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 shall be submitted and shall 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 in 21 CFR Part 176

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 part 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

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

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

2. Section 176.300 is amended by alphabetically adding an entry to the table in paragraph (c) to read as follows:

§ 176.300 Slimicides.

* * * * *

(c) * * *

List of Substances	Limitations
* * * * * * *	
Tetrakis(hydroxymethyl)phosphonium sulfate (CAS Reg. No. 55566–30–8)	Maximum use level of 84 mg/kg in the pulp slurry. The additive may also be added to water, which when introduced into the pulp slurry, results in a concentration in the pulp slurry not to exceed 84 mg/kg.
* * * * * * *	

* * * * *

Dated: August 12, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–21851 Filed 8–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 98F–0871]

Indirect Food Additives: 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 polyethylene glycol monoisotridecyl ether sulfate, sodium salt as a component of coatings on paper and paperboard intended for use in contact with dry food. This action is in response to a petition filed by Servo Deldon BV.

DATES: This regulation is effective August 24, 1999; submit written objections and requests for a hearing by September 23, 1999.

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 October 13, 1998, (63 FR 54717), FDA announced that a food additive petition (FAP 8B4630) had been filed by Servo Deldon BV, c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180) to provide for the safe use of polyethylene glycol monoisotridecyl ether sulfate, sodium salt as a component of coatings on paper and paperboard intended for use in contact with dry food.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of unreacted 1,4-dioxane and ethylene oxide, carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as 1,4-dioxane and ethylene oxide, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the general safety standard of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), 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.''

The food additives anticancer, or Delaney, clause of the act (21 U.S.C. 348(c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the intended use of the additive (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).

II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, polyethylene glycol monoisotridecyl ether sulfate, sodium salt as a surfactant in coatings for paper and paperboard in contact with dry foods, will result in exposure to no greater than 50 parts per billion (ppb) of the additive in the daily diet (3 kilogram (kg)) or an estimated daily intake (EDI) of 0.15 milligrams per person per day (mg/p/d) (Ref. 1).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the additive and concludes that the estimated small dietary exposure resulting from the petitioned use of the additive is safe.

FDA has evaluated the safety of this additive under the general safety standard, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by 1,4-dioxane and ethylene oxide, the carcinogenic chemicals that may be present as impurities in the additive. This risk evaluation of 1,4-dioxane and ethylene oxide has two aspects: (1) Assessment of the exposure to the impurities from the petitioned use of the additive and (2) extrapolation of the risk observed in the animal bioassays to the conditions of exposure to humans.

A. 1,4–Dioxane

FDA has estimated the exposure to 1,4-dioxane from the petitioned use of the additive as a surfactant in coatings for paper and paperboard in contact with dry foods to be no more than 0.2 ppb of the daily diet (3 kg) or 0.6 micrograms per person per day (µg/p/d) (Ref. 1). The agency used data from a carcinogenesis bioassay on 1,4-dioxane, conducted by the National Cancer Institute (Ref. 3), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of the additive. The authors reported that the test material caused a significantly increased incidence of squamous cell carcinomas and hepatocellular tumors in female rats. Based on the agency's estimate that exposure to 1,4-dioxane will not exceed 0.6 µg/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 2.1×10^{-8} (or 2.1 in 100 million) (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to 1,4-dioxane is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to 1,4-dioxane would result from the petitioned use of the additive.

B. Ethylene Oxide

FDA has estimated the exposure to ethylene oxide from the petitioned use of the additive as a surfactant in coatings for paper and paperboard in contact with dry foods to be no more than 3.9 parts per trillion in the daily diet (3 kg) or 12 nanograms per person per day (ng/p/d) (Ref. 1). The agency used data from a carcinogenesis bioassay on ethylene oxide conducted by the Institute of Hygiene, University of Mainz, Germany (Ref. 5), to estimate the upper-bound limit of lifetime human risk from exposure to ethylene oxide resulting from the petitioned use of the additive. The authors reported that the test material caused significantly increased incidence of squamous cell carcinomas of the forestomach and carcinomas in situ of the glandular stomach in female rats. Based on the agency's estimate that exposure to ethylene oxide will not exceed 12 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 2.24×10^{-8} (or 2.24 in 100 million)) (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to ethylene oxide is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to ethylene oxide would result from the petitioned use of the additive.

C. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of 1,4-dioxane and ethylene oxide as impurities in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which 1,4-dioxane and ethylene oxide may be expected to remain as impurities following production of the additive, the agency would not expect the impurities to become components of food at other than extremely small levels; and (2) the upper-bound limits of lifetime risk from exposure to 1,4-dioxane and ethylene oxide is very low, 2.1 in 100 million and 2.24 in 100 million, respectively.

III. Conclusion

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

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 previously. 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.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8B4630 (October 13, 1998, 63 FR 54717). 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.

V. 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.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before September 23, 1999, 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 objection. Three copies of all documents shall be submitted and shall 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.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memoranda, dated January 13, 1999, and March 8, 1999, from the Chemistry Review Team, FDA, to the file concerning FAP 8B4630 (MATS No. 1011), Servo Delden BV, concerning the use of polyethylene glycol monoisotridecyl ether sulfate sodium salt as a surfactant in coatings in food-contact paper and paperboard,

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in ''Chemical Safety Regulation and Compliance,'' edited by F. Homburger and J. K. Marquis, published by S. Karger, New York, NY, pp. 24–33, 1985.

3. ''Bioassay of 1,4–Dioxane for Possible Carcinogenicity,'' National Cancer Institute, NCI–CG–TR–80, 1978.

4. Memorandum, dated January 25, 1999, from the Indirect Additives Branch, FDA, to the Executive Secretary, Quantitative Risk Assessment Committee, FDA, concerning estimation of upper-bound lifetime risk from ethylene oxide and 1,4-dioxane in polyethylene glycol monoisotridecyl ether sulfate, sodium salt (PGMES): food additive petition No. 8B4630 (Servo Delden BV).

5. Dunkelberg, H., ''Carcinogenicity of Ethylene Oxide and 1,2-propylene Oxide Upon Intragastric Administration to Rats,''*British Journal of Cancer,* 46: pp. 924–933, 1982.

List of Subjects in 21 CFR Part 176

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

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

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

2. Section 176.180 is amended in the table in paragraph (b)(2) by alphabetically adding an entry under the headings ''Lists 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
* * * * * * *	
Polyethylene glycol monoisotridecyl ether sulfate, sodium salt (CAS Reg. No. 150413–26–6).	For use only as a surfactant at levels not to exceed 3 percent in latex formulations used in pigment binders for paper and paperboard.
* * * * * * *	

Dated: August 5, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–21850 Filed 8–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 91F–0399]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of May 14, 1999 (64 FR 26281). The document amended the food additive regulations to provide for the safe use of 1,3-propanediamine, N,N″-1,2-ethanediylbis-, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine as a light stabilizer for polypropylene and polyethylene. The document was published with an error. This document corrects that error.

DATES: Effective on May 14, 1999.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 14, 1999 (64 FR 26281), FDA amended the food additive regulations to provide for the safe use of 1,3-propanediamine, N,N″-1,2-ethanediylbis-, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine as a light stabilizer for polyethylene and polypropylene complying with 21 CFR 177.1520. It has been recently called to the attention of the agency that the Chemical Abstract Services (CAS) Registry has a slightly different nomenclature for the additive 1,3-propanediamine, N,N″-1,2-ethanediylbis-, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine (CAS Reg. No. 136504–96–6). The preferred nomenclature for the additive is 1,3-propanediamine, N,N″-1,2-ethanediylbis-, polymer with 2,4,6-trichloro-1,3,5-triazine, reaction products with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine. Therefore, the agency is amending 21 CFR 178.2010 to correct the nomenclature of the additive.

In FR Doc. 99–12177, appearing on page 26281, in the **Federal Register** of Friday, May 14, 1999, the following correction is made:

§ 178.2010 [Corrected]

1. On page 26282, in the table in paragraph (b), under the heading ''Substances'' ''1,3-propanediamine, N,N″-1,2-ethanediylbis-, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine (CAS Reg. No. 136504–96–