UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 3, 2006

MEMORANDUM

SUBJECT: Tolerance Reassessment Decisions for 40 CFR § 180.940 Tolerance Exemptions

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This memorandum presents the tolerance reassessment decision for use of the following chemicals in food-contact sanitizing solutions:

1. Ammonium chloride
2. Boric acid, sodium salt
3. Calcium chloride
4. n-Carboxylic acids
5. Decanoic acid
6. Ethanol
7. Ethanol, 2-butoxy
8. Ethylenediaminetetra-acetic acid (EDTA) disodium salt
9. Ethylenediaminetetra-acetic acid (EDTA)
10. Fatty acids, coco, potassium salts
11. FD&C Yellow No. 5
12. D-Gluconic acid, monosodium
13. Magnesium oxide
14. Nonanoic acid
15. Octadecanoic acid, calcium salt
16. Octanoic acid
17. Propanoic acid
18. Sulfuric acid

In accordance with, 40 CFR § 180.940, residues of the above chemicals are exempt from the requirement of a tolerance when used in accordance with good manufacturing practice as ingredients in an antimicrobial pesticide formulation, provided that the 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.

Several divisions within OPP, primarily the Registration Division (RD), have performed tolerance reassessments for these chemicals as inerts present in agricultural pesticide products and antimicrobial uses, as food-contact surface sanitizing solutions. Many of these assessments were conducted prior to the exemptions being established in 40 CFR § 180.940. Table 1 identifies the tolerance exemptions being reassessed in this document.

Table 1. Tolerances Being Reassessed in this Document

Tolerance Exemption Expression	CAS No. 40 CFR	Use Pattern	Location in 40 CFR 180.940	Previous Tolerance Reassessment Actions Document Title (Date)
Ammonium Chloride	12125-02-9	Food-contact surface sanitizing solution	(a) (c)	Inert Ingredient Focus Group Decisions Document for Hydrochloric Acid and Salts (July 24, 2002)
Boric Acid, Sodium Salt	7775-19-1	Food-contact surface sanitizing solution	(c)	Boric Acid TRED 2006 (SRRD)
Calcium chloride	10043-52-4	Food-contact surface sanitizing solution	(b) (c)	Inert Ingredient Focus Group Decision Document for Hydrochloric Acid and Salts (July 24, 2002)
n-Carboxylic acids	(none)	Food-contact surface sanitizing solution	(b) (c)	Lower Toxicity Pesticide Chemical Focus Group Science Assessment for Fatty Acids: Soybean Oil derived Fatty Acids; Perlargonic acid (nonanoic acid) and n-Carboxylic Acids (C6-C12) (September 25, 2003)
Decanoic acid	3347-48-5	Food-contact surface sanitizing solution	(c)	Inert Ingredient Focus Group Decision Document for Free Fatty Acids (July 31, 2002)
Ethanol, 2 butoxy	111-76-2	Food-contact surface sanitizing solution	(c)	Memorandum from K. Farwell/HED to P. Wagner/RD

Ethylenediaminetetraacetic acid (EDTA), disodium salt	139-33-3	Food-contact surface sanitizing solution	(b) (c)	Lower Risk Pesticide Chemical Focus Group Science Assessment for Ethylenediaminetetraacetic acid (EDTA) and the salts of EDTA (January 26, 2004)
EDTA	64-02-8	Food-contact surface sanitizing solution	(a) (c)	Lower Risk Pesticide Chemical Focus Group Science Assessment for Ethylenediaminetetraacetic acid (EDTA) and the salts of EDTA (January 26, 2004)
Fatty acids, coco, potassium salts.	61789-30-8	Food-contact surface sanitizing solution	(c)	Lower Toxicity Pesticide Chemical Focus Group Science Assessment for Salts of Fatty Acids (September 25, 2003)
FD&C Yellow No. 5	1934-21-0	Food-contact surface sanitizing solution	(b) (c)	Reregistration Eligibility Decision (SRRD) Document for Aquashade CASE 4010 (September 23, 2005)
D-Gluconic acid, monosodium	527-07-1	Food-contact surface sanitizing solution	(b) (c)	Inert Ingredient Tolerance Reassessment Gluconic acid and sodium salt (February 22, 2005)
Magnesium oxide	1309-48-4	Food-contact surface sanitizing solution	(a) (c)	Inert Ingredient Focus Group Decision Document for Weathered Materials (January 31, 2003)
Nonanoic acid	112-05-0	Food-contact surface sanitizing solution	(b) (c)	Lower Toxicity Pesticide Chemical Focus Group Science A assessment for Fatty Acids: Soybean Oil derived Fatty Acids; Pelargonic acid (nonaoic acid); and n-Carboxylic Acids (C6-C12) (September 25, 2003)
Octadecanoic acid, calcium salt	1592-23-0	Food-contact surface sanitizing solution	(a) (c)	Inert Ingredient Focus Group Decision Document for Stearic Acid Salts (July 31, 2002)
Octanoic acid	124-07-2	Food-contact surface sanitizing solution	(a) (b) (c)	Inert Ingredient Focus Group Decision Document for Free Fatty Acids (July 31, 2002)
Propanoic acid	79-09-4	Food-contact surface sanitizing solution	(b) (c)	Inert Ingredient Focus Group Decision Document for Propionic Acid and its Calcium and Sodium Salts (April 8, 2002)
Sulfuric acid	7664-93-9	Food-contact surface sanitizing solution	(b) (c)	Inert Ingredient Focus Group Decision Document for Sulfuric Acid and Salts

FQPA Assessment:

The FQPA safety determination for the chemicals in Table 1 is as follows:

Sensitivity of Infants and Children

At this time, there is no concern for potential sensitivity to infants and children. A safety factor analysis has not been used to assess the risk. For the same reasons, the additional tenfold safety factor is unnecessary.

Aggregate Exposure

In considering aggregate exposure, FFDCA Section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). In developing these assessments for the chemicals above, a quantitative assessment was not performed; therefore, an aggregate assessment was not needed.

Cumulative Exposure

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to these chemicals and any other substances, and these chemicals do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that these chemicals have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/

Determination of Safety

Based on the information available for these chemicals, the Agency concludes that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to these chemicals.

Conclusion

Therefore, AD considers the 31 tolerance exemptions from the requirement of a tolerance established for the previously mentioned chemicals when used in food contact surface sanitizing solutions under 40 CFR Part 180.940 be considered reassessed as safe under section 408 (q) of the FFDCA.

cc: Chemical Files