PART 430—PERSONNEL

Authority: Section 702(a)(5) of the Social Security Act (42 U.S.C. 902(a)(5))

Indemnification of SSA Employees

§ 430.101 Policy.

(a) The Social Security Administration (SSA) may indemnify, in whole or in part, its employees (which for the purpose of this regulation includes former employees) for any verdict, judgment or other monetary award which is rendered against any such employee, provided that the conduct giving rise to the verdict, judgment or award was taken within the scope of his or her employment with SSA and that such indemnification is in the interest of the United States, as determined by the Commissioner, or his or her designee, in his or her discretion.

(b) SSA may settle or compromise a personal damage claim against its employee by the payment of available funds, at any time, provided the alleged conduct giving rise to the personal damage claim was taken within the scope of employment and that such settlement or compromise is in the interest of the United States, as determined by the Commissioner, or his or her designee, in his or her discretion.

(c) Absent exceptional circumstances, as determined by the Commissioner or his or her designee, SSA will not entertain a request either to agree to indemnify or to settle a personal damage claim before entry of an adverse verdict, judgment or monetary award.

(d) When an employee of SSA becomes aware that an action has been filed against the employee in his or her individual capacity as a result of conduct taken within the scope of his or her employment, the employee should immediately notify SSA that such an action is pending.

(e) The employee may, thereafter, request either:

(1) Indemnification to satisfy a verdict, judgment or award entered against the employee; or

(2) Payment to satisfy the requirements of a settlement proposal. The employee shall submit a written request, with documentation including copies of the verdict, judgment, award or settlement proposal, as appropriate, to the Deputy Commissioner or other designated official, who shall thereupon submit to the General Counsel, in a timely manner, a recommended disposition of the request. The General Counsel shall also seek the views of the Department of Justice. The General Counsel shall forward the request, the Deputy Commissioner's or other designated official's recommended disposition, and the General Counsel's recommendation to the Commissioner or his or her designee for decision.

(f) Any payment under this section either to indemnify an SSA employee or to settle a personal damage claim shall be contingent upon the availability of appropriated funds.

[FR Doc. 97–19478 Filed 7–24–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 96F–0384]

Indirect Food Additives: Adhesives and Components of Coatings

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 epichlorohydrin-dipropylene glycol and epichlorohydrin-polypropylene glycol as reactants in the preparation of epoxy-based resins used as adhesives for articles or components of articles intended for use in food-contact applications. This action is in response to a petition filed by the Dow Chemical Co.

DATES: Effective July 25, 1997; written objections and requests for a hearing by August 25, 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: 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 October 22, 1996 (61 FR 54801), FDA announced that a food additive petition (FAP 6B4523) had been filed by the Dow Chemical Co., 2030 Dow Center, Midland, MI 48674. The petition proposed to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) to provide for the safe use of epichlorohydrin-dipropylene glycol and epichlorohydrin-polypropylene glycol as reactants in the preparation of epoxy-based resins used as adhesives for articles or components of articles intended for use in food-contact applications.

In FDA's evaluation of the safety of this additive, the agency 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 propylene oxide and epichlorohydrin, carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as propylene oxide and epichlorohydrin, 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 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 the 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 The Petitioned Use of The Additive

FDA estimates that the petitioned use of the additives, reaction products of epichlorohydrin-dipropylene glycol and epichlorohydrin-polypropylene glycol, will result in exposure to the additive of no greater than 7 parts per billion in the daily diet (Ref. 1).

FDA does not ordinarily consider chronic toxicological testing 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 from acute toxicity studies 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 propylene oxide and epichlorohydrin, the carcinogenic chemicals that may be present as impurities in the additive. This risk evaluation of propylene oxide and epichlorohydrin 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. Propylene Oxide

FDA has estimated the exposure to polypropylene oxide from the petitioned use of each of the two additives in the manufacture of adhesives to be 0.7 parts per quadrillion (ppq) of the daily diet or 2.1 picogram (pg)/person/day or a total of 4.2 pg/person/day (Ref. 1). The agency used data from a carcinogenesis bioassay on propylene oxide, conducted for the Institute of Hygiene, University of Mainz, Germany (Ref. 3), to estimate the upper-bound lifetime human risk from exposure to this chemical stemming from the petitioned use of the additive. The results of the bioassay on propylene oxide demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused carcinomas and papillomas in the squamous epithelium of the forestomach.

