

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[OPP-2004-0040; FRL-7362-3]

**Lactic acid, n-propyl ester, (S);  
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 lactic acid, n-propyl ester, (S) on raw agricultural commodities when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, or animals. PURAC America, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, 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 lactic acid, n-propyl ester, (S).

**DATES:** This regulation is effective June 23, 2004. Objections and requests for hearings must be received on or before August 23, 2004.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket ID number OPP-2004-0040. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Princess Campbell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection

Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8033; e-mail address: [campbell.princess@epa.gov](mailto:campbell.princess@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. General Information***A. Does this Action Apply to Me?*

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

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Access Electronic Copies of this Document and Other Related Information?*

In addition to using EDOCKET at (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR BetaSite Two at <http://www.gpoaccess.gov/ecfr/>.

**II. Background and Statutory Findings**

In the **Federal Register** of October 24, 2003 (68 FR 60987) (FRL-7330-6), EPA issued a notice pursuant to section 408(d)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP OF6180) by PURAC America, Inc., 111 Barclay Blvd., Lincolnshire Corporate Center, Lincolnshire, IL 60069. This notice included a summary of the petition prepared by the petitioner PURAC America, Inc.

The petition requested that 40 CFR 180.950 be amended by establishing an exemption from the requirement of a

tolerance for residues of n-propyl lactate, also known as lactic acid, n-propyl ester, (S) (CAS Reg. No. 53651-69-7). There were no comments received in response to the notice of filing.

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) of the FFDCA 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) of the FFDCA 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. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCFA, 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 lactic acid, n-propyl ester, (S) are discussed in this unit.

##### A. Agency-Reviewed Studies

1. *Acute dermal toxicity in the rat.* Five males and five female adult outbred albino rats received 24-hour occluded dermal exposure to a dose of 2,000 milligram per kilogram (mg/kg) of n-propyl lactate (99.5%). There was no mortality. All five males and four of five females lost weight from day 0 to day 3, but five males and three females had slight weight gains during the period from day 0 to day 14. Two males and

one female had slight dermal encrustation on day 1. No treatment related findings were observed on necropsy. The dermal lethal dose (LD)<sub>50</sub> was greater than 2,000 milligrams/liter (mg/L). This is Toxicity Category III.

2. *Acute dermal irritation study in the rabbit.* One half milliliter (mL) of n-propyl lactate (99.5%) was distributed over each of three patches measuring approximately 2.5 x 2.5 centimeter (cm). Three rabbits were used and each rabbit received one patch applied to a skin site with 4-hour occluded exposure. All scores were zero for erythema and for oedema at 7 and 14 days. There was slight scaliness at all three sites at day 7 but not at day 14. This is Toxicity Category IV.

3. *Acute eye irritation study in the rabbit.* One-tenth mL of n-propyl lactate (99.5%) was instilled into the right eye of a single young adult New Zealand White rabbit with no subsequent wash. The exposed eye scored positive for corneal opacity at 1, 24, 48, and 72 hours, and at 7, 14, 21, 25, 28, 35, and 42 days. At 35, and 42 days three quarters of the cornea was still showing

opacity and there was a vascularization of the cornea. Iridial and conjunctival effects were also present. The iridial irritation cleared by day 14 and the eye was no longer positive for chemosis and conjunctival redness at 21 days. This is Toxicity Category I.

##### B. Structure-Activity-Relationship (SAR) Assessment

Lactic acid, n-propyl ester, (S), belongs to the same class of lactate esters as lactic acid, ethyl ester and lactic acid, n-butyl ester. Structurally these three chemicals which are all esters of lactic acid differ only in the presence of the ethyl, n-propyl, or n-butyl side chain. SAR assessments in which the chemical's structural similarity to other chemicals is used to determine toxicity have been performed for all three chemicals. The assessments did not identify any concerns for carcinogenicity or developmental toxicity for the lactate esters. In fact, all three chemicals were judged to be of low concern. For comparison purposes the physical/chemical properties are given in Table 1 below.

