

Authority: 42 U.S.C. 7401 *et seq.*

Subpart MM—Oregon

■ 2. Section 52.1970 is amended by adding paragraph (c)(151)(ii)(B) to read as follows:

§ 52.1970 Identification of plan.

* * * * *

- (c) * * *
- (151) * * *
- (ii) * * *

(B) The remaining portions of the December 20, 2010, SIP revision, which relate to establishing reasonable progress goals, and a long term strategy to achieve these reasonable progress goals.

* * * * *

■ 3. Section 52.1973 is amended by adding paragraph (g)(2) to read as follows:

§ 52.1973 Approval of plans.

* * * * *

- (g) * * *

(2) EPA approves the remaining portions of the Regional Haze SIP revision submitted by the Oregon Department of Environmental Quality on December 20, 2010, and adopted by the Oregon Department of Environmental Quality Commission on December 9, 2010, as meeting the requirements of the Clean Air Act section 169A and 40 CFR 51.308(d)(1) regarding establishing reasonable progress goals, and 51.308(d)(3) for developing a long term strategy to achieve these goals.

[FR Doc. 2012-20496 Filed 8-21-12; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0950; FRL-9359-5]

Didecyl Dimethyl Ammonium Carbonate and Didecyl Dimethyl Ammonium Bicarbonate; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the exemption from the requirement of a tolerance for residues of Didecyl Dimethyl Ammonium Carbonate and Didecyl Dimethyl Ammonium Bicarbonate, jointly referred to as DDACB on food contact surfaces when applied or used in public eating places, dairy processing equipment, and/or

food processing equipment and utensils. Lonza, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment which would provide for an increase in the final use concentration of DDACB in products eligible for the exemption from the requirement of a tolerance. As amended, the regulation will exempt solutions from the requirement of tolerance residues resulting from contact with surfaces treated with solutions where the end-use concentration of the DDACB does not exceed 400 parts per million (ppm).

DATES: This regulation is effective August 22, 2012. Objections and requests for hearings must be received on or before October 22, 2012, 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: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0950, is available at <http://www.regulations.gov> or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Velma Noble, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 308-6233; email address: noble.velma@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Dairy Cattle Milk Production (NAICS code 11212).

- Food manufacturing (NAICS code 311).
- Beverage Manufacturing (NAICS code 3121).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0950 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 22, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0950, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>. Additional instructions on commenting or visiting the docket, along with more

among Quats and Measured Food Surrogate Transfer Efficiency (Master Record Identification Number 46870703), a conservative transfer rate of 43% was used to demonstrate the amount of residues on the surface that will be transferred to food and subsequently ingested. The maximum application rate for DDACB on utensils is 0.0033 lbs active ingredient (a.i.) per gallon of treatment solution.

There are two levels of refinement for assessing dietary exposure to antimicrobial products used on countertops. The three dimensional approach, Tier 2, was utilized for this assessment. This conservative approach uses food consumption and preparation patterns, food-specific conversion factors that relate the surface area contacting the countertop with the corresponding weight of the food item, transfer efficiency, and likelihood of contact with a countertop. Food ingredients, as presented in the model, are separated into nine categories and reflect a person's daily diet. Based on the structure of the model, available countertop residues are estimated and presented as the amount of residue that is expected to be available for each of the nine food categories. These calculated available residues are then combined with the food consumption rate, as extracted from the USDA Continuing Survey for Food Intake by Individuals (CSFII) consumption data, and a total daily exposure value is provided as the output. This value is then compared to the toxicological endpoint to determine risk to those consuming foods that have come into contact with a freshly sanitized countertop.

For the assessment of the food bottling/packaging use, EPA assumed a 100% transfer rate because the food is potentially in contact with the treated surfaces for very long periods of time. The maximum application rate for DDACB for bottling/packing of food is 0.0033 lbs a.i. per gallon of treatment solution. EDI values were calculated using an approach similar to that used for treated food utensils. Exposure was assumed to occur through the ingestion of three food products that might be packaged with treated material: Beverages (alcoholic and non-alcoholic), egg products, and milk. A calorie intake modification factor of 0.64 was applied to the EDI for a child to account for the differences between intake values among children and adults.

2. *Drinking water exposure.* DDACB outdoor uses are as an algaecide in wood preservative treatment and a slimicide in secondary oil field uses. The oil field uses are considered to be

contained. The other uses are not expected to significantly contaminate drinking water sources. Therefore, the DDACB contributions for drinking water exposure are considered to be negligible and are not quantified.

