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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. FDA-2011-F-0853]

# Secondary Direct Food Additives Permitted in Food for Human Consumption; Sodium Dodecylbenzenesulfonate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of sodium dodecylbenzenesulfonate (CAS No. 25155-30-0) as an antimicrobial agent for use in wash water for fruits and vegetables without the requirement of a potable water rinse. This action is in response to a petition filed by Ecolab, Inc.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written objections and requests for a hearing by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section VII of this document for information on the filing of objections.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA-2011-F-0853, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

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

Written Submissions

Submit written objections in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2011-F-0853 for this rulemaking. All objections received will be posted without change to http://www.regulations.gov, including any personal information provided. For detailed instructions on submitting objections, see the "Objections" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or objections received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Molly Harry,

Center for Food Safety and Applied Nutrition (HFS-265),

Food and Drug Administration,

5100 Paint Branch Pkwy.,

College Park, MD 20740,

240-402-1075.

SUPPLEMENTARY INFORMATION:

## I. Background

In a notice published in the Federal Register of February 2, 2012 (77 FR 5201), FDA announced that a food additive petition (FAP 2A4785) had been filed by Ecolab, Inc., 370 North Wabasha St., St. Paul, MN 55102-1390. The petition proposed to amend the food additive regulations in part 173, "Secondary Direct Food Additives Permitted in Food for Human Consumption" (21 CFR part 173), to provide for the safe use of sodium dodecylbenzenesulfonate (SDBS) as an antimicrobial agent used as a component of an antimicrobial formulation added to wash water for fruits and vegetables (e.g., whole fruits and vegetables as well as fruits, vegetables, and herbs that have been chopped, sliced, cut, or peeled) to reduce microorganisms in wash water and on the surfaces of treated fruits and vegetables. Fruits and vegetables treated by the additive do not require a potable water rinse. The petition requested that the additive be considered for use only in certain food service facilities. The additive may be used at a level not to exceed 111 milligrams per kilogram of the wash water.

The use of SDBS is currently approved in washing or to assist in the peeling of fruits and vegetables under § 173.315 provided its use is followed by a potable water rinse. In addition, FDA food additive regulations permit the use of SDBS as an indirect food additive for use as a component of single and repeated use food contact substances (21 CFR 177.1010, 177.1200, 177.1630, 177.2600, and 177.2800), in sanitizing solutions (21 CFR 178.1010), and in the production of animal glue (21 CFR 178.3120).

The definition of "pesticide chemical" under section 201(q)(1)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(q)(1)(B)(i)), excludes an antimicrobial added to water that comes into contact with food, in the preparing, packing, or holding of the

food for commercial purposes. This exclusion applies whether the water is to contact raw agricultural commodities or processed food. Consequently, such an antimicrobial is a "food additive" under section 201(s) of the FD&C Act and subject to the requirements in section 409 of the FD&C Act (21 U.S.C. 348). The petitioned use of SDBS as an antimicrobial agent in processing water is for a food additive use in certain food service facilities. Although the petitioned use of SDBS is regulated under section 409 of the FD&C Act as a food additive, this intended use of SDBS may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Therefore, manufacturers intending to use this food additive for this intended use should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

## II. Evaluation of Safety

Under the general safety standard in section 409 of the FD&C Act, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define "safe" as "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."

To establish with reasonable certainty that a food additive is not harmful under its intended conditions of use, FDA considers the projected human dietary intake of the additive, the additive's toxicological data, and other relevant information (such as published literature) available to FDA. As part of FDA's safety evaluation, FDA reviewed data from published studies in animals on the safety of SDBS, including a 2-year carcinogenicity study in rats and a multigeneration reproductive study with rats. Based on the results from these studies and FDA's estimated dietary intake to SDBS from current and the proposed food uses, FDA concludes that

there is a reasonable certainty of no harm and the petitioned use of SDBS is safe within the meaning of section 409 of the FD&C Act.

## III. Conclusion

FDA reviewed data in the petition and other available relevant material to evaluate the safety of SDBS as an antimicrobial agent for use in wash water for fruits and vegetables without the requirement of a potable water rinse. Based on this information, FDA concludes that the proposed use of the additive is safe and the additive will achieve its intended technical effect as an antimicrobial agent under the proposed conditions of use. Therefore, the regulations in part 173 should be amended as set forth in this document.

## IV. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see FOR FURTHER INFORMATION CONTACT). As provided in § 171.1(h), FDA will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

## V. Environmental Impact

FDA has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

## VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## VII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. It is only necessary to send only one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## VIII. Section 301(ll) of the FD&C Act

FDA's review of this petition was limited to section 409 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(ll) (21

U.S.C. 331(ll)). Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) to (ll)(4) applies. In our review of this petition, FDA did not consider whether section 301(ll) or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173--SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.405 is added to subpart D to read as follows:

§ 173.405 Sodium dodecylbenzenesulfonate.

Sodium dodecylbenzenesulfonate (CAS No. 25155-30-0) may be safely used in accordance with the following prescribed conditions:

(a) The additive is an antimicrobial agent used in wash water for fruits and vegetables. The additive may be used at a level not to exceed 111 milligrams per kilogram in the wash water. Fruits and vegetables treated by the additive do not require a potable water rinse.

(b) The additive is limited to use in commissaries, cafeterias, restaurants, retail food establishments, nonprofit food establishments, and other food service operations in which food is prepared for or served directly to the consumer.

(c) To assure safe use of the additive, the label or labeling of the additive container shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, adequate directions to assure use in compliance with the provisions of this section.

Dated: November 28, 2012.

Susan M. Bernard,

Director,

Office of Regulations, Policy and Social Sciences,

Center for Food Safety and Applied Nutrition.

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