TABLE 1.—PHYSICAL/CHEMICAL PROPERTIES

Parameter	Test Results (M) measured (E) estimated		
	Ethyl Lactate (taken from SAR Assessment, submitted information)	n-Propyl lactate	Butyl Lactate (taken from SAR Assessment, NIOSH pocket guide, submitted information)
Physical form	Liquid	Liquid	Liquid
Molecular weight	118	132.16	146
Solubility (water) @ 20 °C	Completely miscible	Miscible	Slight (NIOSH) 4.5 g in 100 g water
Vapor pressure (mmHg) @ 20 °C	1.7	1.3	0.4 (NIOSH) 0.2
Octanol/water partition coefficient log K <sub>ow</sub>	0.06 0.31 (E) (SAR)	0.51	1.1 1.4 (E) (SAR)

Detailed discussions of the toxicity data for ethyl and butyl lactate esters were published in the Final Rule entitled "Lactic Acid, n-Butyl Ester and Lactic Acid, Ethyl Ester"; Exemptions from the Requirement of a Tolerance, in

the **Federal Register** of September 3, 2002 (67 FR 56225) (FRL-7196-6). Table 2 below compares the toxicity data discussed in that final rule and the available data for lactic acid, n-propyl ester, (S).

##### C. Comparison of Toxicity Data for Lactate Esters

TABLE 2.—COMPARISON OF TOXICITY DATA FOR LACTATE ESTERS

Toxicity Study	Ethyl Lactate	n-Propyl Lactate	Butyl Lactate
Acute oral	LD <sub>50</sub> > 2,000 mg/kg	*LD <sub>50</sub> > 2,000 mg/kg (Toxicity Category III)	LD <sub>50</sub> > 2,000 mg/kg
Acute inhalation	----	*LC <sub>50</sub> > 5,000 mg/m <sup>3</sup> (Toxicity Category IV)	LC <sub>50</sub> > 5.14 mg/L
Acute dermal	*LD <sub>50</sub> > 5 g/kg	LD <sub>50</sub> > 2,000 mg/kg (Toxicity Category III)	*LD <sub>50</sub> > 5 g/kg

TABLE 2.—COMPARISON OF TOXICITY DATA FOR LACTATE ESTERS—Continued

Toxicity Study	Ethyl Lactate	n-Propyl Lactate	Butyl Lactate
Dermal irritation	Non-irritating	Non-irritating to skin (Toxicity Category IV)	Irritating
Eye irritation	Possible eye irritant	Severely irritating to eye (Toxicity Category I)	Possible eye irritant
Dermal developmental	NOAEL 3,619 mg/kg	----	----

\*These values were obtained from an article entitled "Safety Assessment of n-Propyl-L-Lactate," published by Clary et al., 1998, in the Journal of Regulatory Toxicology and Pharmacology. The Agency did not review these studies which were supplied as supporting information; however, the studies which provided these results were conducted according to OECD guidelines.

#### D. Metabolism of Lactate Esters

In mammals simple esters such as ethyl, butyl, and n-propyl lactate readily undergo hydrolysis, yielding the alcohol and acid from which the ester was formed. For example in the case of ethyl lactate, the breakdown products would be ethyl alcohol (ethanol) and lactic acid, and in the case of n-propyl lactate, this would be n-propyl alcohol (1-propanol) and lactic acid. The metabolism of lactic acid is well understood; it is an intermediate in human metabolism of glucose. The World Health Organization (WHO) has examined the metabolism of 1-propanol, and has determined that it is rapidly absorbed and distributed throughout the body following ingestion.

#### V. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA 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).

As previously stated, lactic acid, n-propyl ester, (S) belongs to the same class of lactate esters as lactic acid, ethyl ester, and lactic acid, n-butyl ester. The SAR assessments for each of these three chemicals supports the conclusion that as a class, lactate esters, including lactic acid, n-propyl ester, (S) are of low toxicity.

Given their physical/chemical properties, lactate esters could have a variety of uses in and around the home. According to information on the Internet they are being considered as "green" replacements for many of the organic solvents traditionally used in the manufacturing industry. The Agency has estimated a generic dietary exposure estimate for an inert ingredient of 0.12 milligrams/kilogram/day (mg/kg/day). To assure that the exposure is not

underestimated, it is assumed that the inert ingredients are used on all crops and 100% of all crops are "treated" with the inert ingredient. Given the low toxicity of the lactate esters as a class and the body's ability to metabolize lactic acid, n-propyl ester, (S) to n-propyl alcohol and lactic acid, which are well-absorbed and metabolized by the human body, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate.

#### VI. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Lactic acid, n-propyl ester, (S) is structurally related to lactic acid, ethyl ester and lactic acid, n-butyl ester. All are lower toxicity chemicals; therefore, the resultant risks separately and/or combined should also be low. These chemicals do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that these chemical substances have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

#### VII. Safety Factor for Infants and Children

Section 408 of FFDCA 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 on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Due to the expected low oral toxicity of lactic acid, n-propyl ester, (S), a safety factor analysis has not been used to assess its risk. For the same reasons, the additional tenfold safety factor for the protection of infants and children is unnecessary.

