

## TENNESSEE-LEAD

| Designated area                                                                                                                                       | Designation        |                  | Classification |       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|------------------|----------------|-------|
|                                                                                                                                                       | Date               | Type             | Date           | Type  |
| Shelby County (part): Area encompassed by a circle with a ¾ mile radius with center being the intersection of Castex and Mallory Avenue, Memphis, TN. | July 2, 2001 ..... | Attainment ..... | .....          | ..... |
| *                                                                                                                                                     | *                  | *                | *              | *     |

[FR Doc. 01-11090 Filed 5-2-01; 8:45 am]  
BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-301119; FRL-6778-9]

RIN 2070-AB78

### Sucroglycerides; Exemption From the Requirement of a Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of sucroglycerides when used as an inert ingredient in or on growing crops or when applied to raw agricultural commodities after harvest. Rhodia Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sucroglycerides.

**DATES:** This regulation is effective May 3, 2001. Objections and requests for hearings, identified by docket control number OPP-301119, must be received by EPA on or before July 2, 2001.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301119 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone

number: 703-305-6304; and e-mail address: boyle.kathryn@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

| Categories | NAICS codes                | Examples of potentially affected entities                                             |
|------------|----------------------------|---------------------------------------------------------------------------------------|
| Industry   | 111<br>112<br>311<br>32532 | Crop production<br>Animal production<br>Food manufacturing<br>Pesticide manufacturing |

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

##### B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly

to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301119. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

##### II. Background and Statutory Findings

In the **Federal Register** of July 7, 1998 (63 FR 36681) (FRL-5795-6), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP) 6E4714 by Rhodia Inc., CN 7500, Cranbury, NJ 08512-7500. This notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001(c), be amended by establishing an exemption from the requirement of a tolerance for residues of sucroglycerides.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

### III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

### IV. Sucroglycerides

Sucroglycerides are a mixture of substances, primarily of mono-, di-, and tri-glycerides and mono- and di-sucrose esters of fatty acids. The product is produced through a process of transesterification of an edible fat or oil with sucrose. Thus, sucroglycerides are composed of and basically produced from sugar and oil.

Sucroglycerides have self-affirmed GRAS (generally recognized as safe) status. A GRAS substance is one that is generally recognized, among experts

qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures to be safe under the conditions of its intended use.

Under the FFDCA, there is no requirement that GRAS status can be determined only by the Food and Drug Administration (FDA). The GRAS determination may also be made by a company providing that the quantity and quality of data would be the same as if the data were submitted to FDA for review and evaluation.

The sucroglycerides Independent Safety Determination was affirmed by an expert panel in 1991 which examined only sucroglycerides manufactured from palm oil. The same expert panel re-convened in 1994 to evaluate sucroglycerides manufactured from edible fats and oils. This addendum to the Independent Safety Determination differed only in that the starting materials could be any edible fat or oil as opposed to palm oil only as originally evaluated in 1991. The panel concluded that sucroglycerides are GRAS for use in the food applications considered when used in accordance with good manufacturing practices.

The intended food applications evaluated as part of the Independent Safety Determination included use as a texturizer in biscuit mixes, and as an emulsifier in baked goods and baking mixes, dairy product analogs, frozen dairy desserts and mixes, and whipped milk products. The maximum estimated content of sucroglycerides in these anticipated food uses is 1.5%. Under 21 CFR 172.859, a related mixture, sucrose fatty acid esters, can be used as direct food additives as emulsifiers in various baked goods and baking mixes, dairy and dairy analog products, chewing gum, confections and frostings, and coffee and tea beverages with added dairy or dairy analog products, as texturizers in chewing gum, confections and frostings, and surimi-based fabricated seafood products, and as components of protective coatings applied to fresh fruit to retard ripening and spoiling. Under 21 CFR 184.1505, mono- and di-glycerides prepared from fats or oils are GRAS.

### V. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major

identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by sucroglycerides are discussed in this unit.