B. *Other Non-Occupational Exposure*

The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). DDACB is currently registered for the following residential non-dietary sites: Homes and day-care nurseries. EPA assessed residential exposure using the following assumptions:

- Residential exposure may occur during the application as well as post application of DDACB to indoor hard surfaces (e.g., mopping, trigger pump sprays, wiping).
- The residential handler scenarios were assessed to determine dermal and inhalation exposures.
- Residential post application scenarios such as children's exposure to treated toys and floors were also assessed to determine dermal and incidental oral exposures.
- Surrogate dermal, inhalation, and incidental oral unit exposure values were estimated using Pesticide Handler Exposure Database (PHED) data and the Chemical Manufacturers Association Antimicrobial Exposure Assessment Study (EPA, 1999). Note that for this assessment, EPA assumed that residential users complete all elements of an application (mix/load/apply) without the use of personal protective equipment.
- The duration for most residential exposures is believed to be best represented by the short-term duration (1 to 30 days). The short-term duration was chosen for this assessment because the residential handler and post-application scenarios are assumed to be performed on an episodic, not daily basis.

Specific information on the residential exposure assessment for DDACB can be found at <http://www.regulations.gov>. Docket ID Number EPA-HQ-OPP-2006-1024, Review of Petition to Amend 40 CFR 180.940 to add Didecyl Dimethyl Ammonium Carbonate/Bicarbonate.

C. *Additional Safety Factor for the Protection of Infants and Children*

1. *In general.* Section 408 of FFDCFA provides that EPA shall apply an additional tenfold ("10X") margin of safety for infants and children in the case of threshold effects to account for

prenatal and postnatal toxicity and the completeness of the data base on toxicity and EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) safety factor (SF). In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional uncertainty/safety factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.*

There is no evidence that Aliphatic Alkyl ammonium chloride quaternaries result in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X except for assessments addressing inhalation exposure. For inhalation exposure assessments the 10X FQPA safety factor is retained. Those decisions are based on the following findings:

i. The toxicity database for Aliphatic Alkyl Quaternaries is complete except for a 90-day inhalation toxicity study in the rat which was requested in the Aliphatic Alkyl Quaternary Reregistration Eligibility Document. Due to the absence of the 90-day inhalation toxicity study, a FQPA safety factor of 10X has been applied to the oral endpoint to calculate inhalation risks in order to be protective of any uncertainties associated with route-to-route extrapolation.

ii. There is no indication that Aliphatic Alkyl Quaternaries are neurotoxic chemicals and there is no need for a developmental neurotoxicity study or additional uncertainty factors to account for neurotoxicity.

iii. There is no evidence that Aliphatic Alkyl Quaternaries result in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental toxicity studies or in young rats in the 2-generation reproductive toxicity study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessment was performed based on 10% transfer rate and tolerance-level residues. Similarly conservative Residential SOPs were used to assess post-application exposure to children as well as incidental oral exposure of toddlers.

These assessments will not underestimate the exposure and risks posed by Aliphatic Alkyl Quaternaries.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

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

EPA’s risk assessment for the Group I Cluster is based on an assessment of the cumulative exposure to all aliphatic alkyl quaternary compounds. The individual exposure scenarios in the DDAC assessments (as well as the aggregate assessment in the Aliphatic Alkyl Quaternary (DDAC) Reregistration Eligibility Decision (RED)) were developed by assuming that a DDAC compound was used on 100% of the surfaces authorized on the label that could result in human exposure and summing the percent active ingredients on the labels for all of the aliphatic alkyl quaternary compounds when used in combination. Thus, because the risk assessment for DDAC accounts for exposures to all of the aliphatic alkyl quaternary compounds, there is no need for a separate cumulative risk assessment for those compounds. The Agency has not identified any other substances as sharing a common mode of toxicity with DDACB.

VI. Aggregate Risks and Determination of Safety

1. *Dietary risk from food and feed uses.* EPA compares the estimated dietary exposures to an acute population adjusted dose (aPAD) and a chronic population adjusted dose (cPAD), 0.1 mg/kg/day, which are the same value for DDACB. Generally, a dietary exposure estimate that is less than 100% of the aPAD or the cPAD does not exceed the Agency’s LOC.

The antimicrobial indirect food use acute and chronic risk estimates from exposure to treated utensils and countertops are below the Agency’s LOC. For adult males, the acute and chronic dietary exposure risk estimates are 9.9% for utensils and 0.8% for countertops. The aPAD and cPAD for adult females (13–69) is 11.5% for utensils. The aPAD from countertops for adult females is 0.8% and the cPAD is 0.5%. For children ages 1–2, the most highly exposed population subgroup, the acute and chronic dietary risk estimates are 68.9% for utensils and 2.6% and 1.8%, respectively for acute

and chronic dietary risks for countertops. Therefore, dietary exposure estimates are below Agency’s LOC for all population subgroups. The antimicrobial indirect food use chronic risk estimates from exposure to treated food packaging and beverage bottles are also below the Agency’s LOC.