#### VIII. Determination of Safety for U.S. Population, Infants and Children

Lactic acid, n-propyl ester, (S) belongs to the same class of lactate esters as lactic acid, ethyl ester, and lactic acid, n-butyl ester. The hydrolysis products of lactic acid, n-propyl ester, (S) are n-propanol and lactic acid which are readily metabolized by the human body. The SAR assessment did not identify any concerns for carcinogenicity or developmental toxicity. EPA concludes that lactic acid, n-propyl ester, (S) does not pose a dietary risk under reasonably foreseeable circumstances, and that there is a reasonable certainty of no harm from aggregate exposure to residues of lactic acid, n-propyl ester, (S).

#### IX. Other Considerations

##### A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing

lactic acid, n-propyl ester, (S) for endocrine effects may be required.

#### *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 tolerances or tolerance exemptions for lactic acid, n-propyl ester, (S).

#### *D. International Tolerances*

The Agency is not aware of any country requiring a tolerance for lactic acid, n-propyl ester, (S) nor have any CODEX maximum residue levels been established for any food crops at this time.

#### *E. List 4B Classification*

It has been determined that lactic acid, n-propyl ester, (S) is to be classified as a List 4B inert ingredient. This classification is due to the Toxicity Category I determination for the acute eye irritation study. Tolerance exemptions for lactic acid, n-propyl ester, (S) will be established in 40 CFR 180.910 and 180.930 instead of 40 CFR 180.950 as requested by the petitioner PURAC.

### **X. Conclusions**

Based on the Agency's review and evaluation of information on the toxicity of lactic acid, n-propyl ester, (S) as summarized in this preamble, and the previous evaluation of the structurally-related chemicals, lactic acid, ethyl ester and lactic acid, n-butyl ester (see the September 3, 2002 Final Rule), and considering the SAR assessments, and an understanding of the metabolism of lactate esters as a chemical class, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of lactic acid, n-propyl ester, (S). Accordingly, EPA finds that exempting lactic acid, n-propyl ester, (CAS Reg. No. 53651-69-7) from the requirement of a tolerance will be safe.

### **XI. 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of the FFDCA, as was provided in the old FFDCA sections 408 and 409 of the FFDCA. 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 ID number OPP-2004-0040 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 August 23, 2004.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14<sup>th</sup> St., NW., Washington, DC 20005. 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) 564-6255.

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 20460-0001.

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 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit XI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2004-0040, 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 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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).

## XII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 section 408(d) of the FFDCA, 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

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 section 408(n)(4) of the FFDCA. 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.

## XIII. Congressional Review Act

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: June 9, 2004.

**Lois Rossi,**

*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), 346a and 371.

■ 2. In § 180.910, the table is amended by adding alphabetically the following inert ingredient to read as follows:

### § 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

Inert Ingredients	Limits	Uses
* * * * *		
Lactic acid, n-propyl ester, (S); (CAS Reg. No. 53651-69-7).	.....	Solvent
* * * * *		

■ 3. In § 180.930, the table is amended by adding alphabetically the following inert ingredient to read as follows:

### § 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

Inert Ingredients	Limits	Uses
* * * * *		
Lactic acid, n-propyl ester, (S); (CAS Reg. No. 53651-69-7).	.....	Solvent
* * * * *		

Inert Ingredients	Limits	Uses
* *	*	* *

[FR Doc. 04-14221 Filed 6-22-04; 8:45 am]

BILLING CODE 6560-50-S

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 25

[MM Docket No. 93-25; FCC 04-44]

RIN 3060-AF39

### Implementation of the Cable Television Consumer Protection and Competition Act of 1992; Direct Broadcast Satellite Public Interest Obligations

**AGENCY:** Federal Communications Commission.

**ACTION:** Correcting amendments.

**SUMMARY:** The Commission is correcting a final rule that appeared in the **Federal Register** of April 28, 2004 (69 FR 23155). This document corrects typographical errors in the effective date and in the preamble. The corrected effective date appears below.

**DATES:** The rule published at 69 FR 23155 is effective May 28, 2004, except for §§ 25.701(d)(1)(i), 25.701(d)(1)(ii), 25.701(d)(2), 25.701(d)(3), 25.701(e)(3), 25.701(f)(6)(i), and 25.701(f)(6)(ii) which contain information collection requirements that have not been approved by OMB. The Federal Communications Commission will publish a document in the **Federal Register** announcing the effective date.

