

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

Display Date 8-21-07
Publication Date 8-22-07
Certifier L. CLAWSON
DDM

[Docket No. 2006F-0225]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Glycerol Ester of Tall Oil Rosin

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 glycerol ester of tall oil rosin (GETOR) to adjust the density of citrus oils used in the preparation of beverages and to provide for the use of steam stripping as a purification method for producing glycerol ester of wood rosin, gum rosin, or tall oil rosin. This action is in response to a petition filed by Georgia-Pacific Resins, Inc.

DATES: This rule is effective [*insert date of publication in the Federal Register*]. Submit written or electronic objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*]. See section VI of this document for information on the filing of objections.

ADDRESSES: You may submit written or electronic objections and requests for a hearing, identified by Docket No. 2006F-0225, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written objections in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:
Division of Dockets Management (HFA-305), Food and Drug Administration,
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting objections, see the “Objections” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1304.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of June 15, 2006 (71 FR 34623), FDA announced that a food additive petition (FAP 6A4765) had been filed by Georgia-Pacific Resins, Inc., P.O. Box 105734, Atlanta, GA 30348. The petition proposed to amend the food additive regulations in 21 CFR 172.735 (§ 172.735) *Glycerol ester of wood or gum rosin* to provide for the following: (1) The safe use of GETOR to adjust the density of citrus oils used in the preparation of beverages; and (2) the use of steam stripping as a purification method for producing glycerol ester of wood rosin, gum rosin, or tall oil rosin.

GETOR, as well as glycerol ester of wood rosin (GEWR) and glycerol ester of gum rosin (GEGR), are approved for use in chewing gum bases (§ 172.615 (21 CFR 172.615)) and for several indirect additive uses (e.g., 21 CFR 175.125 and 178.3870). The proposed additive, GETOR, is intended to substitute for GEWR or GEGR in adjusting the density of citrus oils used in the preparation of beverages at the same use level (up to 100 parts per million of the finished beverage).

On March 29, 2005, FDA published a final rule that amended § 172.735 by approving the use of GEGR as a substitute for GEWR for adjusting the density of citrus oils in the preparation of beverages (70 FR 15756). The rule was issued in response to a petition and was based on FDA's conclusion that GEGR is chemically similar to GEWR, such that any increase in the estimated daily intake (EDI) of the individual resin acids and resin acid esters (the major

components of both GEGR and GEWR) would be insignificant and of no toxicological concern. The current petitioner has taken a similar approach to demonstrate that GETOR may be safely substituted for GEWR, and thereby for GEGR.

II. Evaluation of Safety

The petitioner provided information concerning the following: (1) The chemical composition of GETOR in comparison with GEWR; (2) the process used to manufacture GETOR; (3) physiochemical properties of GETOR in comparison to GEWR; (4) conformance of GETOR with the specifications in § 172.735; (5) the functional equivalence of GETOR to GEWR; and (6) relevant safety information.

Based on its evaluation of the information provided by the petitioner and other available information, the agency has determined that GETOR is chemically and functionally similar to GEWR and GEGR and that any increase in the EDI of the individual resin acids and resin acid esters resulting from the proposed use of GETOR will not be of toxicological concern. Therefore, the agency concludes that the proposed use of GETOR is safe, that the additive will achieve the intended technical effect, and that § 172.735 should be amended as set forth in this document.

To encompass the three glycerol ester of rosins (wood, gum, and tall oil) in the section heading for § 172.735, the petitioner has requested, and the agency concurs, that the section heading for § 172.735 should be changed from *Glycerol ester of wood or gum rosin* to *Glycerol ester of rosin*.

FDA also considered the petitioner's request to include steam stripping as an alternative method to countercurrent steam distillation (presently listed in § 172.735) for purifying the rosin esters in § 172.735. Steam stripping is the

method listed in the chewing gum base regulation (§ 172.615) for purifying GEWR, GEGR, and GETOR. As additional information, the petitioner provided the most recent specifications for GEWR adopted by the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JEFCA, 46th session, 1996), which lists steam stripping, as well as countercurrent steam distillation as purification methods. FDA concludes that steam stripping is an acceptable method for purifying the rosin esters in § 172.735 and that this method, along with the specifications in the regulation, will ensure that the additive is of suitable purity for the intended use. Therefore § 172.735 is amended to include steam stripping as a purification method.

III. Inspection of Documents

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 will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any material that is 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 6A4765 (71 FR 34623). 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 file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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, and re delegated

to the Director, Center for Food Safety and Applied Nutrition, 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 172.735 is amended by revising the section heading, introductory text, and paragraph (a) to read as follows:

§ 172.735 Glycerol ester of rosin.

Glycerol ester of wood rosin, gum rosin, or tall oil rosin may be safely used in food in accordance with the following prescribed conditions:

(a) It has an acid number of 3 to 9, a drop-softening point of 88 to 96 °C; and a color of N or paler as determined in accordance with Official Naval Stores Standards of the United States. It is purified by countercurrent steam distillation or steam stripping.

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Dated: 8/15/07
August 15, 2007.

Leslye M. Fraser

Leslye M. Fraser,
Director,
Office of Regulations and Policy,
Center for Food Safety and Applied Nutrition.
[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

BILLING CODE 4160-01-S

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