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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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**21 CFR Part 172**

[Docket No. 00F-0812]

**Food Additives Permitted for Direct Addition to Food for Human Consumption;  
Dimethyl Dicarbonate**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for a more descriptive term, in place of “inhibitor of yeast,” for the safe use of dimethyl dicarbonate (DMDC). The more descriptive term is “microbial control agent.” This document also involves adding related limitations to our regulations on dimethyl dicarbonate. This action is in response to a petition filed by Bayer Co.

**DATES:** This rule 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:** Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3077.

**SUPPLEMENTARY INFORMATION:****I. Introduction**

In a notice published in the **Federal Register** of March 7, 2000 (65 FR 12014), FDA announced that a food additive petition (FAP 0A4718) had been filed by Bayer Co., c/o McKenna & Cuneo LLP, 1900 K St. NW., Washington, DC 20006-1108. The petition proposed to amend the food additive regulations in § 172.133 *Dimethyl dicarbonate* (21 CFR 172.133) both to provide for the safe use of DMDC in noncarbonated juice beverages containing up to and including 100 percent juice and to provide for a more descriptive term in place of “inhibitor of yeast,” for the safe use of DMDC.

In a notice published in the **Federal Register** of September 27, 2000 (65 FR 58091), FDA announced that it was amending the filing notice of March 7, 2000, to clarify that the proposed amendment to provide for a more descriptive term in place of “inhibitor of yeast,” for the safe use of DMDC will also involve adding related limitations to § 172.133. In the September 27, 2000, notice, FDA also announced that the petitioner’s additional request, to amend the food additive regulations to provide for the safe use of DMDC in noncarbonated juice beverages containing up to and including 100 percent juice, was converted to a food-contact substance notice (FCN 0035) (21 U.S.C. 348(h)(5)). Subsequently, this request was withdrawn from the petition as of the effective date of FCN 0035 (June 9, 2000).

DMDC is currently listed in § 172.133 for use as a yeast inhibitor in wine, dealcoholized wine, and low alcohol wine (53 FR 41325, October 21, 1988; and 58 FR 6088, January 26, 1993); in ready-to-drink teas (59 FR 5317, February 4, 1994); in carbonated or noncarbonated, nonjuice-containing flavored or unflavored beverages containing added electrolytes (61 FR 26786, May 29, 1996); and in carbonated, dilute beverages containing juice, fruit flavor, or both, with juice content not to exceed 50 percent (61 FR 26786, May 29, 1996). In addition, there is an effective notification for the use of DMDC as a microbial control agent in noncarbonated juice beverages containing up to and including 100 percent juice (FCN 0035, June 9, 2000).

## II. Evaluation of Safety

DMDC is used in the beverage industry for supplemental microbial control in beverages during the final stages of filling. It is added to beverages, whose viable microorganism load was previously reduced by other technologies, immediately prior to bottling, canning, or other forms of final packaging. To ensure its safe use, the agency set the maximum amount of DMDC that may be added to food at 250 parts per million (ppm). DMDC is currently approved under § 172.133(b)(1) and (b)(2) as an inhibitor of yeast in various beverages under normal circumstances of bottling or canning where the viable yeast count has been reduced to 500 per milliliter (mL) or less by current good manufacturing practices. DMDC is also approved under § 172.133(b)(3) and (b)(4) as an inhibitor of yeast in additional beverages. During its review of the subject petition, FDA found that restrictions given in paragraphs (b)(1) and (b)(2) were inadvertently omitted from paragraphs (b)(3) and (b)(4).

Bayer Co. petitioned the agency to change the term “inhibitor of yeast” to “microbial control agent” to better describe the actual functional effect of DMDC (at levels up to 250 ppm) in beverages during the final stages of filling. In support of the more descriptive term “microbial control agent,” the petitioner provided studies of the effect of DMDC (at levels up to 250 ppm) on various yeast strains and on *Escherichia coli* 0157:H7 in several noncarbonated juice beverages.

In its review of the proposed use of the term “microbial control agent,” the agency evaluated the information submitted with FAP 0A4718, as well as previously submitted information. FDA has determined that DMDC is effective in microbial control for beverages under normal circumstances of bottling, canning, and other forms of final packaging where the viable microorganism load has been reduced to 500 microorganisms/mL or less by current technologies.

## 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 renaming of the use of the additive is appropriate provided that related limitations are added to § 172.133, (2) the uses of the additive

specified in this section remain safe, (3) the additive will achieve its intended technical effect, and therefore, (4) the regulations in § 172.133 should be amended as set forth in this document.

The agency is also taking this opportunity to correct an inadvertent error in and to make editorial changes to § 172.133 in response to the ongoing initiative regarding plain language in government writing.

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 determined subsequent to the amended filing notice of this petition that the categorical exclusion in 21 CFR 25.30(i) is no longer appropriate. The agency is relying instead on the categorical exclusion in 21 CFR 25.32(k) for this action. Because this action is of a type that does not individually or cumulatively have a significant effect on the human environment, neither an environmental assessment nor an environmental impact statement is required.

