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. Memorandum from CFSAN's Chemistry Review Branch (HFS–247) to CFSAN's Direct Additives Branch (HFS–217) concerning ''FAP 4A3774 & FAP 4A3824: Ethylene Oxide and 1,4-dioxane Residues in Polysorbate 60, Direct Additives Branch Request of 9/3/93,'' dated September 28, 1993.

2. Memorandum from CFSAN's Additives Evaluation Branch No. 1 (HFS–226) to CFSAN's Direct Additives Branch (HFS-217) concerning ''Chemistry Review Branch (HFS–247) Memorandum of March 1, 1996, EDI's for Polyoxyethylene (20) Sorbitan Monostearate (Polysorbate 60) in Frozen Dairy Desserts and Coconut Milk Drinks, and Risks Estimates for Residual Ethylene Oxide and 1,4-dioxane,'' dated March 13, 1996.

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

4. Memorandum from CFSAN's Division of Petition Control (HFS–215) to the Executive Secretary, Quantitative Risk Assessment Committee (HFS–308) concerning ''Estimation of Upper-bound Lifetime Risk from Ethylene Oxide (EO) and 1,4-dioxane (DX) Residues in Polysorbate 60: Subject of Food Additive Petition 4A3774 (ICI Americas, Inc.),'' dated December 14, 1998.

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.

6. Memorandum to the Record from CFSAN's Division of Petition Control (HFS–215) concerning ''FAP 4A3774—Consideration of a Need for Specification for 1,4-dioxane in a Regulation for Polysorbate 60 use in Frozen Dairy Desserts,'' dated December 14, 1998.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.836 is amended by adding new paragraph (c)(16) to read as follows:

§ 172.836 Polysorbate 60.

* * * * *

(c) * * *

(16) As an emulsifier in ice cream, frozen custard, fruit sherbet, and nonstandardized frozen desserts when used alone or in combination with polysorbate 65 and/or polysorbate 80, whereby the maximum amount of the additives, alone or in combination, does not exceed 0.1 percent of the finished frozen dessert.

* * * * *

Dated: October 19, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28113 Filed 10–27–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 99F–0345]

Indirect Food Additives: Polymers

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 mono- and bis-(octadecyldiethylene oxide)phosphates as components of coatings on cellophane intended for use in contact with food. This action is in response to a petition filed by UCB Films PLC.

DATES: The regulation is effective October 28, 1999; written objections and requests for a hearing by November 29, 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: 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 March 18, 1999 (64 FR 13431), FDA announced that a food additive petition (FAP 9B4642) had been filed by UCB Films PLC, 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 § 177.1200 *Cellophane* (21 CFR 177.1200) to provide for the safe use of mono- and bis-(octadecyldiethylene oxide)phosphates as component of coatings on cellophane intended for use in contact with 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, mono- and bis-(octadecyldiethylene oxide)phosphates as a component of coatings (as a release agent) on cellophane will result in exposure to no greater than 43.5 parts per billion of the additive in the daily diet (3 kilogram (kg)) or an estimated daily intake of 0.13 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 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 in the coating on cellophane to be 0.22 part per trillion of the daily diet (3 kg) or 0.66 nanogram (ng)/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 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 0.66 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 2.3×10^{-11} (or 2.3 in 100 billion) (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 in coatings on cellophane to be 22 parts per quadrillion in the daily diet (3 kg) or 66 picograms (pg)/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 exposure that to ethylene oxide of 66 pg/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 1.2×10^{-10} (or 1.2 in 10 billion) (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 also has 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 additives, 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, 2.3 in 100 billion and 1.2 in 10 billion, respectively.

III. Conclusion

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in § 177.1200 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 9B4642 (64 FR 13431). 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 November 29, 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. Memorandum from the Chemistry Review Team, FDA, to the file concerning ''FAP 9B4642 (MATS #1025, M2.0 & 2.1): UCB Films PLC, dated March 30, 1999. Use of Mono- and Bis-(octadecyldiethylene oxide)phosphates as a Release Agent in Food-contact Coatings Applied to Cellophane.''

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in *Chemical Safety Regulation and Compliance*, edited by F. Homburger, J. K. Marquis, and 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 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 Mono- and Bis-(octadecyldiethylene oxide)phosphates as a Release Agent in Food-contact Coating Applied to Cellophane: Food Additive Petition No. 9B4642 (UCB Films PLC),'' dated June 10, 1999.

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

List of Subjects in 21 CFR Part 177

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 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

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

2. Section 177.1200 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:

§ 177.1200 Cellophane.

* * * * *

(c) * * *

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
* * * *	* * *
Mono- and bis-(octadecyldiethylene oxide) phosphates (CAS Reg. No. 62362–49–6).	For use only as a release agent at a level not to exceed 0.6 percent by weight of coatings for cellophane.
* * * *	* * *

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Dated: October 19, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28112 Filed 10–27–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 925

[SPATS No. MO–035–FOR]

Missouri Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is approving an amendment to the Missouri regulatory program (Missouri program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Missouri proposed normal husbandry practices that the permittee may use without causing the Phase III liability period or the five-year responsibility period to be extended. The practices include applying pesticides and soil amendments; subsoiling; repairing rills and gullies; burning; overseeding; and planting and pruning trees. Missouri intends to revise its program to be consistent with the corresponding Federal regulations.

EFFECTIVE DATE: October 28, 1999.

FOR FURTHER INFORMATION CONTACT: John W. Coleman, Office of Surface Mining, Mid-Continent Regional Coordinating Center, Alton Federal Building, 501 Belle Street, Alton, Illinois 62002. Telephone: (618) 463–6460. Internet: jcoleman@mcrgw.osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Missouri Program
II. Submission of the Proposed Amendment
III. Director's Findings
IV. Summary and Disposition of Comments
V. Director's Decision
VI. Procedural Determinations

I. Background on the Missouri Program

On November 21, 1980, the Secretary of Interior conditionally approved the Missouri program. You can find general background information on the Missouri program, including the Secretary's findings, the disposition of comments, and the conditions of approval in the November 21, 1980, **Federal Register** (45 FR 77017). You can find later actions on the Missouri program at 30 CFR 925.12, 925.15, and 925.16.

II. Submission of the Proposed Amendment

By letter dated October 10, 1990, Missouri sent us an amendment to its program under SMCRA (Administrative Record No. MO–519). We announced receipt of the amendment in the November 1, 1990, **Federal Register** (55 FR 46076) and invited public comment on its adequacy. The public comment period closed December 3, 1990. In the September 29, 1992, **Federal Register** (57 FR 44660), we approved the amendment with exceptions. The exceptions included revisions to