propose to amend 28 CFR part 523 as follows.

SUBCHAPTER B—INMATE ADMISSION, CLASSIFICATION, AND TRANSFER

PART 523—COMPUTATION OF SENTENCE

1. The authority citation for 28 CFR part 523 is revised to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3568 (repealed November 1, 1987, as to offenses committed on or after that date), 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to conduct occurring on or after November 1, 1987), 4161–4166 (repealed October 12, 1984, as to offenses committed on or after November 1, 1987), 5006–5024 (Repealed October 12, 1984, as to conduct occurring after that date), 5039; 28 U.S.C. 509, 510.

2. Revise § 523.20 to read as follows:

§ 523.20 Good conduct time.

(a) For inmates serving a sentence for offenses committed on or after

November 1, 1987, but before September 13, 1994, the Bureau will award 54 days credit toward service of sentence (good conduct time credit) for each year served. This amount is prorated when the time served by the inmate for the sentence during the year is less than a full year.

(b) For inmates serving a sentence for offenses committed on or after September 13, 1994, but before April 26, 1996, all yearly awards of good conduct time will vest for inmates who have earned, or are making satisfactory progress (*see* § 544.73(b) of this chapter) toward earning a General Educational Development (GED) credential.

(c) For inmates serving a sentence for an offense committed on or after April 26, 1996, the Bureau will award:

(1) 54 days credit for each year served (prorated when the time served by the inmate for the sentence during the year is less than a full year) if the inmate has earned or is making satisfactory progress toward earning a GED credential or high school diploma; or

(2) 42 days credit for each year served (prorated when the time served by the inmate for the sentence during the year is less than a full year) if the inmate has not earned or is not making satisfactory progress toward earning a GED credential or high school diploma.

(d) Notwithstanding the requirements of paragraphs (b) and (c) of this section, an alien who is subject to a final order of removal, deportation, or exclusion is eligible for, but is not required to, participate in a literacy program, or to be making satisfactory progress toward earning a General Educational Development (GED) credential, to be eligible for a yearly award of good conduct time.

(e) The amount of good conduct time awarded for the year is also subject to disciplinary disallowance (*see* tables 3 through 6 in § 541.13 of this chapter).

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0121; FRL–7302–2]

Pesticides; Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations (Food-Contact Surface Sanitizing Solutions)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to add a new section to part 180 which lists the pesticide chemicals that are exempt from the requirement of a tolerance when used in food-contact surface sanitizing solutions. The initial list of exempt pesticide chemicals in the new section is duplicated from the Food and Drug Administration's (FDA) regulations in 21 CFR 178.1010. EPA is also changing FDA's naming conventions for some of the chemical substances that were duplicated.

Until recently, FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 409, regulated food-contact surface sanitizing solutions. With the amendments to FFDCA by the Food Quality Protection Act (FQPA) of 1996 and by the Antimicrobial Regulation Technical Corrections Act (ARTCA) of 1998, these responsibilities have been restructured. Under FFDCA section 408, EPA will now regulate the pesticide uses of these chemical substances and FDA under FFDCA section 409 will continue to regulate any indirect food additive uses of these chemical substances.

Registrants of existing food-contact surface sanitizing solutions that contain chemical substances other than those listed in this proposed rule should identify these chemical substances and support their claim that the chemical substance is generally recognized as safe (GRAS), or permitted by FDA prior sanction, or approval, or subject to a letter of no objection in order to remain exempt from the requirement of a FFDCA section 408 tolerance.

DATES: Comments, identified by docket ID number OPP–2003–0121, must be received on or before July 25, 2003.

Registrants should identify chemical substances not listed in this document and support their claims of GRAS, or prior sanction, or approval, or no objection of these chemical substances by submission of such information to the person listed under **FOR FURTHER INFORMATION**, on or before October 1, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

Registrants identifying chemical substances not listed in this document and the supporting documentation for their claims of GRAS, or prior sanction, or approval, or no objection of these chemical substances for inclusion in 40 CFR 180.940 should submit the information directly to the person listed under **FOR FURTHER INFORMATION**.

Identification of a chemical substance is not a comment and should be identified as "Submission of Non-designated Prior Approved Substance."

FOR FURTHER INFORMATION CONTACT:

Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6304; fax number: (703) 305-0599; e-mail address: boyle.kathryn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you formulate or market pesticide products. Potentially affected categories and entities may include, but are not limited to:

- Food manufacturing (NAICS 311)
- Antimicrobial pesticides (NAICS 32561)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0121. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing 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.

2. *Electronic access.* 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 http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the

copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and

follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2003-0121. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to: *opp-docket@epa.gov*, Attention: Docket ID Number OPP-2003-0121. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2003-0121.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP-2003-0121. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI To the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be

disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. What is the Agency's Authority for Taking this Action?

This proposed rule is issued under FFDCA section 408, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), and ARTCA (Public Law 105-324).

Section 408 of FFDCA authorizes the establishment of tolerances, exemptions from the requirement of a tolerance, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Section 408(j)(2) of FFDCA provides that all regulations issued by FDA under FFDCA section 409 that stated conditions for safe use of substances that are now, post-FQPA, considered pesticide chemical residues

in or on processed food or that otherwise stated the conditions under which such pesticide chemicals could be safely used, shall be deemed to be regulations issued under FFDCA section 408.

Due to the FQPA and ARTCA amendments to FFDCA, those chemical substances originally regulated by FDA under FFDCA section 409 as food-contact surface sanitizing solutions are now the responsibility of EPA. These pesticide chemical regulations are now subject to modification or revocation at EPA's initiative under FFDCA section 408(e). The Agency is proposing to duplicate the substance of FDA's food additive regulations for those chemical substances found in 21 CFR 178.1010 which are now pesticide tolerance exemptions in a format consistent with EPA's authority under section 408 in a new section, 40 CFR 180.940.

EPA's rulemaking activity will have no effect on any of the FDA regulated FFDCA section 409 food additive regulations in 21 CFR 178.1010.

III. Summary of this Action

A. Why is There an Overlap of EPA's and FDA's Regulatory Authorities?

Since EPA was created in 1970, EPA and FDA have shared authority under FFDCA over pesticide chemical residues in food. Enactment of FQPA in 1996 amended FFDCA, and shifted to EPA regulatory authority over certain pesticide residues which were previously subject to FDA authority. Prior to 1996, products used to sanitize or disinfect permanent or semi-permanent food-contact surfaces were regulated by FDA as indirect food additives under FFDCA section 409. Under the FQPA and ARTCA amendments to FFDCA, antimicrobial formulations used on permanent or semi-permanent food-contact surfaces other than food packaging are now considered "pesticide chemicals" and are regulated by EPA under FFDCA section 408.

