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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 98F-0569]

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 ethylene-norbornene copolymers as articles or components of articles in contact with dry food. This action responds to a petition filed by Ticona.

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Submit written objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*].

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: 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 a notice published in the **Federal Register** of July 23, 1998 (63 FR 39583), FDA announced that a food additive petition (FAP 8B4597) 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 § 177.1520 *Olefin polymers* (21 CFR

177.1520) to provide for the safe use of ethylene-norbornene copolymers as articles or components of articles in contact with dry foods.

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 residual amounts of benzene, a carcinogenic impurity resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as benzene, 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 the Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, ethylene-norbornene copolymers, will result in exposure to no greater than 2.5 parts per billion of the additive in the daily diet (3

kilograms (kg)) or an estimated daily intake of 7.5 micrograms per person per day (Refs. 1 and 2).

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. 3), 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 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 benzene, the carcinogenic chemical that may be present as an impurity in the additive. The risk evaluation of benzene 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. Benzene

FDA has estimated the exposure to benzene from the petitioned use of the additive to be no more than 15 parts per trillion in the daily diet (3 kg) or 50 nanograms/person/day (ng/p/d) (Ref. 1). The agency used data from a carcinogenesis bioassay of benzene using B6C3F1 hybrid mice (Ref. 4), sponsored by the National Toxicology Program, 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 there were significantly increased incidences of mice with neoplasms at several organ sites associated with the administration of benzene by the oral route.

Based on the agency's estimate that exposure to benzene will not exceed 50 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 3.6×10^{-8} , or 3.6 in 100 million (Refs. 1 and 5). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to benzene 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 benzene 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 benzene 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 benzene may be expected to remain as an impurity following production of the additive, the agency would not expect this impurity to become a component of food at other than extremely low levels; and (2) the upper-bound limit of lifetime risk from exposure to benzene from the petitioned use is very low, 3.6 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: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in § 177.1520 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 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.

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 [*insert date 30 days after date of publication in the **Federal Register***], 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 office above 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 Division of Product Manufacture and Use, Chemistry Review Team (HFS-246), to the Division of Petition Control (HFS-215), entitled "FAP 8B4597 (MATS# 974, M2.0 & 2.1): Ticona Submission, Through Their Agent Keller and Heckman, Dated 5-8-98. Ethylene-Norbornene Copolymers for Use in Contact With Dry Food," February 16, 1999.

2. Memorandum from the Division of Product Manufacture and Use, Chemistry Review Team (HFS-246), to the Division of Petition Control (HFS-215), entitled "FAP 8B4597 (MATS# 974, M2.2): Ticona Submission, Through Their Agent Keller and Heckman, Dated 5-8-98. Ethylene-Norbornene Copolymers for Use in Contact With Dry Food," June 15, 1999.

3. Kokoski, C. J., "Regulatory Food Additive Toxicology," *Chemical Safety Regulation and Compliance*, edited by F. Homburger, J. K. Marquis, published by S. Karger, New York, NY, pp. 24-33, 1985.

4. "Toxicology And Carcinogenesis Studies of Benzene (CAS No. 71-43-2) in F344/N Rats And B6C3F1 Mice (Gavage Studies)," *National Toxicology Program Technical Report Series, No. 289*, April 1986.

5. Memorandum from the Division of Petition Control (HFS-215), to Executive Secretary, Quantitative Risk Assessment Committee (QRAC) (HFS-308), entitled "Estimation of the Upper-Bound Lifetime Risk From Benzene, an Impurity in Ethylene-Norbornene Copolymers, the Subject of Food Additive Petition 8B4597 (Ticona Co.)," March 23, 1999.

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, 379(e).

2. Section 177.1520 is amended by adding paragraph (a)(3)(vii), and by amending paragraph (c) in the table by adding item 3.9 to read as follows:

