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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 94F-0454]

**Food Additives Permitted for Direct Addition to Food for Human Consumption; White Mineral Oil, USP**

**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 the safe use of white mineral oil as a dust control agent for rough rice at an application rate of 800 parts per million (ppm). This action is in response to a petition filed by Lyondell-Citgo Refining Co., Ltd.

**DATES:** This regulation is effective (*insert date of publication in the **Federal Register***); 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:** Blondell Anderson, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3106.

**SUPPLEMENTARY INFORMATION:**

## **I. Introduction**

In a notice published in the **Federal Register** of January 25, 1995 (60 FR 4920), FDA announced that a food additive petition (FAP 5A4440) had been filed by Lyondell-Citgo Refining Co., Ltd., P.O. Box 2451, Houston, TX 77252-2451, proposing that the food additive regulations be amended in § 172.878 *White mineral oil* (21 CFR 172.878), to provide for the safe use of white mineral oil as a dust control agent for rough rice at an application rate of 800 ppm (0.08 percent of the weight of the rice). An application rate of 200 ppm (0.02 percent of the weight of the grain) is currently permitted under § 172.878(c) for use on wheat, corn, soybean, barley, rice, rye, oats, and sorghum as a dust suppressant. On September 17, 1996, the petitioner amended the petition to limit its request to the use of white mineral oil of ISO 100 oil viscosity (100 centistokes (cSt) at 100°F).

## **II. Comments**

The agency has received nine comments from rice warehouses and an oil supply company in support of the proposed application rate of food grade white mineral oil for rough rice indicating that the current regulated rate of 200 ppm does not effectively control rice dust. Because the comments are consistent with the regulation as set forth in the codified section of this document, FDA sees no need to address them.

## **III. Conclusion**

The agency has evaluated all the data in the petition and other information and concludes that the proposed use of white mineral oil of ISO 100 oil viscosity (centistokes (cSt) at 100 °F) is safe for use as a dust control agent for rough rice and that the additive will achieve its technical effect. Therefore, the agency concludes that the food additive regulations should be amended as set forth as follows.

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 Effects**

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.

#### **V. Paperwork Reduction Act of 1995**

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.

#### **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 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 172.878 is amended in the table in paragraph (c) by adding an entry under the headings “Use” and “Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)” to read as follows:

**§ 172.878 White mineral oil.**

\* \* \* \* \*

(c) \* \* \*

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)
16. As a dust control agent for rice.	ISO 100 oil viscosity (100 centistokes (cSt) at 100°F) applied at a level of no more than 0.08 percent by weight of the rice grain.

Dated: 11/7/98  
 November 7, 1998

L. Robert Lake

L. Robert Lake  
 Director, Office of Policy, Planning  
 and Strategic Initiatives  
 Center for Food Safety and Applied Nutrition

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

*Jen Wundisot*

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