FQPA added a provision to FFDCA to assure an orderly transition to the new regulatory system. Section 408(j)(2) of FFDCA provides that all food additive regulations issued under FFDCA section 409 prior to the enactment of FQPA for antimicrobial uses that became pesticide chemical uses subsequent to FQPA and that were not affected by ARTCA shall be deemed to be regulations issued under FFDCA section 408. Thus, FQPA converted existing food additive regulations issued by FDA under FFDCA section 409, for chemical substances that post-FQPA became pesticide chemicals, into FFDCA section

408 pesticide chemical tolerances or tolerance exemptions. This “grandfather” provision of FFDC section 408(j) assures that pesticide chemical residues conforming to regulations issued under the authority of FFDC section 409 will not render food adulterated as a result of the jurisdictional shift from FDA to EPA.

In 1998, ARTCA amended the definition of “pesticide chemical” in FFDC section 201(q) so as to exclude certain antimicrobial pesticide residues from the authority of FFDC section 408. Consistent with FFDC section 408(j)(4), these residues now fall within the authority of FFDC section 409. As a result, certain uses of food-contact surface sanitizing solutions identified in FDA’s regulations at 21 CFR 178.1010 remain subject to FFDC section 409 regulations just as they did pre-FQPA, while other uses are now subject to EPA’s jurisdiction under FFDC section 408.

B. Why are these Tolerance Exemptions not Subject to Tolerance Reassessment at this Time?

Under FFDC section 408(q), EPA is required to reassess all tolerance exemptions that were in effect on the day before the enactment of the FQPA. The tolerance exemptions for inert ingredients as well as those active ingredients not yet completed will be reassessed in accordance with EPA’s schedule for tolerance reassessment published in the **Federal Register** of August 4, 1997 (62 FR 42019) (FRL-5734-6).

The tolerance exemptions in this proposed rule to be codified in 40 CFR 180.940 already exist as valid FFDC section 408 regulations. FDA promulgated the food additive regulations in 21 CFR 178.1010 under the authority of FFDC section 409 prior to the enactment of FQPA. By operation of FFDC section 408(j)(2), those portions of 21 CFR 178.1010 that pertain to chemical substances that are pesticide chemicals post-FQPA and remain as such post-ARTCA were converted to FFDC section 408 tolerance exemptions. EPA’s duplication of these tolerance exemptions is not “establishing, modifying, or revoking a tolerance” under FFDC section 408(b). EPA is, therefore, not required to conduct a full reassessment of these tolerance exemptions at this time.

C. Why is 40 CFR 180.940 being Created?

The Agency is duplicating in 40 CFR 180.940 only those portions of the regulations in 21 CFR 178.1010 that

pertain to pesticide chemicals. This duplication will have no effect on any of FDA’s regulated FFDC section 409 food additive regulations in 21 CFR 178.1010.

In establishing food additive regulations for food-contact surface sanitizing solutions in 21 CFR 178.1010, FDA used a formulation-specific approach. Consistent with its authority under FFDC section 409, FDA issued regulations prescribing the conditions under which food-contact surface sanitizing solutions might be safely used. FDA approved the use of each food-contact surface sanitizing solution formulation as a whole, rather than regulating each component chemical substance individually. In addition, FDA included a generic exemption for any chemical substance considered to be GRAS, and in some cases, issued letters not objecting to certain additional chemical substances in the formulations.

By contrast, FFDC section 408 authorizes EPA to issue regulations establishing tolerances or exemptions from the requirement of a tolerance. EPA’s practice has been to issue these regulations on a chemical-specific basis, whereby each ingredient in the product is the subject of a separate tolerance or exemption regulation. Food-contact surface sanitizing solutions meet the requirements of FFDC if each ingredient has an appropriate clearance under FFDC, either a tolerance or an exemption from the requirement of a tolerance, and any conditions on the clearance are observed.

Translating the regulatory decisions made by FDA into a comparable EPA scheme requires considerably greater work on EPA’s part than merely copying those portions of the existing regulations in 21 CFR 178.1010 that pertain to pesticide chemicals directly into 40 CFR 180.940. EPA must disaggregate the formulations in 21 CFR 178.1010 that pertain to pesticide chemicals into their component ingredients. EPA must also provide a mechanism to address those ingredients not identified by name in 21 CFR 178.1010 but that were, for example, permitted by prior sanction or approval, not objected to, or generally recognized as safe. This, in fact, places a higher initial demand on EPA resources than would be required to simply copy FDA’s approach. However, EPA is convinced that the long-term administrative convenience of using a consistent regulatory scheme for all pesticide chemicals subject to FFDC section 408 outweighs the initial burdens.

FDA’s formulation-specific approach is different from EPA’s chemical-

specific approach. Under EPA’s approach, a tolerance exemption would be approved once for each particular pesticide chemical, and would not need to be repeated as new products containing that chemical substance enter the market. EPA’s approval process is not complex, will allow for a wide variety of potential products, and fosters innovative formulation approaches. In addition, by listing in one place (40 CFR 180.940) all chemical substances exempted from the requirement of a tolerance when used in food-contact surface sanitizing solutions, EPA’s approach will increase the transparency of its regulatory process.

This duplication will not allow any residues beyond those already permitted by 21 CFR 178.1010. EPA believes that the chemical-specific approach and FDA’s formulation-specific approach are equivalent from a risk management perspective, inasmuch as each would result in the same levels of residues from these chemical substances.

As part of the duplication, EPA changed the naming conventions (chemical nomenclature), as well as combining, as appropriate, chemical substances that appear in 21 CFR 178.1010 under two or more names under a single name. The Agency has attempted to identify each of the listed chemical substances using the Chemical Abstracts Service Registry Number (CAS No.). The CAS No. provides one of the most distinct and universally accepted means of identifying chemical substances. Generally, there will be only one CAS No. per listed chemical substance; however, it is possible that more than one CAS No. may be appropriate for some chemical substances. The lack of a CAS No. will not preclude EPA from including chemical substances in 40 CFR 180.940.

The lower-concentration limits specified in 21 CFR 178.1010 are not included in 40 CFR 180.940 because of the differences between FDA’s approach and EPA’s approach. Although EPA establishes tolerance exemptions for use in food-contact surface sanitizing solutions under FFDC, all pesticide products must also meet the criteria for registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) before being offered for sale. EPA relies on conditions imposed through the FIFRA registration process to address safety and for antimicrobial-formulated products efficacy. Accordingly, the lower limits on concentrations of pesticide chemicals, that appear in 21 CFR 178.1010 will not appear in 40 CFR 180.940. Three types of food-contact surface sanitizing

solutions are described in 21 CFR 178.1010:

- Those used on food-contact surfaces in public eating places.
- Those used on dairy-processing equipment.
- Those used on food-processing equipment and utensils.

