

**3E201 "Technology" according to the General Technology Note for the "use" of items controlled by 3A001.e.2, e.3, and e.5, 3A201, 3A225 to 3A233**

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**3E292 "Technology" according to the General Technology Note for the "development", "production", or "use" of items controlled by 3A292**

**License Requirements**

Reason for Control: NP, AT

Control(s)	Country Chart
NP applies to entire entry.	NP Column 2
AT applies to entire entry.	AT Column 1

**License Exceptions**

CIV: N/A

TSR: N/A

**List of Items Controlled**

Unit: N/A

Related Controls: N/A

Related Definitions: N/A

Items: The list of items controlled is contained in the ECCN heading.

\* \* \* \* \*

Dated: July 29, 1997.

**Iain S. Baird,**

Acting Assistant Secretary for Export Administration.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 177**

**Indirect Food Additives: Polymers**

*CFR Correction*

In title 21 of the Code of Federal Regulations, parts 170 to 199, revised as of April 1, 1997, on page 263, in § 177.1520 in the table in paragraph (b) in the entry for "Polymethylsilsesquioxane" the CAS number should read "68554-70-1".

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 178**

[Docket No. 89F-0176]

**Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers**

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 disodium 4-isodecyl sulfosuccinate as an emulsifier in the production of food-contact polymers.

This action responds to a petition filed by American Cyanamid Co.

**DATES:** The regulation is effective August 5, 1997; written objections and request for a hearing by September 4, 1997.

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Richard H. White, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3094.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of June 13, 1989 (54 FR 25174), FDA announced that a food additive petition (FAP 9B4122) had been filed by American Cyanamid Co., One Cyanamid Plaza, Wayne, NJ 07470 (currently Cytec Industries Inc., c/o Keller and Heckman, 1001 G St. NW., Washington, DC 20001). The petition proposed to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) and § 178.3400 *Emulsifiers and/or surface active agents* (21 CFR 178.3400) to provide for the safe use of disodium 4-isodecyl sulfosuccinate as a component of adhesives and as an emulsifier in the production of food-contact polymers. The petitioner later requested that the agency proceed with a decision regarding the regulation of the additive for use only as a component of adhesives in food-contact materials. The agency published a final rule in the **Federal Register** of April 20, 1993 (58 FR 21257) amending § 175.105 to provide for the use of disodium 4-isodecyl sulfosuccinate as a component of adhesives. In that final rule, the agency stated that its decision regarding

the petitioned use of the additive as an emulsifier in the production of food-contact polymers would be addressed in a future **Federal Register** document. The agency is addressing that decision in this final rule.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the subject additive as an emulsifier in the production of food-contact polymeric coatings is safe, that the additive will have the intended technical effect, and that therefore, § 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 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. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before September 4, 1997, file with the Dockets Management Branch (address above) written objections thereto. 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