

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 175, 176, and 178

[Docket No. 99F-2081]

DWB

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Certifier	<i>[Signature]</i>

Indirect Food Additives: Adhesives and Components of Coatings and Paper and Paperboard Components

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 butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt as a surface active agent in adhesive formulations, and in components of paper and paperboard intended to contact food. This action is in response to a petition filed by Troy Corp.

DATES: This rule is effective [*insert date of publication in the Federal Register*]. Submit written objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 2, 1999 (64 FR 36021), FDA announced that a food additive petition (FAP 9B4678) had been filed by Troy Corp., c/o S. L. Graham & Associates, 1801 Peachtree Lane, Bowie, MD 20721. The petition proposed to amend the food additive regulations in § 175.125 *Pressure-sensitive adhesives* (21 CFR

175.125) to provide for the safe use of butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt as a surface active agent in pressure sensitive adhesives.

Subsequent to the publication of the filing notice, the petition was amended to include a proposal to further amend the food additive regulations in §§ 175.105 *Adhesives* (21 CFR 175.105), 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170), 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180), and 178.3400 *Emulsifiers and/or surface active agents* (21 CFR 178.3400) to provide for the safe use of butanedioic acid, sulfo-1, 4-diisodecyl ester, ammonium salt as a surface active agent in adhesives, and in paper and paperboard intended to contact food. Therefore, in a notice published in the **Federal Register** of January 3, 2001 (66 FR 375), FDA announced that it was amending the filing notice of July 2, 1999, to indicate that the petitioner requests that the food additive regulations be amended to provide for the safe use of butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt as a surface active agent in adhesives, pressure sensitive adhesives, and paper and paperboard intended to contact food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in §§ 175.105, 175.125, 176.170, 176.180, and 178.3400 should be amended as set forth below.

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 are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in §171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the potential environmental effects of this rule as announced in the notices of filing for FAP 9B4678. No new information or comments have been

received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

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

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by *[insert date 30 days after date of publication in the **Federal Register**]*. 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. Three copies of all documents are to be submitted and are to be identified 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 175

Adhesives, Food additives, Food packaging.

21 CFR Parts 176 and 178

Food additives, Food packaging.

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 parts 175, 176, and 178 are amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 175.105 is amended in the table in paragraph (c)(5) by alphabetically adding an entry under the headings “Substances” and “Limitations” to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
Butanedioic acid, sulfo-1,4-di-(C ₉ -C ₁₁ alkyl) ester, ammonium salt (also known as butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093-88-9]).	For use as a surface active agent in adhesives.

2. Section 175.125 is amended by adding paragraph (a)(9) and by revising paragraph (b)(1) to read as follows:

§ 175.125 Pressure-sensitive adhesives.

* * * * *

(a) * * *

(9) Butanedioic acid, sulfo-1,4-di-(C₉-C₁₁ alkyl) ester, ammonium salt (also known as butanedioic acid sulfo-1, 4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093-88-9]) as a

surface active agent at a level not to exceed 3.0 percent by weight of the finished pressure-sensitive adhesive.

(b) * * *

(1) Substances listed in paragraphs (a)(1), (a)(2), (a)(3), (a)(5), (a)(6), (a)(7), (a)(8), and (a)(9) of this section, and those substances prescribed by paragraph (a)(4) of this section that are not identified in paragraph (b)(2) of this section.

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PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

4. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

5. Section 176.170 is amended in the table in paragraph (b)(2) by alphabetically adding an entry under the headings "List of Substances" and "Limitations" to read as follows:

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * *

(b) * * *

(2) * * *

List of substances	Limitations
Butanedioic acid, sulfo-1,4-di-(C ₉ -C ₁₁ alkyl) ester, ammonium salt (also known as butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093-88-9]).	For use as a surface active agent in package coating inks at levels not to exceed 3 percent by weight of the coating ink.

6. Section 176.180 is amended in the table in paragraph (b)(2) by alphabetically adding an entry under the headings "List of substances" and "Limitations" to read as follows:

§ 176.180 Components of paper and paperboard in contact with dry food.

* * * * *

(b) * * *

(2) * * *

List of substances	Limitations
Butanedioic acid, sulfo-1,4-di-(C ₉ -C ₁₁ alkyl) ester, ammonium salt (also known as butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093-88-9]).	For use as a surface active agent in package coating inks at levels not to exceed 3 percent by weight of the coating ink.

