unnecessary for establishment of the uniform compliance date. Nonetheless, under 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether this uniform compliance date should be modified or revoked.

Interested persons may, on or before March 8, 1999, submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday though Friday. After its review of any comments received to this final rule, FDA will either publish a document providing its conclusions concerning the comments or will initiate document and comment rulemaking to modify or revoke the uniform compliance date established by this final rule.

The new uniform compliance date will apply only to final FDA food labeling regulations that require changes in the labeling of food products and that publish after January 1, 1999, and before December 31, 2000. Those regulations will specifically identify January 1, 2002, as their compliance date. All food products subject to the January 1, 2002, compliance date must comply with the appropriate regulations when initially introduced into interstate commerce on or after January 1, 2002. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2002, the agency will determine for that regulation an appropriate compliance date, which will be specified when the final regulation is published.

Dated: December 15, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98–33984 Filed 12–22–98; 8:45 am]

**BILLING CODE 4160–01–F**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 175

**[Docket No. 92F–0443]**

### 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 dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen polysiloxane and dimethylmethylhydrogen polysiloxane using a platinum catalyst. FDA is also amending the food additive regulations to provide for the safe use of 3,5-dimethyl-1-hexyne-3-ol, 1-ethynylcyclohexene, bis(methoxymethyl)ethyl maleate, methylvinyl cyclosiloxane, and tetramethyltetravinylcyclotetrasiloxane as optional polymerization inhibitors. This action is in partial response to a petition filed by Dow Corning Corp.

**DATES:** The regulation is effective December 23, 1998; written objections and requests for a hearing by January 22, 1999.

**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 February 12, 1993 (58 FR 8290), FDA announced that a petition (FAP 3B4346) had been filed by Dow Corning Corp., P.O. Box 994, Midland, MI 48686–0994. The petition proposed to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300), § 175.320 *Resinous and polymeric coatings for polyolefin films* (21 CFR 175.320), and § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen-containing polysiloxane and dimethylmethylhydrogen polysiloxane polymers using a platinum catalyst. The petition further proposed that the food additive regulations be amended to provide for the safe use 3,5-dimethyl-1-hexyne-3-ol, 1-ethynylcyclohexene, bis(methoxymethyl)ethyl maleate and methylvinyl cyclosiloxane as optional polymerization inhibitors. Additionally, the petition proposed that the regulations be amended to provide for the safe use of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one mixture, optionally containing magnesium nitrate, as an antimicrobial agent for emulsion-based silicone coating formulations.

Subsequent to the filing of the petition, the petitioner requested that tetramethyltetravinylcyclotetrasiloxane be included in the petition. Therefore, in a notice published in the **Federal Register** of July 2, 1998 (63 FR 36246), FDA announced that it was amending the filing notice of February 12, 1993, to indicate that the petitioner was also proposing that the food additive regulations be amended to provide for the safe use of tetramethyltetravinylcyclotetrasiloxane as an optional polymerization inhibitor in the manufacture of dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen-containing polysiloxane and dimethylmethylhydrogen polysiloxane polymers using a platinum catalyst.

In 1996, Congress enacted the Food Quality Protection Act (the FQPA). As a result of certain changes made by that law, antimicrobial formulations used in or on food contact articles were made subject to regulation as pesticide chemicals by the U.S. Environmental Protection Agency. Thus, after the FQPA, the proposed use of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one mixture, with magnesium nitrate as an optional ingredient, intended for use as an antimicrobial agent for emulsion-based silicone coating formulations was no longer under the jurisdiction of FDA. Because FDA lacked the authority to regulate this substance for the antimicrobial use, the agency did not complete its review of the safety of this additive.

Congress recently passed the Antimicrobial Regulation Technical Corrections Act of 1998 (the ARTCA) (Pub. L. 105–324) that reverses some of the jurisdictional changes made by the FQPA. As a result of the ARTCA, the antimicrobial use of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one mixture, with magnesium nitrate as an optional ingredient, is once again subject to regulation by FDA as a food additive. The safety of the proposed use of this substance will be considered by FDA and the agency's decision announced in a subsequent issue of the **Federal Register**.

As noted, the petition proposed to amend § 176.170, however, because the petitioned additives will be listed under § 175.300(b)(3) they may, by cross-reference, be used under § 176.170(b)(2). Therefore, this action does not include an amendment that would establish a

separate listing for the additives under § 176.170(b)(2).