According to FDA, food-contact surface sanitizing solutions that are acceptable for use on food-contact surfaces in public eating places can also be used on dairy-processing equipment, and on food-processing equipment and utensils. Food-contact surface sanitizing solutions that are acceptable for use on dairy equipment can also be used on food-processing equipment and utensils. EPA has separated the component ingredients by both chemical and concentration for these three types of food-contact surface sanitizing solutions, which will be included in 40 CFR 180.940.

IV. Issuance and Withdrawal of Direct Final Rule

In the **Federal Register** of December 3, 2002 (67 FR 71847) (FRL-6824-2), the Agency published a direct final rule to establish 40 CFR 180.940. Comments were received. In the December 3, 2002 **Federal Register** notice, EPA announced that it would withdraw the direct final rule if it received adverse comment, and proceed with proposed rule as provided by section 553 of the Administrative Procedure Act, 5 U.S.C. 553. Because some of the comments were of a nature that would warrant a response if made on a proposed rule, they are adverse comments that require withdrawal of the direct final rule. Accordingly, EPA withdrew the direct final rule on March 24, 2003 (68 FR 14165) (FRL-7299-4).

Several of the comments reflected some understandable confusion on the part of the commenters. While EPA's chemical-specific approach and FDA's formulation specific approach are essentially equivalent, the two approaches look and read differently. EPA disaggregated the 46 formulations in 21 CFR 178.1010 into a list of chemicals. This list of chemicals was then subdivided into three separate lists based on use categories in 21 CFR 178.1010 (i.e., food-contact surfaces in public eating places, dairy processing equipment, and food-processing equipment and utensils). The 40 CFR 180.940(a) list contains only the chemicals specified in those formulations that were designated by FDA for use in public eating places. The 40 CFR 180.940(b) list contains only the chemicals specified in those formulations that were designated by FDA for use on dairy equipment. The 40

CFR 180.940(c) list contains all chemicals because all formulations in 21 CFR 178.1010 can be used on food-processing equipment and utensils.

The maximum concentration level for each chemical was determined by evaluating the range derived from the lists in 40 CFR 180.940(a), (b), or (c). Where 21 CFR 178.1010 authorized several different sanitizing solutions each containing a particular chemical, but at different concentrations, EPA will use only the highest concentration as the upper limit, reflecting FDA's implicit determination that concentrations up to and including that limit do not compromise food safety. As an example, if three solutions authorized under 21 CFR 178.1010 for use on dairy equipment contain chemical "X" at concentrations of 150, 200, and 240 parts per million (ppm), then 240 ppm would be used as the upper limit in 40 CFR 180.940(b). If for chemical "Y," concentrations of 150 and 200 ppm were specified, but in a third solution the concentration was not specified, then the upper limit for chemical "Y" in 40 CFR 180.940(c) would be specified as "none." This reflects FDA's implicit determination in regard to that third sanitizing solution that chemical "Y" could be used in any concentration without significant risk to food safety.

In addition to the disaggregation, the Agency also in some cases used a different chemical nomenclature. CI (chemical index) names and CAS Nos. were used to the greatest extent possible. This is part of an Agency-wide effort to provide a common and consistent way to identify and represent chemical substances across the Agency. Thus, sodium hypochlorite became hypochlorous acid, sodium salt. In other instances (most commonly involving polymers or quaternary ammonium compounds), FDA approved in one solution a particular chemical that falls within a more inclusive chemical designation approved in another solution. If practicable in such instances, EPA has stated the tolerance exemption only in terms of the more inclusive chemical designation, implicitly exempting all chemical substances that fall within that designation. For example, n-alkyl (C₁₂-C₁₆) benzyl dimethyl ammonium chloride would be considered to be a subset of n-alkyl (C₁₂-C₁₈) benzyl dimethyl ammonium chloride. Another example, n-alkyl (C₁₂-C₁₈) benzyl dimethyl ammonium chloride (mw 351 to 380) would also be considered a subset of n-alkyl (C₁₂-C₁₈) benzyl dimethyl ammonium chloride. Both of the example chemicals would be

accounted for under the nomenclature quaternary ammonium compounds alkyl (C₁₂-C₁₈) benzyl dimethyl, chlorides. For each comment questioning whether a particular chemical substance appeared in the direct final rule, the Agency was able to verify that the chemical for which the commenter expressed concern was included in 40 CFR 180.940, albeit under a different designation.

A commenter asked that instead of using the term "oxychloro species," that sodium chlorite or chlorine dioxide should be used instead. The "generated by" language was considered to be confusing in a listing of chemical names. The Agency (as acknowledged by the commenter) used FDA's language, which is an approach which describes the process for generating the solution, not the components of the solution. If the end-products of the generation process were specific chemicals already included in the other solutions (and therefore already line-items), then the Agency used the disaggregated approach. However, for the oxychloro species generation methods described in 21 CFR 178.1010(b)(34), the chlorite, chlorate, and/or chlorine dioxide is actually an equilibrium mixture. There are no separate line-item entries for these chemicals. In fact, the upper concentration limit is specified in terms of chlorine dioxide only, thus making it difficult to separate the chemicals into line items. The Agency determined therefore to maintain the original FDA language at this time. The Agency also considered that other generation methods for oxychloro species could be submitted as part of the non-designated prior approved chemical substances, which could impact the handling of this in the future.

Several commenters asked if a specific combination of quaternary ammonium compounds expressly identified in 21 CFR 178.1010(b)(22) were included in 40 CFR 180.940. Each of the component chemicals identified in 21 CFR 178.1010(b)(22) are identified in 40 CFR 180.940 as subject to a tolerance exemption. The two components listed in 21 CFR 178.1010(b)(22) are di-n-alkyl (C₈-C₁₀) dimethylammonium chloride (mw 332 to 361) and n-alkyl (C₁₂-C₁₈) benzyl dimethyl ammonium chloride (mw 351 to 380). The first chemical is listed in 40 CFR 180.940 as "Quaternary ammonium compounds, di-n-alkyl (C₈-C₁₀) dimethyl ammonium chloride average molecular weight (in amu) 332 to 361." 21 CFR 178.1010(b)(22) and 21 CFR 178.1010(c)(17) together allow a maximum end-use concentration of 400

ppm of the two quaternary ammonium compounds in this solution, of which this particular chemical must comprise 60%. EPA's regulation exempts this chemical substance from the requirement of a tolerance in sanitizing solutions up to 240 ppm, which is 60% of the 400 ppm authorized in the FDA regulations. The second chemical is listed in 40 CFR 180.940 as "Quaternary ammonium compounds, alkyl (C₁₂-C₁₈) benzyl dimethyl, chlorides." The end use concentration as specified in 21 CFR 178.1010(b)(22) and 21 CFR 178.1010(c)(17) for this chemical would be 40% of 400 ppm or 160 ppm. Because other solutions in 21 CFR 178.1010 included chemical substances within the description "quaternary ammonium compounds, alkyl (C₁₂-C₁₈) benzyl dimethyl, chlorides" without molecular weight limitations and/or with higher concentration limits, the description of this chemical in 40 CFR 180.940 is more broad than that of 21 CFR 178.1010(b)(22).