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

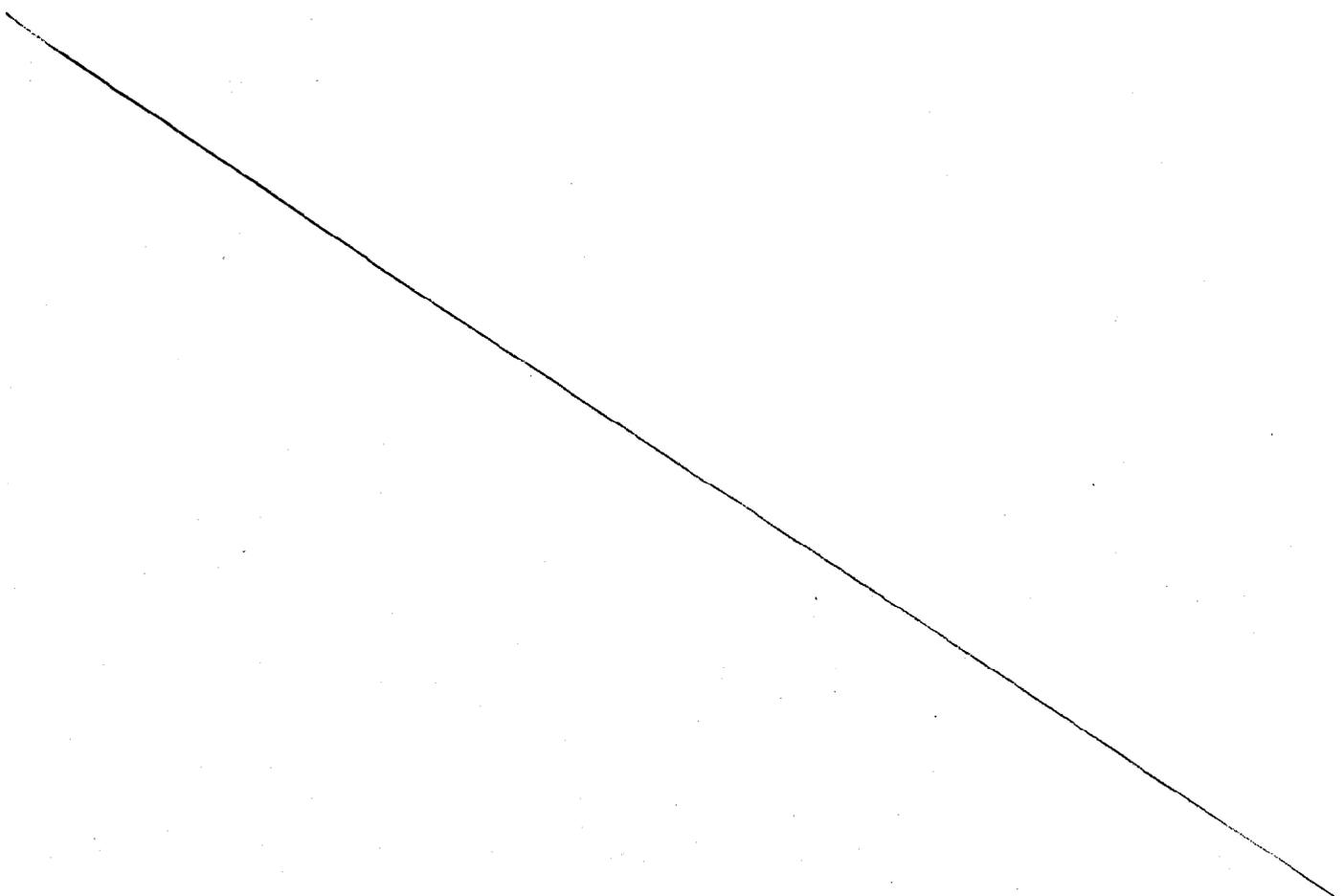
7. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

8. Section 178.3400 is amended in the table in paragraph (c) by alphabetically adding an entry under the headings “List of substances” and “Limitations” to read as follows:

§ 178.3400 Emulsifiers and/or surface active agents.

* * * * *



(c) * * *

List of substances	Limitations
Butanedioic acid, sulfo-1,4-di-(C ₉ -C ₁₁ alkyl) ester, ammonium salt (also known as butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093-88-9]).	For use as a surface active agent as provided in §§ 175.105, 175.125, 176.170, and 176.180 of this chapter.

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Dated: 2/21/01
February 21, 2001.

L. Robert Lake

L. Robert Lake,
Director of Regulations and Policy,
Center for Food Safety and Applied Nutrition.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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J. Windsor