DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 98F–0183]

Indirect Food Additives: Adhesives and Components of Coatings

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-hydroxy-1-[4-(2-hydroxyethoxy)phenyl]-2-methyl-1-propanone as a photoinitiator for adhesives and pressure-sensitive adhesives intended for use in food-contact applications. This action responds to a petition filed by Ciba Specialty Chemicals Corp.

DATES: This regulation is effective September 28, 1998. Submit written objections and requests for a hearing by October 28, 1998.

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 March 31, 1998 (63 FR 15425), FDA announced that a food additive petition (FAP 8B4589) had been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY 10591–9005. The petition proposes to amend the food additive regulations to provide for the safe use of 2-hydroxy-1-[4-(2-hydroxyethoxy)phenyl]-2-methyl-1-propanone as a photoinitiator for adhesives complying with § 175.105 *Adhesives* (21 CFR 175.105) and pressure-sensitive adhesives complying with § 175.125 *Pressure-sensitive adhesives* (21 CFR 175.125) intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in §§ 175.105 and 175.125 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 (address above) 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.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8B4589 (63 FR 15425). 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 collection 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 anytime on or before October 28, 1998, file with the Dockets Management Branch (address above) written objection 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 objection 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 175

Adhesives, 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 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

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

2. Section 175.105 is amended in the table in paragraph (c)(5) by alphabetically adding an entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * *	* * * *
2–Hydroxy-1-[4-(2-hydroxyethoxy)phenyl]-2-methyl-1-propanone(CAS Reg. No. 106797–53–9).	For use only as a photoinitiator at a level not to exceed 5 percent by weight of the adhesive.
* * *	* * * *

3. Section 175.125 is amended by adding paragraph (a)(8) and by revising paragraph (b)(1) to read as follows:

§ 175.125 Pressure-sensitive adhesives.

* * * * *

(a) * * *

(8) 2-Hydroxy-1-[4-(2-hydroxyethoxy)phenyl]-2-methyl-1-propanone (CAS Reg. No. 106797–53–9) as a photoinitiator at a level not to exceed 5 percent by weight of the pressure-sensitive adhesive.

(b) * * *

(1) Substances listed in paragraphs (a)(1), (a)(2), (a)(3), (a)(5), (a)(6), (a)(7), and (a)(8) of this section, and those substances prescribed by paragraph (a)(4) of this section that are not identified in paragraph (b)(2) of this section.

* * * * *

Dated: September 15, 1998.

L. Robert Lake,

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

[FR Doc. 98–25795 Filed 9–25–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 281

[FRL–6167–7]

Virginia; Final Approval of Underground Storage Tank Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final determination on Virginia's application for program approval.

SUMMARY: The Commonwealth of Virginia (State) has applied for approval of its underground storage tank program under Subtitle I of the Resource Conservation and Recovery Act (RCRA). The Environmental Protection Agency (EPA) has reviewed the State's application and has made a final determination that the State's underground storage tank program satisfies all of the requirements necessary to qualify for approval. Thus, EPA is granting final approval to the State to operate its program.

EFFECTIVE DATES: Program approval for Virginia shall be effective on October 28, 1998.

FOR FURTHER INFORMATION CONTACT: Rosemarie Nino, State Programs Branch, Waste & Chemicals Management Division (3WC21), U.S. EPA Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103–2029, (215) 814–3377.

SUPPLEMENTARY INFORMATION:

A. Background

Section 9004 of the Resource Conservation and Recovery Act (RCRA) authorizes EPA to approve a State's underground storage tank program to operate in the State in lieu of the Federal underground storage tank (UST) program. To qualify for approval, a State's program must be ''no less stringent'' than the Federal program in all seven elements set forth at section 9004(a)(1) through (7) of RCRA, 42 U.S.C. 6991c(a)(1) through (7), as well as the notification requirements of section 9004(a)(8) of RCRA, 42 U.S.C. 6991c(a)(8) and must provide for adequate enforcement of compliance with UST standards (section 9004(a) of RCRA, 42 U.S.C. 6991c(a)).

On July 15, 1998, the State submitted an official application for EPA approval to administer its underground storage tank program. On July 30, 1998, EPA published a tentative determination announcing its intent to approve the State's program. Further background on the tentative decision to grant approval appears at 63 FR 40683–40685, (July 30, 1998).

Along with the tentative determination, EPA announced the availability of the application for public review and comment, and the date of a tentative public hearing on the application and EPA's tentative determination. EPA requested advance notice for testimony and reserved the right to cancel the public hearing in the event of insufficient public interest. EPA did not receive any public comments and since there were no requests to hold a public hearing, it was cancelled.

B. Final Decision

I conclude that the State's application for program approval meets all of the statutory and regulatory requirements established by Subtitle I of RCRA and 40 CFR part 281. Accordingly, the State is granted approval to operate its underground storage tank program in lieu of the Federal program.

C. Compliance With Executive Order 12866

The Office of Management and Budget has exempted this action from the requirements of Section 6 of Executive Order 12866.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of certain regulatory actions on State, local, and tribal governments and the private sector. Under sections 202 and 205 of the UMRA, EPA generally must prepare a written statement of economic and regulatory alternatives analyses for proposed and final rules with Federal mandates, as defined by the UMRA, that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. The section 202 and 205 requirements do not apply to today's action because it is not a ''Federal mandate'' and because it does not impose annual costs of $100 million or more.

Today's rule contains no Federal mandates for State, local or tribal governments or the private sector for two reasons. First, today's action does not impose new or additional enforceable duties on any State, local or tribal governments or the private sector because the requirements of the State program are already imposed by the State and subject to State law. Second, the Act also generally excludes from the definition of a ''Federal mandate'' duties that arise from participation in a voluntary Federal program. A State's participation in an authorized UST program is voluntary.

Even if today's rule did contain a Federal mandate, this rule will not result in annual expenditures of $100 million or more for State, local, and/or tribal governments in the aggregate, or the private sector. Costs to State, local and/or tribal governments already exist under the State program, and today's action does not impose any additional obligations on regulated entities. In fact, EPA's approval of state programs generally may reduce, not increase, compliance costs for the private sector.

The requirements of section 203 of UMRA also do not apply to today's action. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, section 203 of the UMRA requires EPA to develop a small government agency plan. This rule contains no regulatory requirements that might significantly or uniquely affect small governments. The Agency recognizes that although small governments may own and/or operate USTs, they are already subject to the regulatory requirements under existing state law which are being authorized by EPA, and, thus, are not subject to any additional significant or unique requirements by virtue of this program approval.