#### **V. Paperwork Reduction Act 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 [*insert date 30 days after date of publication in the Federal Register*]. 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 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 redelegated 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 172.133 is amended by redesignating paragraph (c)(2) as paragraph (c)(3), by adding a new paragraph (c)(2), and by revising newly redesignated paragraph (c)(3) and paragraphs (b), (b)(1), (b)(2), (b)(3), and (b)(4) to read as follows:

**§ 172.133 Dimethyl dicarbonate.**

\* \* \* \* \*

(b) The additive is used or intended for use as a microbial control agent in the following beverages under normal circumstances of bottling, canning, or other forms of final packaging, where the viable microbial load has been reduced to 500 microorganisms per milliliter or less by current good manufacturing practices such as heat treatment, filtration, or other technologies prior to the use of dimethyl dicarbonate:

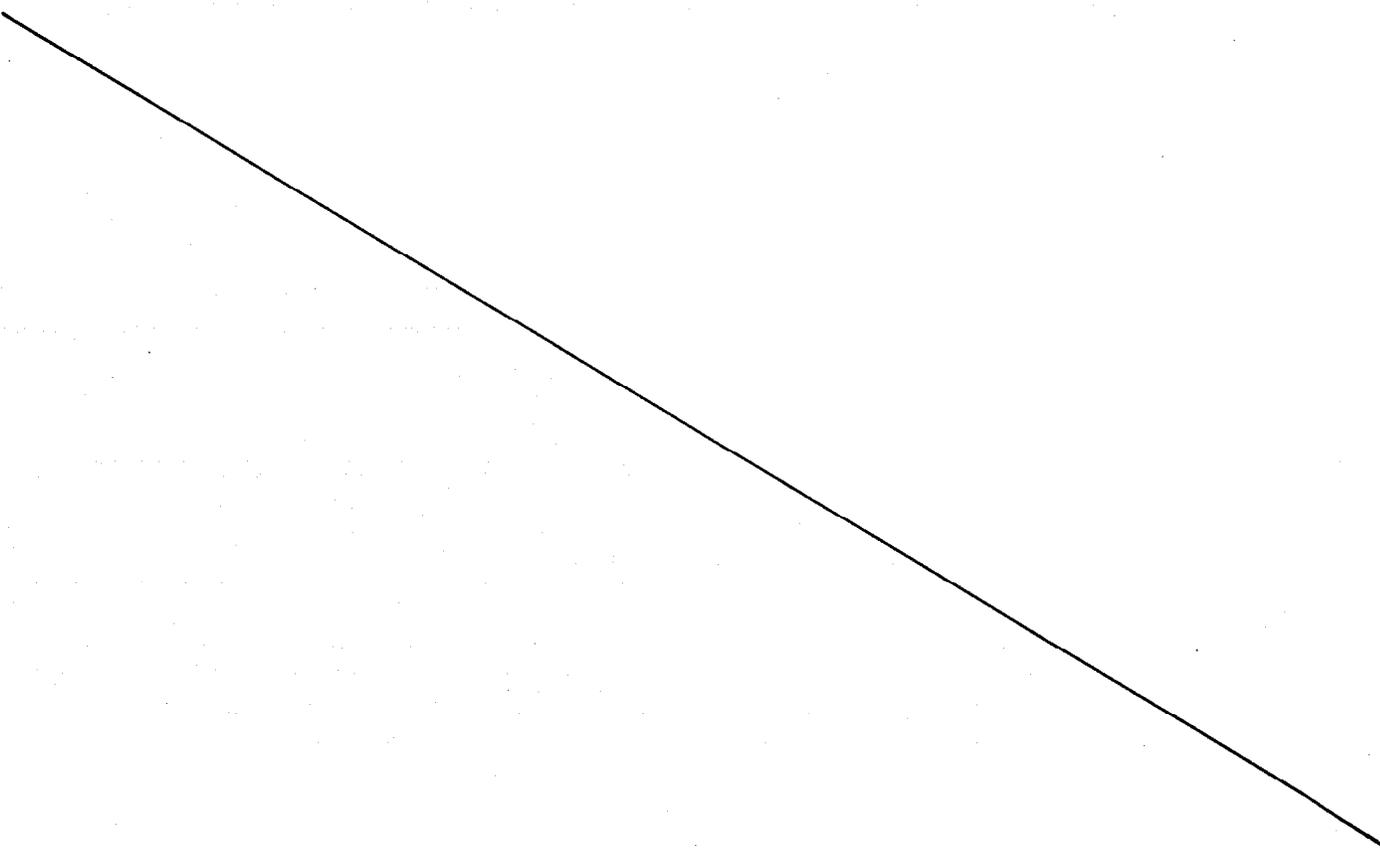
(1) In wine, dealcoholized wine, and low alcohol wine in an amount not to exceed 200 parts per million.

(2) In ready-to-drink teas in an amount not to exceed 250 parts per million.

(3) In carbonated or noncarbonated, nonjuice-containing (less than or equal to 1 percent juice), flavored or unflavored beverages containing added electrolytes (5–20 milliequivalents/liter sodium ion (Na<sup>+</sup>) and 3–7 milliequivalents/liter potassium ion (K<sup>+</sup>)) in an amount not to exceed 250 parts per million.

(4) In carbonated, dilute beverages containing juice, fruit flavor, or both, with juice content not to exceed 50 percent, in an amount not to exceed 250 parts per million.

(c) \* \* \*



(2) The intended use of the additive.

(3) Adequate directions for use to ensure compliance with this section.

Dated: 2/20/01  
February 20, 2001

L. Robert Lake

L. Robert Lake  
Director of Regulations and Policy,  
Center for Food Safety and  
Applied Nutrition.

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

J. W. Windsor

[FR Doc. 01-???? Filed ??-??-01; 8:45 am]

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