Based on the estimated worst-case exposure to propylene oxide of 4.2 pg/person/day, FDA estimates that the upper-bound limit of individual lifetime risk from the use of the subject additives is in the range of 6.5×10^{-13} (or 6.5 in 10 trillion) to 2.9×10^{-12} (or 2.9 in 1 trillion) (Ref. 4). FDA's estimate of the upper-bound limit of individual lifetime risk has been stated as a range because the agency evaluated complex tumor data in an oral toxicity study using rats. Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to propylene 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 propylene oxide would result from the petitioned use of the additives.

B. Epichlorohydrin

FDA has estimated the exposure to epichlorohydrin from the petitioned use of each of the two additives in the manufacture of adhesives to be 0.7 ppq of the daily diet (3 kg), or 2.1 pg/person/day or a total of 4.2 pg/person/day (Ref. 1). The agency used data from a carcinogenesis bioassay conducted in Japan on epichlorohydrin fed to rats via their drinking water (Ref. 5), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of the additives. The results of the bioassay demonstrated that epichlorohydrin was carcinogenic under the conditions of the study. The test material caused significantly increased incidences of stomach papillomas and carcinomas in the rats.

Based on the agency's estimate that exposure to epichlorohydrin will not exceed 4.2 pg/person/day, FDA estimates that the upper-bound limit of individual lifetime human risk from the use of the subject additives is 1.9×10^{-13} (or 1.9 in 10 trillion) (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to epichlorohydrin would 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 epichlorohydrin would result from the petitioned use of the additives.

C. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of propylene oxide and epichlorohydrin 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 propylene oxide and epichlorohydrin 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 propylene oxide and epichlorohydrin, even under worst-case assumptions, is very low, in the range of less than 6.5 in 10 trillion to 2.9 in 1 trillion for propylene oxide and 1.9 in 10 trillion for epichlorohydrin.

III. Conclusion

FDA has evaluated data in the petition and other relevant material. The agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and (3) the regulations in § 175.105 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 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. No comments were received during the 30 day comment period specified in the filing notice for comments on the environmental assessment submitted with the petition.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before August 25, 1997, 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.

VI. 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 6B4523 (MATS #887, M2.0 & 2.1): Dow Chemical Co., dated September 18, 1996. Epichlorohydrin-dipropylene Glycol and Epichlorohydrin-polypropylene Glycol as Reactants in the Preparation of Epoxy Resins Used in Adhesives,'' dated October 29, 1996.

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. 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.

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 Propylene Oxide and Epichlorohydrin Epoxy Resins Employed as Reactants in the Preparation of Epoxy Resins Used in Adhesives: Subject of Food Additive Petition No. 6B4523 (Dow Chemical Company),'' dated November 12, 1996.

5. Konishi, Y. et al., ''Forestomach Tumors Induced by Orally Administered Epichlorohydrin in Male Wistar Rats,'' *Gann,* 71: pp. 922–923, 1980.

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, 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: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 175.105 is amended in the table in paragraph (c)(5) by alphabetically adding new entries under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * *	* * * *
α-(oxiranylmethyl)-ω-(oxiranylmethoxy)poly[oxy(methyl-1,2-ethanediyl)], (alternative name: epichlorohydrin-polypropylene glycol) (CAS Reg. No. 26142–30–3).	For use as a reactant in the preparation of epoxy-based resins.
2,2'-[oxybis[(methyl-2,1-ethanediyl)-oxymethylene]]bisoxirane, (alternative name: epichlorohydrin-dipropylene glycol) (CAS Reg. No. 41638–13–5).	For use as a reactant in the preparation of epoxy-based resins.
* * *	* * * *

Dated: July 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–19567 Filed 7-24-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 96F–0291]

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 12-hydroxystearic acid-polyethylene glycol (minimum MW 200) block copolymer as a surfactant in the manufacture of paper and paperboard intended for use in contact with food. This action is in response to a petition filed by ICI Americas, Inc.

DATES: Effective July 25, 1997; written objections and requests for a hearing by August 25, 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: 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 August 26, 1996 (61 FR 43772), FDA announced that a food additive petition (FAP 6B4519) had been filed by ICI Americas, Inc., 3411 Silverside Rd., Wilmington, DE 19850. The petition proposed to amend the food additive regulations in § 176.170 Components of paper and paperboard in contact with aqueous and fatty foods (21 CFR 176.170) to provide for the safe use of 12-hydroxystearic acid-polyethylene glycol (minimum MW 200) block copolymer as a surfactant in the manufacture of paper and paperboard 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