The submission to the Agency consisted of two studies (subchronic and chronic toxicity/carcinogenicity) that contained individual animal data. These two studies were reviewed as guideline studies, that is, studies that meet the Agency's criteria for a well-conducted study that supplies the necessary information. The other submissions consisted of toxicology study summaries. The summaries varied in the amount of information presented. Some were literature reports and partial translations of studies conducted in France. Thus, these summaries provided useful information to the Agency which was used during the weight-of-the-evidence evaluation.

1. *Acute.* The summary reported an acute toxicity study in which no adverse effects were reported. The LD<sub>50</sub> was estimated to be greater than 30 gram/kilogram body weight (g/kg bwt).

2. *Subchronic toxicity.* In a 13-week dog feeding study sucroglycerides were administered to 5 pure bred Beagle dogs/sex/dose in the diet at dose levels of 0, 5, 10, or 20% (control, 1.19, 2.59, or 5.61 gram/kilogram/day (g/kg/day) for males and control, 1.31, 2.57, or 4.7 g/kg/day for females). Three animals/sex/dose were sacrificed after 13 weeks, and the remaining two animals/sex/dose continued on for an additional 8 weeks of observation on control diets, and were then sacrificed.

No animals died on study and there was no overt toxicity. The decreased cholesterol levels, increased SGPT (serum glutamic pyruvic transaminase) values, and hepatic pathology are effects that are comparable to those seen as a result of a high fat dietary intake. The grossly high doses of this fatty compound were over the limit dose and effects seen cannot readily be distinguished from those observed with a high fat diet. The NOAEL (no observed adverse effect level) was at the 10% level (2.6 g/kg/day for males and females). The LOAEL (lowest-observed adverse effect level) was determined to be at the 20% level (5.6 g/kg/day for males and 4.7 g/kg/day for females). This study is classified as acceptable and satisfies the guideline requirement for a subchronic oral study in dogs.

In a different study, the summary reported that administration of sucroglycerides to rats for 100 days at concentrations up to 10% in the diet resulted in increased body weight gain and increased hepatic, total lipids and

lipid fractions with normal plasma lipid levels.

3. *Combined chronic toxicity/carcinogenicity 2-year rat study.* In this study sucroglycerides were administered via the diet to 50 rats/sex/group at dose levels of 0, 5, 10, or 20% (control, 1.59, 3.37, or 7.70 g/kg/day in males and control, 1.86, 4.01, or 9.25 g/kg/day in females for up to 108 weeks). No adverse effects were observed in mortality, hematology, blood chemistry, ophthalmoscopy, organ weights, or gross pathology parameters for either sex at any treatment level. The NOAEL for this combined chronic/carcinogenicity rat feeding study is 5% (3.37 g/kg/day for males and 4.01 g/kg/day for females). The LOAEL is 10% (7.70 g/kg/day for males and 9.25 g/kg/day for females) based on decreased food efficiency in males.

Under the conditions of this study, dosing is considered adequate to assess the carcinogenic potential of sucroglycerides based on the fact that the compound was administered at doses above the limit dose, food efficiency was reduced at 10% in males, and body weight and body weight gain, along with food efficiency was increased at 20% in both sexes. The administration of sucroglycerides to rats up to 20% in the diet did not result in an overall treatment-related increase in incidence of tumor formation. This study is classified as acceptable and satisfies the guideline requirement for a chronic toxicity/carcinogenicity oral study in rats.

In a different study, the summary reported that in a 25 to 28-month rat study, food efficiency was decreased at 10% lard sucroglyceride in the diet. No other effects were noted.

Summaries of another two long-term rat studies with 5 g/kg bw sucroglycerides in the diet were submitted. These also demonstrated no adverse effects and no evidence of carcinogenicity.

4. *Mutagenicity.* No mutagenicity studies were submitted to the Agency. However, none of the components of sucroglycerides are known mutagens. Given this information and since the combined chronic toxicity/carcinogenicity study did not result in an overall treatment-related increase in incidence of tumor formation, mutagenicity studies will not be required.