Based on one comment, the Agency was made aware of a typographical error in the December 3, 2002 **Federal Register** notice which has been corrected in this notice of proposed rulemaking. In 40 CFR 180.940(a) the upper limit should be not 150 ppm, but 200 ppm for C₁₂-C₁₆ benzyl dimethyl ammonium chloride (mw 351-380). With the change in upper limit to 200 ppm, C₁₂-C₁₆ benzyl dimethyl ammonium chloride (mw 351 to 380) can be appropriately held under the more inclusive quaternary ammonium compounds alkyl (C₁₂-C₁₈) benzyl dimethyl, chlorides.

Another commenter requested that the Agency change the language describing the upper limit concentration for all quaternary ammonium compounds. The commenter has suggested the use of the phrase "when ready to use, the end-use concentration is not expected to exceed 'X' ppm of this active quaternary ammonium compound," instead of the phrasing used by the Agency "when ready for use, concentration is not to exceed 'X' ppm of active quaternary compound." The commenter cited the concern that state enforcement personnel would apply the limitation for a particular quaternary ammonium compound to a mixture. The Agency believes that the language it has used is clear and concise. The concentration limits specified in 40 CFR 180.940 apply only to the chemical substance described in the particular table entry. However, the 30-day comment period will allow the Agency to take further comment on this issue.

A commenter asked that the Agency not distinguish between food-contact surfaces in public eating places, dairy-processing equipment, and food processing equipment and utensils. These categories were originally created by the FDA and reflect different assumptions especially with regard to dietary exposure to sanitizer residues, and thus are an intrinsic part of FDA's risk assessments. Although EPA has the authority to reconsider FDA's risk assessments, EPA can do so only upon fully reassessing these tolerance exemptions in accordance with FFDCA section 408, as amended by FQPA. EPA is not reassessing these tolerance exemptions at this time, but instead merely duplicating FDA's previous clearances in a format consistent with EPA's authority under FFDCA section 408. EPA is required under FFDCA section 408(q)(1)(C) to complete tolerance reassessment for all pesticide chemicals by 2006, and will consider the commenter's suggestion during tolerance reassessment.

Although not raised by commenters, EPA has made three additional changes from the December 3, 2003 **Federal Register** notice. D&C Blue No. 1 (methylene blue) is now referenced as methylene blue. Similarly, FD&C Yellow No. 5 (tartrazine) is now referenced as FD&C Yellow No. 5. A CAS No. was added to one entry (quaternary ammonium compounds, alkyl (C₁₂-C₁₈) benzyl dimethyl, chlorides) in 40 CFR 180.940(a).

V. Addition of Non-Designated, Prior Approved Chemical Substances

21 CFR 178.1010 allows the use of GRAS chemical substances and chemical substances "permitted by prior sanction or approval," that are not expressly identified. These chemical substances were subject to the sanitizer formulation approval under FDA's regulation before these uses became FFDCA section 408 tolerance exemptions under FFDCA section 408(j)(2). Accordingly, many food-contact sanitizing solutions that presently are authorized for use under 21 CFR 178.1010 contain ingredients which are not identified in this direct final rule. As discussed in this unit, EPA is asking registrants to identify these other ingredients that they believe should be included in 40 CFR 180.940. EPA intends to publish a revision to 40 CFR 180.940 adding these chemical substances. In the interim, to preserve the use of food-contact surface sanitizing solutions that were cleared for use before FQPA's enactment and that contain chemical substances that are not specifically identified in 21 CFR

178.1010, EPA has decided to honor those approvals under 21 CFR 178.1010 until EPA has received and reviewed registrant's claims with respect to unspecified pesticide chemicals, as discussed in this unit.

FDA's regulations (21 CFR 178.1010(b)) allowed the addition to food-contact surface sanitizing solutions of GRAS components, and components permitted by prior sanction or approval or subject to a letter of no objection. Much of this information should be in EPA's files. The Agency will access this information. However, EPA may not have ready access to all information on all chemicals in existing food-contact surface sanitizing solution formulations which could meet these criteria. Submission of this information to EPA would also reduce the possibility of an existing food-contact surface sanitizing solution having a component that lacks a tolerance exemption under 40 CFR 180.940. Therefore, registrants who believe that components of their food-contact surface sanitizing solutions are exempted under 21 CFR 178.1010(b) should advise EPA in writing that these chemical substances (along with the CAS No.) should be included in 40 CFR 180.940. The submission of this information facilitates EPA's process for adding these chemical substances cleared under 21 CFR 178.1010(b), but not specifically listed by name, to 40 CFR 180.940. The EPA will also need any available information documenting the claim that the component is GRAS, prior sanctioned or approved, or subject to a letter of no objection.

Claims and supporting documentation should be sent to the person listed under **FOR FURTHER INFORMATION CONTACT**. Claims are not comments on this direct final rule and should be identified on the subject line as "Submission of Non-designated Prior Approved Chemical Substance." If you have any questions about the many types of information that could be submitted please consult the person listed under **FOR FURTHER INFORMATION CONTACT**. The Agency does not anticipate that registrants will be required to submit an excessive amount of information, and, in fact, believes that most registrants will be able to submit the necessary information with minimal effort. EPA will review and evaluate the information provided. Chemical substances identified in claims received not later than October 1, 2003, may be eligible for inclusion in 40 CFR 180.940 under FFDCA section 408(j)(2). EPA anticipates publishing a notice of proposed rulemaking identifying those chemical substances shortly after that date.

VI. Statutory and Executive Order Reviews

This proposed rule would add a new § 180.940 to 40 CFR part 180, subpart D, which lists the pesticide chemicals that are exempt from the requirement of a tolerance when used in food-contact surface sanitizing solutions. The initial list duplicates pesticide chemicals in 40 CFR 180.940 that are active and inert ingredients listed in 21 CFR 178.1010. Since this proposed rule does not impose any new requirements, it is not subject to review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed 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 proposed rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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).

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 proposed 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 the FFDCA. For these same reasons, the Agency has determined that this proposed 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 proposed 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 proposed rule.

