under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before December 7, 1998, file with the Dockets Management Branch (address above) written objection 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.

List of Subjects in 21 CFR Part 175

Adhesives, 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 175 is 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 175.300 is amended in paragraph (b)(3)(vii)(*a*) by alphabetically adding two entries to read as follows:

§ 175.300 Resinous and polymeric coatings.

* * * * *

(b) * * *

(3) * * *

(vii) * * *

(*a*) * * *

* * * * *

2,6-Naphthalenedicarboxylic.

2,6-Naphthalenedicarboxylic, dimethyl ester.

* * * * *

Dated: October 16, 1998.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives.

[FR Doc. 98–29615 Filed 11–4–98; 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–0054]

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 octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol and urea, and the acetate salts thereof, which may be emulsified with ethoxylated tallow alkyl amines, for use in the manufacture of paper and paperboard intended for use in contact with dry food. This action is in response to a petition filed by Sequa Chemicals, Inc.

DATES: The regulation is effective November 5, 1998; submit written objections and requests for a hearing by December 7, 1998.

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: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 9, 1998 (63 FR 6571), FDA announced that a food additive petition (FAP 8B4576) had been filed by Sequa Chemicals, Inc., c/o Keller and Heckman, 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 octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol and urea, and the acetate salts thereof, which may be emulsified with ethoxylated tallow alkyl amines, for increasing opacity and thickness, employed prior to the sheet forming operation in the manufacture of 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 ethylene oxide, a carcinogenic impurity resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as ethylene oxide, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the so-called ''general safety clause'' 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 additive 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, octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol and urea, and the acetate salts thereof, which may be emulsified with ethoxylated tallow alkyl amines, 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 milligram 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 proposed use of this 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 ethylene oxide, the carcinogenic chemical that may be present as an impurity in the additive. The risk evaluation of ethylene oxide has two aspects: (1) Assessment of exposure to the impurity from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassay to the conditions of exposure to humans.

A. Ethylene Oxide

FDA has estimated the exposure to ethylene oxide from the petitioned use of the additive in the manufacture of paper and paperboard to be no more than 6.9 parts per trillion (ppt) in the daily diet (3 kg), or 6.3 nanograms (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. 3), to estimate the upper-bound limit of lifetime human risk from exposure to ethylene oxide resulting from the proposed use of the additive. The results of the bioassay on ethylene oxide demonstrated that ethylene oxide was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinomas of the forestomach and carcinomas in situ of the glandular stomach.

Based on the estimated exposure to ethylene oxide of 6.3 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the proposed use of the subject additive is 1.1×10^{-8}, or 1.1 in 100 million (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to 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 proposed use of the additive.

B. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of ethylene oxide present as an impurity in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which ethylene oxide may be expected to remain as an impurity following production of the additive, the agency would not expect the impurity to become a component of food at other than extremely low levels; and (2) the upper-bound limit of lifetime human risk from exposure to the impurity is very low, less than 1.1 in 100 million.

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 the manufacture of paper and paperboard intended for use in contact with dry food is safe, and that the additive will achieve its intended technical effect. Therefore, the agency concludes that the regulations in § 176.180 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.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8B4576 (63 FR 6571, February 9, 1998). 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 December 7, 1998, file with the Dockets Management Branch (address above) written objection 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 objection 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. Memorandum dated May 8, 1998, from the Chemist, Special Project Team (HFS–246), to the file, concerning FAP 8B4576: dietary concentrations of the additive and the impurity (ethylene oxide).

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

4. Memorandum from the Indirect Additives Branch, FDA, to the Executive Secretary, Quantitative Risk Assessment Committee, FDA, concerning: Assessment of upper-bound lifetime risk from exposure to ethylene oxide from the use of octadecanoic acid, reaction product with 2-[(2-aminoethyl)amino]ethanol and urea, and the acetate salts which may be emulsified with

ethoxylated tallow alkyl amines, in the manufacture of paper and paperboard. Subject of Food Additive Petition 8B4576 (Sequa Chemicals, Inc.), dated May 21, 1998.

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 ''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
* * * * * * *	
Octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol and urea (CAS Reg. No. 68412–14–6), and the acetate salts thereof (CAS Reg. No. 68784–21–4), which may be emulsified with ethoxylated tallow alkyl amines (CAS Reg. No. 61791–26–2).	For use prior to sheet forming at levels not to exceed 12 pounds per ton of paper.
* * * * * * *	

Dated: October 21, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29616 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 98F–0432]

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 chromium oxide green, Cr_2O_3 (C.I. Pigment Green 17) as a colorant for polymers intended for use in contact with food. This action is in response to a petition filed by Ticona.

DATES: The regulation is effective November 5, 1998; written objections and requests for a hearing by December 7, 1998.

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: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 22, 1998 (63 FR 33935), FDA announced that a food additive petition (FAP 8B4603) had been filed by Ticona, c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of chromium oxide green, Cr_2O_3 (C.I. Pigment Green 17) as a colorant for polymers intended for use in contact with 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 § 178.3297 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 environmental effects of this rule as announced in the notice of filing for FAP 8B4603 (63 FR 33935). 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 collection 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 on or before December 7, 1998, 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