5. *Developmental/reproductive toxicity.* No developmental or reproductive toxicity guideline studies were submitted to the Agency, although summaries of two chronic toxicity/2-generation reproductive studies were submitted. Both summaries were partial

translations of French studies. Both summaries reported no adverse effects.

In a 1987 article in open literature describing a 2-generation reproductive and developmental toxicity study of a related compound, sucrose polyester (a mixture of hexa-, hepta-, and octa-esters of edible grade fatty acids with sucrose), was fed to rats at up to 10% of the diet. There were no adverse effects on reproductive function, on the development of the fetus, or on the viability or growth of the offspring into adult life.

Given the observed lack of developmental and reproductive effects, and the fact the mono- and di-glycerides are not known developmental toxicants, guideline developmental and reproductive studies will not be required.

6. *Dermal toxicity.* No dermal studies were submitted to the Agency. Sucrose esters of fatty acids and mono- and di-glycerides are unlikely to be absorbed through the skin in sufficient amounts to cause toxicity.

7. *Neurotoxicity.* No neurotoxicity studies were submitted to the Agency. However, no neurotoxicity was observed in the oral guideline studies.

The submitted toxicity studies demonstrate the low toxicity of sucroglycerides. For sucroglycerides, in several studies minimal effects occurred at doses that were expressed as grams of sucroglycerides per kilogram of animal body weight per day. For many chemicals, the Agency has reviewed data that demonstrate significant effects at doses that are expressed in milligrams per kilogram of animal body weight per day. Thus, the minimal toxicity that occurred with consumption of sucroglycerides, occurred at higher dose levels than normally used in testing.

## VI. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert

ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

### A. Dietary Exposure

For the purposes of assessing potential exposure under this exemption, EPA considered that sucroglycerides could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible.

1. *Food.* As previously stated, sucroglycerides have self-affirmed GRAS status. EPA will regulate only the use of sucroglycerides as an inert ingredient in pesticide formulations. Thus, the amount of sucroglycerides that can be applied to food as a result of their use in a pesticide product as an inert ingredient would not significantly increase the amount of sucroglycerides in the food supply above those amounts permitted by FDA.

2. *Drinking water exposure.* The solubility of sucroglycerides in water is very low, less than 1 part per billion. Given this low solubility in water and the low toxicity, both of which were demonstrated in testing, the Agency has determined that exposure for all human population groups through drinking water would be extremely low.

### B. Other Non-Occupational Exposure

Currently, there are no residential uses of sucroglycerides. Given that sucroglycerides are unlikely to be absorbed through the skin in sufficient amounts to cause toxicity, even if residential uses of sucroglycerides were to occur, toxicity would not occur.

## VII. Cumulative Effects

Section 408 (b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider "available information" concerning the cumulative effects of a particular chemical's residues and "other substances that have a common mechanism of toxicity." Sucroglycerides have a demonstrated lack of toxicity, and thus are unlikely to share a common mechanism of toxicity with any other substances.

## VIII. Determination of Safety for U.S. Population

Given the available toxicity information indicating minimal effects, there should be no concerns for human health, whether the exposure is acute, subchronic, or chronic. Thus, based on the low toxicity of sucroglycerides and the low potential for exposure from the EPA regulated uses of sucroglycerides, the Agency has determined that there is a reasonable certainty of no harm to the U.S. population from aggregate exposure to residues of sucroglycerides and that a tolerance is not necessary.

## IX. Determination of Safety for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin safety will be safe for infants and children. Due to the expected low toxicity of sucroglycerides, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary. The Agency has determined that there is a reasonable certainty of no harm to infants and children from aggregate exposure to residues of sucroglycerides and that a tolerance is not necessary.

## X. Other Considerations

### A. Endocrine Disruptors

There is no available evidence that sucroglycerides are an endocrine disruptor.

### B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

### C. Existing Exemptions

There are no existing exemptions for sucroglycerides.

### D. International Tolerances

The Agency is not aware of any country requiring a tolerance for sucroglycerides nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

## XI. Conclusions

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of

sucroglycerides. Accordingly, EPA finds that exempting sucroglycerides from the requirement of a tolerance will be safe.