Under section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that the creation of a new section 180.940 will not have significant negative economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows. This proposed rule does not impose any requirements, it establishes exemptions from the requirement for a tolerance. The Agency is, however, also commencing a process whereby EPA will require certain persons to identify chemical substances considered to be GRAS (which could include self-affirmed GRAS chemicals), or permitted by prior sanction or approval in existing food contact surface sanitizing solutions. The information

available to the Agency indicates that fewer than 500 companies have approximately 1,300 products that could fall under this category. EPA anticipates the economic burden on small entities to be minor, since the Agency is only asking for confirmation that the chemical substances considered to be GRAS or permitted by prior sanction or approval in existing food contact surface sanitizing solutions are in fact part of an existing formulation, and information as to why the chemical is considered to be GRAS, or a copy of an FDA letter not objecting to the use of a chemical substance. By contrast, this proposed rule will be beneficial to the regulated community by increasing the number of inert ingredients for use in antimicrobial formulations and by reducing the regulatory burden on persons seeking to market new combinations of ingredients for certain hard surface sanitizing solutions. Additionally, this proposed rule will provide a more transparent listing of pesticide chemicals used in food-contact surface sanitizing solutions to the public.

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations, after initial display in the preamble of the final rule and in addition to its display on any related collection instrument, are listed in 40 CFR part 9.

This proposed rule does not impose any new information collection requirements that would require separate approval by OMB under the PRA. Under 5 CFR 1320.3(h), the request for information discussed in Unit V. is not subject to approval under the PRA, and the information collection activities related to the Agency’s tolerance exemption process have already been approved by OMB under OMB control numbers 2070-0024 (EPA ICR No. 597). The annual “respondent” (petitioner) burden for the pesticide tolerance petitions program is estimated to average 1,726 hours per petition. According to the PRA, “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other

required paperwork, and storing, filing, and maintaining the data. Send comments regarding this burden estimate or any other aspect of the collection activity, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Include the OMB control number 2070-0024 in any correspondence about this collection activity, but do not submit the requested information or forms to this address.

List of Subjects in 40 CFR Part 180

Environmental protection, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 11, 2003.

James Jones,
Director, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180—[AMENDED]

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

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

2. A new § 180.940 is added to subpart D of part 180 to read as follows.

§ 180.940 Food-contact surface sanitizing solutions; exemptions from the requirement of a tolerance.

Residues of the following chemical substances are exempted from the requirement of a tolerance when used in

accordance with good manufacturing practice as ingredients in an antimicrobial pesticide formulation, provided that the chemical substance is applied on a semi-permanent or permanent food-contact surface (other than being applied on food packaging) with adequate draining before contact with food.

(a) The following chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to: Food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

Pesticide chemical	CAS No.	Limits
Acetic acid	64-19-7	When ready for use, the end-use concentration is not to exceed 290 parts per million (ppm)
α -Alkyl(C ₁₀ -C ₁₄)- ω -hydroxypoly(oxyethylene) poly(oxypropylene) average molecular weight (in amu), 768 to 837	None	None
α -Alkyl(C ₁₂ -C ₁₈)- ω -hydroxypoly(oxyethylene) poly(oxypropylene) average molecular weight (in amu), 950 to 1,120	None	None
Ammonium chloride	12125-02-9	When ready for use, the end-use concentration is not to exceed 48 ppm
Dextrin	9004-53-9	When ready for use, the end-use concentration is not to exceed 16 ppm
Ethanol	64-17-5	None
Ethylenediaminetetraacetic acid (EDTA), tetrasodium salt	64-02-8	None
Hydrogen peroxide	7722-84-1	When ready for use, the end-use concentration is not to exceed 91 ppm
Hypochlorous acid, sodium salt	7681-52-9	When ready for use, the end-use concentration is not to exceed 200 ppm determined as total available chlorine
Iodine	7553-56-2	When ready for use, the end-use concentration is not to exceed 25 ppm of titratable iodine
Magnesium oxide	1309-48-4	None
Methylene blue	61-73-4	When ready for use, the end-use concentration is not to exceed 0.4 ppm
α -(p-Nonylphenyl)- ω -hydroxypoly(oxyethylene) poly(oxyethylene) content 11 moles	None	None
Octadecanoic acid, calcium salt	1592-23-0	When ready for use, the end-use concentration is not to exceed 16 ppm
1-Octanesulfonic acid, sodium salt	5324-84-5	When ready for use, the end-use concentration is not to exceed 46 ppm of total active fatty acids
Octanoic acid	124-07-2	When ready for use, the end-use concentration is not to exceed 52 ppm of total active fatty acids
Oxirane, methyl-, polymer with oxirane, minimum molecular weight (in amu), 1,900	9003-11-6	None

Pesticide chemical	CAS No.	Limits
Peroxyacetic acid	79-21-0	When ready for use, the end-use concentration is not to exceed 58 ppm
Peroxyoctanoic acid	33734-57-5	When ready for use, the end-use concentration is not to exceed 52 ppm
Phosphonic acid, (1-hydroxyethylidene)bis-	2809-21-4	When ready for use, the end-use concentration is not to exceed 14 ppm
Phosphoric acid, trisodium salt	7601-54-9	When ready for use, the end-use concentration is not to exceed 5,916 ppm
Potassium bromide	7758-02-3	When ready for use, the end-use concentration is not to exceed 46 ppm total available halogen
Potassium iodide	7681-11-0	When ready for use, the end-use concentration is not to exceed 25 ppm of titratable iodine
Potassium permanganate	7722-64-7	When ready for use, the end-use concentration is not to exceed 0.7 ppm
2-Propanol (isopropanol)	67-63-0	None
Quaternary ammonium compounds, alkyl (C ₁₂ -C ₁₈) benzyl dimethyl, chlorides	8001-54-5	When ready for use, the end-use concentration is not to exceed 200 ppm of active quaternary compound
Quaternary ammonium compounds, n-alkyl (C ₁₂ -C ₁₄) dimethyl ethylbenzyl ammonium chloride, average molecular weight (in amu), 377 to 384	None	When ready for use, the end-use concentration is not to exceed 200 ppm of active quaternary compound
Quaternary ammonium compounds n-alkyl (C ₁₂ -C ₁₈) dimethyl ethylbenzyl ammonium chloride average molecular weight (in amu), 384	None	When ready for use, the end-use concentration is not to exceed 200 ppm of active quaternary compound
Quaternary ammonium compounds di-n-alkyl (C ₈ -C ₁₀) dimethyl ammonium chloride, average molecular weight (in amu), 332 to 361	None	When ready for use, the end-use concentration is not to exceed 150 ppm of active quaternary compound
Sodium bicarbonate	144-55-8	When ready for use, the end-use concentration is not to exceed 120 ppm
Starch	9005-25-8	When ready for use, the end-use concentration is not to exceed 16 ppm
Sulfuric acid monododecyl ester, sodium salt (sodium lauryl sulfate)	151-21-3	When ready for use, the end-use concentration is not to exceed 3 ppm
1,3,5-Triazine-2,4,6-(1H,3H,5H)-trione, 1,3-dichloro-, sodium salt	2893-78-9	When ready for use, the end-use concentration is not to exceed 100 ppm determined as total available chlorine

(b) The following chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to: Dairy-processing equipment and food-processing equipment and utensils.

Pesticide chemical	CAS No.	Limits
Acetic acid	64-19-7	When ready for use, the end-use concentration is not to exceed 686 ppm
Acetic acid, chloro-, sodium salt, reaction products with 4,5-dihydro-2-undecyl-1H-imidazole-1-ethanol and sodium hydroxide	68608-66-2	When ready for use, the end-use concentration is not to exceed 42 ppm chloroacetic acid
Benzenesulfonic acid, dodecyl-	27176-87-0	When ready for use, the end-use concentration is not to exceed 5.5 ppm
Butanedioic acid, octenyl-	28805-58-5	When ready for use, the end-use concentration is not to exceed 156 ppm
Butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, minimum average molecular weight (in amu), 2400	None	None
Calcium chloride	10043-52-4	When ready for use, the end-use concentration is not to exceed 17 ppm

Pesticide chemical	CAS No.	Limits
n-Carboxylic acids (C ₆ -C ₁₂), consisting of a mixture of not less than 56% octanoic acid and not less than 40% decanoic acid	None	When ready for use, the end-use concentration is not to exceed 39 ppm
Citric acid	77-92-9	None
Decanoic acid	334-48-5	When ready for use, the end-use concentration is not to exceed 90 ppm total active fatty acids
Ethanesulfonic acid, 2-[cyclohexyl (1-oxohexadecyl)amino]-, sodium salt	132-43-4	When ready for use, the end-use concentration is not to exceed 237 ppm
Ethylenediaminetetraacetic acid (EDTA), disodium salt	139-33-3	When ready for use, the end-use concentration is not to exceed 1,400 ppm
FD&C Yellow No. 5 (conforming to 21 CFR 74.705)	1934-21-0	None
D-Gluconic acid, monosodium salt	527-07-1	When ready for use, the end-use concentration is not to exceed 760 ppm
Hydriodic acid	10034-85-2	When ready for use, the end-use concentration is not to exceed 25 ppm of titratable iodine
Hydrogen peroxide	7722-84-1	When ready for use, the end-use concentration is not to exceed 465 ppm
Hypochlorous acid	7790-92-3	When ready for use, the end-use concentration is not to exceed 200 ppm determined as total available chlorine
Iodine	7553-56-2	When ready for use, the end-use concentration is not to exceed 25 ppm of titratable iodine
Lactic acid	50-21-5	When ready for use, the end-use concentration is not to exceed 138 ppm
α-Lauroyl-ω-hydroxypoly (oxyethylene) with an average of 8-9 moles ethylene oxide, average molecular weight (in amu), 400	None	None
Nonanoic acid	112-05-0	When ready for use, the end-use concentration is not to exceed 90 ppm
1-Octanamine, N,N-dimethyl-	7378-99-6	When ready for use, the end-use concentration is not to exceed 113 ppm
1,2-Octanedisulfonic acid	113669-58-2	When ready for use, the end-use concentration is not to exceed 102 ppm
1-Octanesulfonic acid	3944-72-7	When ready for use, the end-use concentration is not to exceed 172 ppm
1-Octanesulfonic acid, sodium salt	5324-84-5	When ready for use, the end-use concentration is not to exceed 297 ppm
1-Octanesulfonic acid, 2-sulfino-	113652-56-5	When ready for use, the end-use concentration is not to exceed 102 ppm
Octanoic acid	124-07-2	When ready for use, the end-use concentration is not to exceed 176 ppm of total active fatty acids
Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediylidinitrilo)tetrakis[propanol] (4:1)	11111-34-5	When ready for use, the end-use concentration is not to exceed 20 ppm in the formulated product
Oxychloro species (including chlorine dioxide) generated by acidification of an aqueous solution of sodium chlorite	None	When ready for use, the end-use concentration is not to exceed 200 ppm of chlorine dioxide as determined by the method entitled, "Iodometric Method for the Determination of Available Chlorine Dioxide" (50-250 ppm available chlorine dioxide)
Peroxyacetic acid	79-21-0	When ready for use, the end-use concentration is not to exceed 315 ppm
Peroxyoctanoic acid	33734-57-5	When ready for use, the end-use concentration is not to exceed 122 ppm

Pesticide chemical	CAS No.	Limits
Phosphonic acid, (1-hydroxyethylidene)bis-	2809-21-4	When ready for use, the end-use concentration is not to exceed 34 ppm
Phosphoric acid	7664-38-2	None
Phosphoric acid, monosodium salt	7558-80-7	When ready for use, the end-use concentration is not to exceed 350 ppm
Potassium iodide	7681-11-0	When ready for use, the end-use concentration is not to exceed 25 ppm of titratable iodine
Propanoic acid	79-09-4	When ready for use, the end-use concentration is not to exceed 297 ppm
2-Propanol (isopropanol)	67-63-0	
2,6-Pyridinedicarboxylic acid	499-83-2	When ready for use, the end-use concentration is not to exceed 1.2 ppm
Sodium mono-and didodecylphenoxy-benzenedisulfonate	None	When ready for use, the end-use concentration is not to exceed 1,920 ppm
Sulfuric acid	7664-93-9	When ready for use, the end-use concentration is not to exceed 288 ppm
Sulfuric acid monododecyl ester, sodium salt (sodium lauryl sulfate)	151-21-3	When ready for use, the end-use concentration is not to exceed 350 ppm

(c) The following chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to: Food-processing equipment and utensils.

Pesticide chemical	CAS No.	Limits
Acetic acid	64-19-7	When ready for use, the end-use concentration is not to exceed 686 ppm
Acetic acid, chloro-, sodium salt, reaction products with 4,5-dihydro-2-undecyl-1H-imidazole-1-ethanol and sodium hydroxide	68608-66-2	When ready for use, the end-use concentration is not to exceed 42 ppm chloroacetic acid
α -Alkyl(C ₁₀ -C ₁₄)- ω -hydroxypoly(oxyethylene) poly(oxypropylene) average molecular weight (in amu), 768 to 837	None	None
α -Alkyl(C ₁₁ -C ₁₅)- ω -hydroxypoly(oxyethylene) with ethylene oxide content 9 to 13 moles	None	None
α -Alkyl(C ₁₂ -C ₁₅)- ω -hydroxypoly(oxyethylene) polyoxypropylene, average molecular weight (in amu), 965	None	None
α -Alkyl(C ₁₂ -C ₁₈)- ω -hydroxypoly(oxyethylene) poly(oxypropylene) average molecular weight (in amu), 950 to 1,120	None	None
Alkyl (C ₁₂ -C ₁₅) monoether of mixed (ethylene-propylene) polyalkylene glycol, cloud point of 70-77 °C in 1% aqueous solution, average molecular weight (in amu), 807	None	None
Ammonium chloride	12125-02-9	When ready for use, the end-use concentration is not to exceed 48 ppm
Benzenesulfonamide, N-chloro-4-methyl, sodium salt	127-65-1	None
Benzenesulfonic acid, dodecyl-	27176-87-0	When ready for use, the end-use concentration is not to exceed 400 ppm
Benzenesulfonic acid, dodecyl-, sodium salt	25155-30-0	When ready for use, the end-use concentration is not to exceed 430 ppm
Benzenesulfonic acid, oxybis[dodecyl-	30260-73-2	When ready for use, the end-use concentration is not to exceed 474 ppm
[1,1'-Biphenyl]-2-ol	90-43-7	When ready for use, the end-use concentration is not to exceed 400 ppm