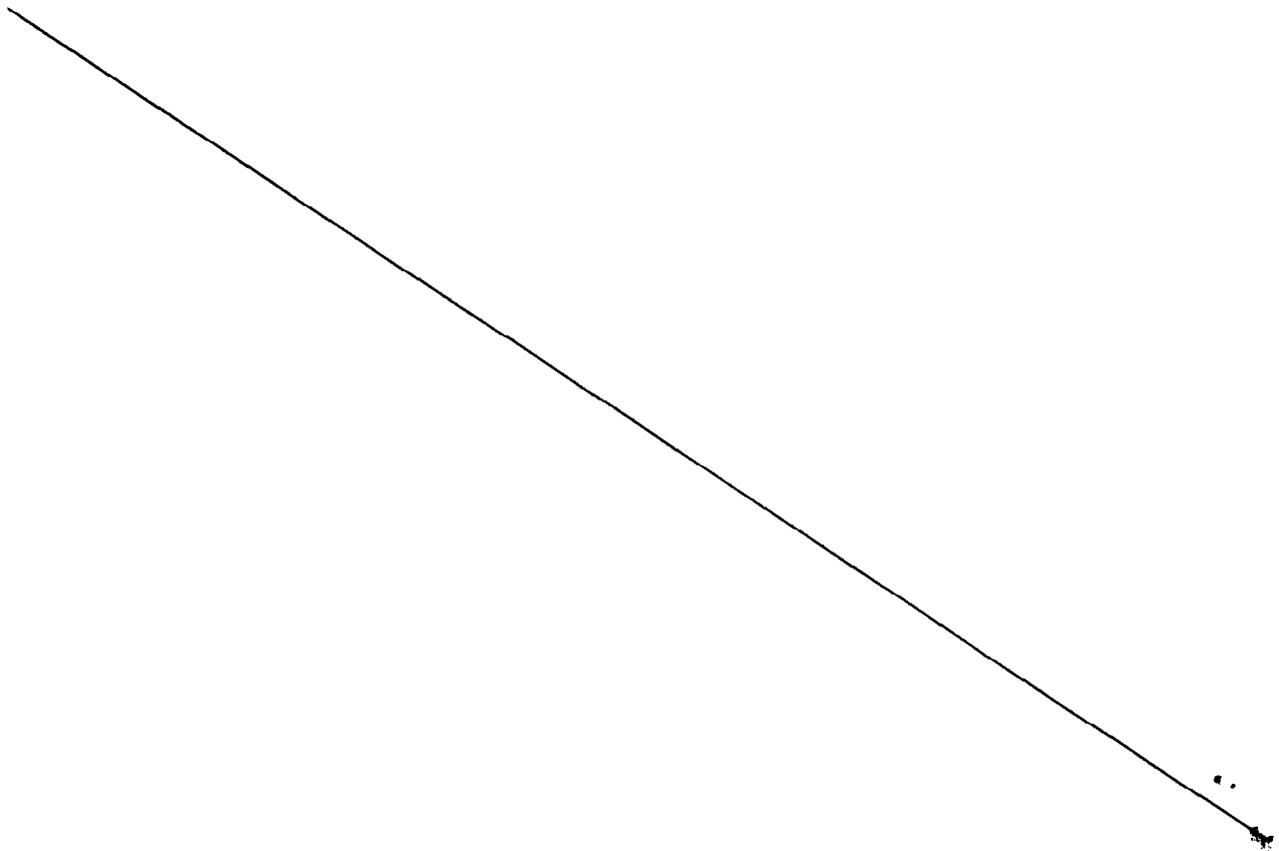
§ 177.1520 Olefin polymers.

(a) * * *

(3) * * *

(vii) Ethylene and 2-norbornene (CAS Reg. No. 26007-43-2) copolymers that shall contain not less than 30 and not more than 70 mole percent of polymer units derived from 2-norbornene.

* * * * *

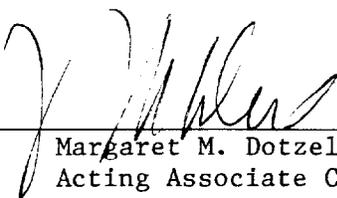


(c) * * *

Olefin Polymers	Density	Melting Point (MP) or softening point (SP) (Degrees Centigrade)	Maximum extractable fraction (expressed as percent by weight of the polymer) in <i>N</i> -hexane at specified temperatures.	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
* 3.9 Olefin copolymers described in paragraph (a)(3)(vii) of this section may only be used in contact with dry foods, Type VIII, as identified in § 176.170(c) of this chapter, Table 1. *	Not less than 1.0	*	*	*

* * * * *

Dated: 1/11/00
 January 11, 2000



Margaret M. Dotzel
 Acting Associate Commissioner for Policy

[FR Doc. ⁰⁰~~99~~-???? Filed ??-??-⁰⁰~~99~~; 8:45 am]

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