## XII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

### A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301119 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before July 2, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania

Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-301119, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov). Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or

ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

*B. When Will the Agency Grant a Request for a Hearing?*

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

### XIII. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section

12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal

government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

### XIV. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 13, 2001.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

### PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346(a) and 371.

2. In § 180.1001, the table in paragraph (c) is amended by adding alphabetically the following inert ingredient to read as follows:

#### § 180.1001 Exemptions from the requirement of a tolerance.

|     |   |   |   |   |
|-----|---|---|---|---|
| *   | * | * | * | * |
| (c) | * | * | * |   |

| Inert ingredients                                                                                                                                                   | Limits |   |   |   |   |   | Uses                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|---|---|---|---|---|-------------------------------|
|                                                                                                                                                                     | *      | * | * | * | * | * | *                             |
| Glycerides, edible fats and oils derived from plants and animals, reaction products with sucrose (CAS Reg. Nos. 100403-38-1, 100403-41-6, 100403-39-2, 100403-40-5) |        |   |   |   |   |   | emulsifier, dispersing agent. |
|                                                                                                                                                                     | *      | * | * | * | * | * | *                             |

[FR Doc. 01-11093 Filed 5-2-01; 8:45 am]  
BILLING CODE 6560-50-S

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 54

[CC Docket No. 96-45; FCC 01-120]

### Federal-State Joint Board on Universal Service: Children's Internet Protection Act

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule, correction.

**SUMMARY:** This document corrects errors in the final rule portion regarding implementation of the Children's Internet Protection Act (CIPA) published in the **Federal Register** on April 16, 2001.

**DATES:** Effective May 3, 2001.

**FOR FURTHER INFORMATION CONTACT:** Jonathan Secrest or Narda Jones, Attorney, Common Carrier Bureau, Accounting Policy Division, (202) 418-7400.

**SUPPLEMENTARY INFORMATION:** This summary contains corrections to the rule portion of the Commission's Report and Order, CC Docket No. 96-45; FCC 01-120, 66 FR 19394 (April 16, 2001). The full text of the Commission's Report and Order is available for public

inspection during regular business hours in the FCC Reference Center, Room CY-A257, 445 Twelfth Street, S.W., Washington, D.C., 20554.

### Correction

1. On page 19396, in the third column, "Subpart H—Administration" is corrected to read "Subpart F—Universal Service Support for Schools and Libraries".

2. On page 19396, in the third column, in paragraph 2, "subpart H" is corrected to read "subpart F".

3. In § 54.20, on page 19397, in the third column, in paragraphs (c)(2)(iii)(A), (c)(2)(iii)(B), and (c)(2)(iii)(C), the phrase "for which you have requested or received Funding Commitments" is corrected to read "on this Form 486."

4. In § 54.520, on page 19397, in the third column, paragraph (c)(3)(i) is corrected by inserting after the phrase "paragraph (a)(3) of this section," the following phrase "other than one requesting only discounts on telecommunications services for consortium members."

5. In § 54.520, on page 19398, in the first column, in paragraph (c)(3)(ii) the phrase "duly completed and signed certifications" is corrected to read "duly completed and signed Forms 479," and the phrase "received under the universal service support mechanism by" is corrected to read "that I have

been approved for discounts under the universal service support mechanism on behalf of," and by inserting opening quotation marks after the phrase "or I certify".

6. In § 54.520, on page 19398, in the third column, in paragraph (f), "December 21, 2000" is corrected to read "April 20, 2001" and by inserting the phrase "or library" after the phrase "in which the school".

Federal Communications Commission.

**Magalie Roman Salas,**

*Secretary.*

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 216

### Regulations Governing the Taking and Importing of Marine Mammals

#### CFR Correction

In Title 50 of the Code of Federal Regulations, parts 200 to 599, revised as of October 1, 2000, Part 216 is corrected by removing Subpart N (§§ 216.151 through 216.157).

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