Pesticide chemical	CAS No.	Limits
Boric acid, sodium salt	7775-19-1	
Butanedioic acid, octenyl-	28805-58-5	When ready for use, the end-use concentration is not to exceed 156 ppm
Butanedioic acid, sulfo-, 1,4-dioctyl ester, sodium salt	1639-66-3	None
Butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, cloudpoint of 90-100 °C in 0.5 aqueous solution, average molecular weight (in amu), 3,300	None	None
Butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, minimum average molecular weight (in amu), 2,400	None	None
Calcium bromide	7789-41-5	When ready for use, the end-use concentration is not to exceed 200 ppm total available halogen
Calcium chloride	10043-52-4	When ready for use, the end-use concentration is not to exceed 17 ppm
<i>n</i> -Carboxylic acids (C ₆ -C ₁₂), consisting of a mixture of not less than 56% octanoic acid and not less than 40% decanoic acid	None	When ready for use, the end-use concentration is not to exceed 39 ppm
Citric acid	77-92-9	None
3-Cyclohexene-1-methanol, $\alpha,\alpha,4$ -trimethyl-	98-55-5	None
1-Decanaminium, N-decyl-N, N-dimethyl-, chloride	7173-51-5	When ready for use, the end-use concentration is not to exceed 200 ppm of active quaternary compound
Decanoic acid	334-48-5	When ready for use, the end-use concentration is not to exceed 234 ppm total active fatty acids
Dextrin	9004-53-9	When ready for use, the end-use concentration is not to exceed 16 ppm
Ethanesulfonic acid, 2-[cyclohexyl (1-oxohexadecyl)amino]-, sodium salt	132-43-4	When ready for use, the end-use concentration is not to exceed 237 ppm
Ethanol	64-17-5	None
Ethanol, 2 butoxy-	111-76-2	None
Ethanol, 2-(2-ethoxyethoxy)-	111-90-0	None
Ethylenediaminetetraacetic acid (EDTA), disodium salt	139-33-3	When ready for use, the end-use concentration is not to exceed 1,400 ppm
Ethylenediaminetetraacetic acid (EDTA), tetrasodium salt	64-02-8	None
Fatty acids, coco, potassium salts	61789-30-8	None
Fatty acids, tall-oil, sulfonated, sodium salts	68309-27-3	When ready for use, the end-use concentration is not to exceed 66 ppm
FD&C Yellow No. 5 (conforming to 21 CFR 74.705)	1934-21-0	None
D-Gluconic acid, monosodium salt	527-07-1	When ready for use, the end-use concentration is not to exceed 760 ppm
Hydriodic acid	10034-85-2	When ready for use, the end-use concentration is not to exceed 25 ppm of titratable iodine
Hydrogen peroxide	7722-84-1	When ready for use, the end-use concentration is not to exceed 1,100 ppm
Hypochlorous acid	7790-92-3	When ready for use, the end-use concentration is not to exceed 200 ppm determined as total available chlorine
Hypochlorous acid, calcium salt	7778-54-3	When ready for use, the end-use concentration is not to exceed 200 ppm determined as total available chlorine

Pesticide chemical	CAS No.	Limits
Hypochlorous acid, lithium salt	13840-33-0	When ready for use, the end-use concentration is not to exceed 200 ppm determined as total available chlorine and 30 ppm lithium
Hypochlorous acid, potassium salt	7778-66-7	When ready for use, the end-use concentration is not to exceed 200 ppm determined as available chlorine
Hypochlorous acid, sodium salt	7681-52-9	When ready for use, the end-use concentration is not to exceed 200 ppm determined as available chlorine
Iodine	7553-56-2	When ready for use, the end-use concentration is not to exceed 25 ppm of titratable iodine
Lactic acid	50-21-5	None
α -Lauroyl- ω -hydroxypoly (oxyethylene) with an average of 8-9 moles ethylene oxide, average molecular weight (in amu), 400	None	None
Magnesium oxide	1309-48-4	None
Methylene blue	61-73-4	When ready for use, the end-use concentration is not to exceed 0.4 ppm
Naphthalene sulfonic acid, sodium salt	1321-69-3	When ready for use, the end-use concentration is not to exceed 332 ppm total naphthalene sulfonates
Naphthalene sulfonic acid sodium salt, and its methyl, dimethyl and trimethyl derivatives	None	When ready for use, the end-use concentration is not to exceed 332 ppm total naphthalene sulfonates
Naphthalene sulfonic acid sodium salt, and its methyl, dimethyl and trimethyl derivatives alkylated at 3% by weight with C ₆ -C ₉ linear olefins	None	When ready for use, the end-use concentration is not to exceed 332 ppm total naphthalene sulfonates
Neodecanoic acid	26896-20-8	When ready for use, the end-use concentration is not to exceed 174 ppm
Nonanoic acid	112-05-0	When ready for use, the end-use concentration is not to exceed 90 ppm
α -(p-Nonylphenyl)- ω -hydroxypoly(oxyethylene) maximum average molecular weight (in amu), 748	None	None
α -(p-Nonylphenol)- ω -hydroxypoly(oxyethylene) average poly(oxyethylene) content 11 moles	None	None
α -(p-Nonylphenyl)- ω -hydroxypoly(oxyethylene) produced by the condensation of 1 mole p-nonylphenol with 9 to 12 moles ethylene oxide	None	None
α -(p-Nonylphenyl)- ω -hydroxypoly(oxyethylene), 9 to 13 moles ethylene oxide	None	None
Octadecanoic acid, calcium salt	1592-23-0	When ready for use, the end-use concentration is not to exceed 16 ppm
9-Octadecenoic acid (9Z)-, sulfonated	68988-76-1	When ready for use, the end-use concentration is not to exceed 312 ppm
9-Octadecenoic acid (9Z)-sulfonated, sodium salts	68443-05-0	When ready for use, the end-use concentration is not to exceed 200 ppm
1-Octanamine, N,N-dimethyl-	7378-99-6	When ready for use, the end-use concentration is not to exceed 113 ppm
1,2-Octanedisulfonic acid	113669-58-2	When ready for use, the end-use concentration is not to exceed 102 ppm
1-Octanesulfonic acid	3944-72-7	When ready for use, the end-use concentration is not to exceed 172 ppm
1-Octanesulfonic acid, sodium salt	5324-84-5	When ready for use, the end-use concentration is not to exceed 312 ppm