Specific information on the dietary exposure assessment for DDACB can be found at <http://www.regulations.gov>. Docket ID Number EPA–HQ–2006–1024, Review of Petition to Amend 40 CFR 180.940 to add Didecyl Dimethyl Ammonium Carbonate/Bicarbonate.

2. *Non-occupational risk.* Aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Using the exposure assumptions described in this unit for other non-occupational exposures, the MOEs are greater than the target of 1,000 for the inhalation route of exposure and 10 for dermal exposure, with the exception of the short term dermal exposures in females which has an MOE of 9. However, there is no significant concern for the proposed increase in use concentrations from 240 ppm to 400 ppm, with regard to dermal exposure, considering the contributing MOEs used to calculate the MOE of 9 were derived using conservative assumptions for the unit exposures and quantity handled. Furthermore there is a low likelihood that all scenarios (mopping, wiping, trigger pump spraying, immersing items into a solution and wearing treated clothing items) that were used to derive an MOE of 9 for dermal exposure would occur simultaneously.

Based on the toxicological and exposure data discussed in this preamble, EPA concludes that DDACB will not pose a risk under reasonably foreseeable circumstances. Accordingly, EPA finds that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to DDACB residues.

VII. Other Considerations

An analytical method for food is not needed. Food-contact sanitizers are typically regulated by the State health departments to ensure that the food industry is using products in compliance with the regulations in 40 CFR 180.940. The end-use solution that is applied to the food-contact surface is analyzed not food items that may come into contact with treated surface. An analytical method is available to analyze the use dilution that is applied to food-contact surfaces. A titration method is used to determine the total amount of

quaternary compound. If the use solution is a mixture of ADBAC and DDACB, then high pressure liquid chromatogram with ultraviolet visible (HPLC–UV) is used to determine the amount of ADBAC. The amount of DDACB is determined by calculating the difference between the total amount of quaternary compounds and ADBAC.

VIII. Conclusion

This regulation amends the exemption from the requirement of a tolerance for residues of DDACB under 40 CFR 180.940(a) resulting from an increase in the final use concentration from 240 ppm to 400 ppm on food contact surfaces in public eating establishments, on dairy processing equipment and food processing equipment and utensils.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions

of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995

(NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Aliphatic alkyl quaternaries, Food-contact sanitizers, Pesticides and pests, Quaternary ammonium compounds, Reporting and recordkeeping requirements.

Dated: August 9, 2012.

Joan Harrigan-Farrelly,
Director, Antimicrobials Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.940(a), the table is amended by revising in its entirety, the entry for “Quaternary ammonium compounds, didecyl dimethyl ammonium carbonate/didecyl dimethyl ammonium bicarbonate” which immediately precedes the pesticide chemical which reads in part “Silver ions resulting * * *” to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *
(a) * * *

Pesticide chemical	CAS Reg. No.	Limits
Quaternary ammonium compounds, didecyl dimethyl ammonium carbonate/didecyl dimethyl ammonium bicarbonate.	148788-55-0/148812-654-1.	When ready for use, the end-use concentration of these specific ammonium compounds is not to exceed 400 ppm of active quaternary ammonium compound.

* * * * *
[FR Doc. 2012-20663 Filed 8-21-12; 8:45 am]
BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0766; FRL-9354-3]

RIN 2070-AJ28

Pesticide Tolerance Crop Grouping Program III; Revisions to General Tolerance Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule revises the current pesticide tolerance crop grouping regulations, which allow for the establishment of tolerances for multiple related crops based on data from a representative set of crops. This rule expands upon existing stone fruit and tree nut crop groups by establishing

new crop subgroups and adding new commodities. This is the third in a series of planned crop group updates expected to be promulgated over the next several years.

DATES: This final rule is effective October 22, 2012.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2006-0766 is available electronically at <http://www.regulations.gov>, or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC 20460. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; email address: nollen.laura@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the agency taking?

This final rule, under the provisions of section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, amends EPA’s regulations governing crop group tolerances for pesticides. Specifically, the rule expands upon existing stone fruit and tree nut crop groups by adding new commodities and establishes crop subgroups for the new stone fruit crop group. This final rule is the third in a series of planned crop group updates expected to be promulgated in the next several years.