**FOR FURTHER INFORMATION CONTACT:** Rosalee Chiara, Federal Communications Commission, Policy Division, Media Bureau, 445 12th St., Washington, DC 20554, (202) 418-0754.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 04-9170 appearing on page 23155 in the issue of April 28, 2004, the effective date is corrected as set forth above, and in paragraph 18 of the preamble, the references to §§ 75.701(d)(2) and 75.701(d)(3) are corrected to read "25.701(d)(2)" and "25.701(d)(3)".

Federal Communications Commission.

**Marlene H. Dortch,**  
Secretary.

[FR Doc. 04-14263 Filed 6-22-04; 8:45 am]

BILLING CODE 6712-01-P

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 64

### Miscellaneous Rules Relating to Common Carriers

#### CFR Correction

In Title 47 of the Code of Federal Regulations, parts 40 to 69, revised as of October 1, 2003, on page 329, § 64.2400 paragraph (b) is corrected by removing "64.2001(a)(2), 64.2001(b), and 64.2001(c)", and adding in its place "64.2401(a)(2), 64.2401(b), and 64.2401(c)".

[FR Doc. 04-55512 Filed 6-22-04; 8:45 am]

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## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 73 and 76

[MM Docket No. 98-204; FCC 04-103]

RIN 3060-AH95

### Review of the Commission's Broadcast and Cable Equal Employment Opportunity Rules and Policies

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** In this document, the Commission adopts new broadcast and multichannel video programming distributor ("MVPD") equal employment opportunity ("EEO") rules. The Commission revised Forms 395-A and 395-B but issued a notice of proposed rulemaking on issues regarding whether to keep annual employment reports confidential or partially confidential.

**DATES:** Sections 73.3612 and 76.1802 contain information collection requirements that have not been approved by the Office of Management and Budget (OMB). The Commission will publish a document in the **Federal Register** announcing the effective date of these rules. Written comments by the public on the modified information collection requirements are due August 23, 2004.

**FOR FURTHER INFORMATION CONTACT:** Lewis Pulley, Policy Division, Media Bureau, (202) 418-1450 or [lewis.pulley@fcc.gov](mailto:lewis.pulley@fcc.gov). For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, contact Leslie F. Smith at

202-418-0217, or via the Internet at [Leslie.Smith@fcc.gov](mailto:Leslie.Smith@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a summary of the Media Bureau's *Third Report and Order* ("3R&O") in MM Docket No. 98-204; FCC 04-103, adopted April 19, 2004, and released on June 4, 2004. The full text of this 3R&O is available for inspection and copying during regular business hours in the FCC Reference Center, 445 Twelfth Street, SW., Room CY-A257, Portals II, Washington, DC, 20554, and may also be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., Room CY-B402, telephone (800) 378-3160, e-mail <http://www.BCPIWEB.com>. This document is available in alternative formats (computer diskette, large print, audio cassette and Braille). Persons who need documents in such formats may send an e-mail to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or call the Consumer & Governmental Affairs Bureau at 202-418-0531 (voice), 418-7365 (tty).

#### Synopsis of Third Report and Order

#### I. Background

1. The *Second Notice of Proposed Rulemaking* ("2NPRM"), 67 FR 1704, January 14, 2002, in this proceeding proposed and requested comment on new broadcast station and multichannel video programming distributor ("MVPD") Equal Employment Opportunity ("EEO") rules and new annual employment report forms to collect data on the race, ethnicity, and gender of the workforce of broadcast and MVPD employment units. In the *Second Report and Order* ("2R&O"), 68 FR 670, January 7, 2003, and *Third Notice of Proposed Rulemaking* ("3NPRM"), 67 FR 77374, December 17, 2002, in this proceeding, we adopted new broadcast and MVPD EEO rules, but deferred action on the issues relating to the Annual Employment Report forms. We now address those issues and adopt revised FCC Form 395-B, the broadcast station Annual Employment Report, and FCC Form 395-A, the multichannel video programming distributor Annual Employment Report. We also seek comment in the *Fourth Notice of Proposed Rulemaking* ("4NPRM") on the Commission's policies regarding public access to data contained in FCC Forms 395-A and 395-B.

2. In previously deferring action with respect to FCC Forms 395-A and 395-B, we stated that a deferral would permit us to coordinate these forms with new standards for classifying data on race, ethnicity, and job categories adopted by the Office of Management