Pesticide chemical	CAS No.	Limits
1-Octanesulfonic acid, 2-sulfino-	113652-56-5	When ready for use, the end-use concentration is not to exceed 102 ppm
Octanoic acid	124-07-2	When ready for use, the end-use concentration is not to exceed 234 ppm of total active fatty acids
Oxirane, methyl-, polymer with oxirane, minimum molecular weight (in amu), 1,900	9003-11-6	None
Oxirane, methyl-, polymer with oxirane, block, average molecular weight (in amu), 1,900	106392-12-5	None
Oxirane, methyl-, polymer with oxirane, block, minimum average molecular weight (in amu), 2,000	None	None
Oxirane, methyl-, polymer with oxirane, block, 27 to 31 moles of polyoxypropylene, average molecular weight (in amu) 2,000	None	None
Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis[propanol] (4:1)	11111-34-5	When ready for use, the end-use concentration is not to exceed 20 ppm
Oxychloro species (predominantly chlorite, chlorate and chlorine dioxide in an equilibrium mixture) generated either: By directly metering a concentrated chlorine dioxide solution prepared just prior to use, into potable water, or by acidification of an aqueous alkaline solution of oxychloro species (predominately chlorite and chlorate) followed by dilution with potable water	None	When ready for use, the end-use concentration is not to exceed 200 ppm of chlorine dioxide as determined by the method entitled, "Iodometric Method for the Determination of Available Chlorine Dioxide" (50-250 ppm available chlorine dioxide)
Oxychloro species (including chlorine dioxide) generated by acidification of an aqueous solution of sodium chlorite	None	When ready for use, the end-use concentration is not to exceed 200 ppm of chlorine dioxide as determined by the method entitled, "Iodometric Method for the Determination of Available Chlorine Dioxide" (50-250 ppm available chlorine dioxide)
2,4-Pentandiol, 2-methyl-	107-41-5	None
Peroxyacetic acid	79-21-0	When ready for use, the end-use concentration is not to exceed 315 ppm in the formulated product
Peroxyoctanoic acid	33734-57-5	When ready for use, the end-use concentration is not to exceed 122 ppm
Phenol, 4-chloro-2-(phenylmethyl)-	120-32-1	When ready for use, the end-use concentration is not to exceed 320 ppm
Phenol, 4-(1,1-dimethylpropyl)-	80-46-6	When ready for use, the end-use concentration is not to exceed 80 ppm
Phosphonic acid, (1-hydroxyethylidene)bis-	2809-21-4	When ready for use, the end-use concentration is not to exceed 34 ppm
Phosphoric acid	7664-38-2	None
Phosphoric acid, monosodium salt	7558-80-7	When ready for use, the end-use concentration is not to exceed 350 ppm
Phosphoric acid, trisodium salt	7601-54-9	When ready for use, the end-use concentration is not to exceed 5916 ppm in the formulated product
Poly(oxy-1,2-ethanediyl), α -[(1,1,3,3-tetramethylbutyl)phenyl]- ω -hydroxy-, produced with one mole of the phenol and 4 to 14 moles ethylene oxide	None	None
Potassium bromide	7758-02-3	When ready for use, the end-use concentration is not to exceed 200 ppm total available halogen
Potassium iodide	7681-11-0	When ready for use, the end-use concentration is not to exceed 25 ppm of titratable iodine
Potassium permanganate	7722-64-7	When ready for use, the end-use concentration is not to exceed 0.7 ppm

Pesticide chemical	CAS No.	Limits
Propanoic acid	79-09-4	When ready for use, the end-use concentration is not to exceed 297 ppm
2-Propanol (isopropanol)	67-63-0	None
2,6-Pyridinedicarboxylic acid	499-83-2	When ready for use, the end-use concentration is not to exceed 1.2 ppm
Quaternary ammonium compounds, alkyl (C ₁₂ -C ₁₈) benzyl dimethyl, chlorides	8001-54-5	When ready for use, the end-use concentration is not to exceed 200 ppm of active quaternary compound
Quaternary ammonium compounds, n-alkyl (C ₁₂ -C ₁₄) dimethyl ethylbenzyl ammonium chloride, average molecular weight (in amu), 377 to 384	None	When ready for use, the end-use concentration is not to exceed 200 ppm of active quaternary compound
Quaternary ammonium compounds, n-alkyl (C ₁₂ -C ₁₈) dimethyl ethylbenzyl ammonium chloride average molecular weight (in amu) 384	None	When ready for use, the end-use concentration is not to exceed 200 ppm of active quaternary compound
Quaternary ammonium compounds, di-n-Alkyl (C ₈ -C ₁₀) dimethyl ammonium chloride, average molecular weight (in amu), 332 to 361	None	When ready for use, the end-use concentration is not to exceed 240 ppm of active quaternary compound
Sodium- α -alkyl(C ₁₂ -C ₁₅)- ω -hydroxypoly (oxyethylene) sulfate with the poly(oxyethylene) content averaging one mole	None	None
Sodium bicarbonate	144-55-8	When ready for use, the end-use concentration is not to exceed 120 ppm
Sodium bromide	7647-15-6	When ready for use, the end-use concentration is not to exceed 200 ppm total available halogen
Sodium iodide	7681-82-5	When ready for use, the end-use concentration is not to exceed 25 ppm of titratable iodine
Sodium mono-and didodecylphenoxy-benzenedisulfonate	None	When ready for use, the end-use concentration is not to exceed 1,920 ppm
Starch	9005-25-8	When ready for use, the end-use concentration is not to exceed 16 ppm
Sulfuric acid	7664-93-9	When ready for use, the end-use concentration is not to exceed 228 ppm
Sulfuric acid monododecyl ester, sodium salt (sodium lauryl sulfate)	151-21-3	None
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-	2782-57-2	When ready for use, the end-use concentration is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-, potassium salt	2244-21-5	When ready for use, the end-use concentration is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-, sodium salt	2893-78-9	When ready for use, the end-use concentration is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-trichloro-	87-90-1	When ready for use, the end-use concentration is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine, N,N',N''-trichloro-2,4,6-triamino-	7673-09-8	When ready for use, the end-use concentration is not to exceed 200 ppm as total available chlorine
Xylenesulfonic acid, sodium salt	1300-72-7	When ready for use, the end-use concentration is not to exceed 62 ppm

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