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of each additive is safe, that each additive will have its intended technical effect, and therefore, that the regulations in §§ 175.300 and 175.320 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.

The agency has previously considered the environmental effects of this action as announced in the amended notice of filing for FAP 3B4346 published in the **Federal Register** of July 2, 1998 (63 FR 36246). 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 any time on or before January 22, 1999, 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 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 175.300 is amended in paragraph (b)(3)(xxviii)(*a*) by alphabetically adding an entry to read as follows:

**§ 175.300 Resinous and polymeric coatings.**

* * * * *

(b) * * *

(3) * * *

(xxviii) * * *

(*a*) * * *

Siloxane resins originating from the platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. No. 68083–18–1 and CAS Reg. No. 68083–19–2) with methylhydrogen polysiloxane (CAS Reg. No. 63148–57–2) and dimethylmethylhydrogen polysiloxane (CAS Reg. No. 68037–59–2), where the platinum content does not exceed 150 parts per million. The following substances may be used as optional polymerization inhibitors:

3,5-Dimethyl-1-hexyne-3-ol (CAS Reg. No. 107–54–0), at a level not to exceed 0.53 weight-percent;

1-Ethynylcyclohexene (CAS Reg. No. 931–49–7), at a level not to exceed 0.64 weight-percent;

Bis(methoxymethyl)ethyl maleate (CAS Reg. No. 102054–10–4), at a level not to exceed 1.0 weight-percent;

Methylvinyl cyclosiloxane (CAS Reg. No. 68082–23–5); and

Tetramethyltetravinylcyclotetrasiloxane (CAS Reg. No. 2554–06–5).

* * * * *

3. Section 175.320 is amended in the table in paragraph (b)(3) in item (i) by alphabetically adding an entry under the headings ''List of substances'' and ''Limitations'' to read as follows:

**§ 175.320 Resinous and polymeric coatings for polyolefin films.**

(b) * * *

(3) * * *

| List of substances | Limitations |
|---|---|
| (i) * * * | |
| Siloxanes and silicones: platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. No. 68083–18–1 and CAS Reg. No. 68083–19–2) with methylhydrogen polysiloxane (CAS Reg. No. 63148–57–2) and dimethylmethylhydrogen polysiloxane (CAS Reg. No. 68037–59–2). The following substances may be used as optional polymerization inhibitors:<br>3,5-Dimethyl-1-hexyne-3-ol (CAS Reg. No. 107–54–0), at a level not to exceed 0.53 weight percent;<br>1-Ethynylcyclohexene (CAS Reg. No. 931–49–7), at a level not to exceed 0.64 weight percent;<br>Bis(methoxymethyl)ethyl maleate (CAS Reg. No. 102054–10–4), at a level not to exceed 1.0 weight percent;<br>Methylvinyl cyclosiloxane (CAS Reg. No. 68082–23–5); and<br>Tetramethyltetravinylcyclotetrasiloxane (CAS Reg. No. 2554–06–5). | Platinum content not to exceed 150 parts per million. |
| * * * * * * * | |

* * * * *

Dated: December 14, 1998.

**L. Robert Lake,**

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

[FR Doc. 98–33914 Filed 12–22–98; 8:45 am]

BILLING CODE 4160–01–F

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–300702; FRL–6024–5]**

**RIN 2070–AB78**

## Triazamate; Time-Limited Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance relative to an Experimental Use Permit for combined residues of triazamate (RH–7988) and its metabolite (RH–0422) in or on apples. Rohm and Haas Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170). The tolerance will expire on December 31, 2001.

**DATES:** This regulation is effective December 23, 1999. Objections and requests for hearings must be received by EPA on or before February 22, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP–300702], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300702], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall (CM) #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300702]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

**FOR FURTHER INFORMATION CONTACT:** By mail: Mark Dow, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703 305–5533, e-mail: dow.mark@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 6, 1998 (63 FR 11240)(FRL–5777–5), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) for tolerance by Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19108–2399. This notice included a summary of the petition prepared by Rohm and Haas Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a time-limited tolerance for combined residues of the insecticide triazamate (RH–7988) and its metabolite (RH–0422), in or on apples at 0.1 part per million (ppm). This tolerance will expire on December 31, 2001.

### I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

#### *A. Toxicity*

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses