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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 98F–1019]

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 polyurethane resins manufactured from diphenylmethane diisocyanate, 1,4-butanediol, and adipic acid as a component of cap liners used on bottles in contact with food. This action responds to a petition filed by BF Goodrich Specialty Chemicals.

DATES: This rule is effective May 9, 2000. Submit written objections and requests for a hearing by June 8, 2000.

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: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 30, 1998 (63 FR 65793), FDA announced that a food additive petition (FAP 8B4631) had been filed by BF Goodrich Specialty Chemicals, 9911 Brecksville Rd., Cleveland, OH 44141. The petition proposed to amend the food additive regulations in § 177.1210 *Closures with sealing gaskets for food containers* (21 CFR 177.1210) to provide for the safe use of polyurethane resins manufactured from diphenylmethane diisocyanate, 1,4-butanediol, and adipic acid as a component of cap liners used on bottles in contact with food.

In its evaluation of the safety of these resins, FDA has reviewed the safety of the additive itself, the starting materials used, 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 residual amounts of methylene dianiline (MDA), which has been shown to cause cancer in test animals. MDA is produced when diphenylmethane diisocyanate (MDI), a starting material used in the manufacture of polyurethane resins, reacts with water. Residual amounts of reactants and manufacturing aids, such as MDA, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the general safety standard of section 409(c)(3)(A) 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 (section 409(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 Petitioned Use of the Additive

The petitioner determined the levels of three migrants extracted from the additive, polyurethane resins manufactured from MDI, 1,4-butanediol, and adipic acid. These three migrants were 1,4-butanediol, oligomers of the additive, and MDA (the hydrolysis product of MDI). FDA agrees that the determination of the levels of these three types of migrants are appropriate to evaluate the safe use of the additive. FDA estimates that the petitioned use of the additive will result in exposure to 1,4-butanediol of not more than 90 micrograms per person per day (μg/p/d) while exposure to the other two migrants will be even lower (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 dietary exposure resulting from the petitioned 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 MDA, the carcinogenic chemical that may be present as an impurity in the additive. This risk evaluation of MDA has two aspects: (1) Assessment of exposure to the impurity from the petitioned use of the additive; and (2) extrapolation of the risk observed in the animal bioassay to the conditions of probable exposure to humans.

A. Methylene Dianiline

FDA has estimated the exposure to MDA from the petitioned use of the additive in the manufacture of cap liners intended to contact food to be no more than 4.1 parts per trillion in the daily diet, or 0.012 μg/p/d (Refs. 1 and 5). The agency used data from a bioassay of MDA, sponsored by the National Toxicology Program, to estimate the upper-bound limit of lifetime human risk from exposure to MDA that may result from the proposed use of the additive (Ref. 3). The bioassay report showed that MDA ingestion produced tumors at multiple sites in both sexes of rats and mice.

Based on the agency's estimate that exposure to MDA will not exceed 0.012 μg/p/d, FDA estimates that the upper-bound limit of lifetime human risk for MDA from the petitioned use of the subject additive is 1×10^{-8} or 1 in 100 million (Ref. 4). Because of numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to MDA 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 MDA would result from the petitioned use of the additive.

B. Need for Specifications

The agency also has considered whether specifications are necessary to control the amount of MDA present as an impurity in the additive. The agency finds that the specifications are not necessary for the following reasons: (1)

Because of the low level at which MDA 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 MDA is very low, less than 1 in 100 million.

III. Conclusion on Safety

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 as a component of cap liners for food-contact articles is safe, that the food additive will achieve its intended technical effect, and that the regulations in § 177.1210 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 contact person listed above. As provided in § 171.1(h), the agency will delete any materials from the documents 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 8B4631 (63 FR 65793, November 30, 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 file with the Dockets Management Branch (address above) written objections by June 8, 2000. 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 are to be submitted and are to 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 to the file dated May 19, 1999, from the Petitions Contract Working Group (HFS–205), concerning FAP 8B4631.

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. ''Carcinogenesis Studies of 4,4'''-Methylenedianiline Dihydrochloride) (CAS Reg. No. 13552–44–8) in F344/N Rats and B6C3F$_1$ Mice (Drinking Water Studies),'' National Toxicology Program Technical Report Series, No. 248, June 1983.

4. Memorandum dated January 28, 1999, from the Regulatory Policy Branch (HFS–206), to Executive Secretary, Quantitative Risk Assessment Committee (QRAC) (HFS–308), entitled ''Estimation of the Upper-Bound Lifetime Risk for Methylene-4,4'''-Dianiline (MDA): Subject of Food Additive Petition 8B4631 (BF Goodrich Specialty Chemicals).''

5. Memorandum dated May 13, 1999, from the Scientific Support Branch (HFS–207), entitled ''FAP 8B4631 (MATS #1041)—Keller & Heckman (K & H), on Behalf of BF Goodrich Specialty Chemicals. Risk Assessment for Methylene Dianiline (MDA).''

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 177.1210 is amended in table 1 in paragraph (b)(5) by alphabetically adding an entry to read as follows:

§ 177.1210 Closures with sealing gaskets for food containers.

* * * * *

(b) * * *

(5) * * *

TABLE 1

List of substances	Limitations (expressed as percent by weight of closure-sealing gasket composition)
* * * * * * *	
Polyurethane resins manufactured from diphenylmethane diisocyanate, 1,4-butanediol, and adipic acid (CAS Reg. No. 26375–23–5).	For use only: No limitation on amount used, but for use only in closure gasket compositions used in contact with food types VI–A and VI–C (up to 15 percent alcohol) under conditions of use D, E, F, and G, as described in § 176.170(c) of this chapter, tables 1 and 2, respectively.
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Dated: April 28, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 99F–1910]

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 2-[4,6-bis(2,4-dimethylphenyl)-1,3,5-triazin-2-yl]-5-(octyloxy)phenol as a stabilizer for olefin polymers intended for use in contact with food. This action is in response to a petition filed by Cytec Industries, Inc.

DATES: This rule is effective May 9, 2000. Submit written objections and requests for a hearing by June 8, 2000.

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, 1999 (64 FR 33306), FDA announced that a food additive petition (FAP 9B4675) had been filed by Cytec Industries, Inc., 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 § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 2-[4,6-bis(2,4-dimethylphenyl)-1,3,5-triazin-2-yl]-5-(octyloxy)phenol as a stabilizer for olefin polymers intended for use in contact with food.

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) that the regulations in § 178.2010 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 21 CFR 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 9B4675. 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 collections 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 file with the Dockets Management Branch (address above) written objections by June 8, 2000. 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 are to be submitted and are to 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 178

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 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

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

2. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding an entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

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(b) * * *