Commodity	Parts per million	Expiration/ revocation date
Sweet potato	1.0	12/31/08

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0230; FRL–7729–5]

Lactic Acid, 2-Ethylhexyl Ester; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes four exemptions from the requirement of a tolerance for residues of lactic acid, 2-ethylhexyl ester or ethylhexyl lactate when used as an inert ingredient (solvent) in or on growing crops, when applied to raw agricultural commodities after harvest, or to animals. Purac America, 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 (FQPA), 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, 2-ethylhexyl ester.

DATES: This regulation is effective August 31, 2005. Objections and requests for hearings must be received on or before October 31, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the**SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2003–0230. 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., Confidential Business Information (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, 1801 S. Bell St., 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: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6304; e-mail address: *boyle.kathryn@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 Get Electronic Documents 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 Beta Site Two at*http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of July 11, 2003 (68 FR 41349) (FRL–7316–1), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 0F6179) by Purac America, Inc., 111 Barclay Boulevard, Lincolnshire, IL 60069. The petition requested that 40 CFR 180.950 be amended by establishing an exemption from the requirement of a tolerance for residues of the (S) isomer of lactic acid, 2-ethylhexyl ester, also known as lactic acid, 2-ethylhexyl ester, (2S)- or 2-ethylhexyl lactate (CAS Reg. No. 186817–80–1) when used as a solvent, an inert ingredient, in pesticide products. That notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

PURAC's petition requested only the establishment of a tolerance exemption for the (S) isomer of lactic acid, 2-ethylhexyl ester. However, according to information on the PURAC website, there is also a general CAS Reg. No. for lactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9). In the simplest terms an isomer can be defined as a substance which has the same molecular formula as another, but the individual elements of the molecule—the links from one element to another within the molecule—are arranged differently. A stereochemical isomer differs in the 3-D spatial arrangement of the elements. In certain cases, this is sometimes referred to as ''mirror images.'' An example of such a mirror image arrangement is a person's right and left hand. A person holding his hands out, both palms up, cannot make the presentation of four fingers and the thumb of the right hand match the orientation of the left hand. They can be viewed as if there is a mirror between the two. The chemical and physical properties of two isomeric chemicals are essentially the same. There can be some differences in the biological properties of the two isomers. The Agency has determined that both of the names are appropriate for this chemical and is therefore establishing tolerance exemptions using the (S) isomer and the general nomenclature of lactic acid, 2-ethylhexyl ester.

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 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 lactic acid, 2-ethylhexyl ester are discussed in this unit.

A. Acute Toxicity

The Agency's review of the following two acute toxicity studies and the toxicity category classification, are shown in the following Table. The Agency uses a scale of I to IV to rate the toxicity of acute studies. Toxicity Category I is indicative of very high acute toxicity. Toxicity Category IV is the Agency's lowest rating of acute toxicity.

ACUTE TOXICITY STUDIES

Study/Species	Results	Toxicity Category
Acute oral toxicity/rat	LD_{50} is equal to or greater than 2,000 mg/kg	III
Primary eye irritation/rabbit	Irritating to the eye	II

B. Repeated Dose Inhalation Toxicity Study

In a 28–day inhalation toxicity study, rats received 6-hour/day nose only exposure, for 5 days/week over a 4-week period. The target concentrations of lactic acid, 2-ethylhexyl ester were 0 (control), 75, 200, 600, or 1,800 mg/cubic meter (mg/m^3). A NOEL (no-observed effect level) was not defined as microscopic effects in the respiratory tract were noted even at 75 mg/m^3. The Agency's reviewer noted that effects seen at 600 mg/m^3 (decreased absolute spleen weight in males), and 1,800 mg/m^3 (gross pathology changes of the lungs, significantly decreased body weight in males, increases in relative liver weight in both sexes, increases in lung weight in males, decreases in absolute spleen weights in both sexes, and in relative spleen weight in females) would be more consistent with consideration of an adverse effect.

C. Developmental Inhalation Toxicity Study

Pregnant rats were exposed to lactic acid, 2-ethylhexyl ester at target concentrations of 0 (control), 200 or 600 mg/m^3 for 6 hours/day nose only exposure from gestation days 6 to 15. Both the 200 and 600 mg/m^3 concentration groups experienced an increased breathing rate. Body weight gains were slightly depressed in both groups. There was also a reduced food consumption relative to controls. A maternal NOAEL (no observed adverse effect level) was not determined. The maternal LOAEL (lowest observed adverse effect level) is 200 mg/m^3.

Mean fetal body weight values for the 600 mg/m^3 group were below those of controls. The only effect at 200 mg/m^3, a slight retardation in fetal ossification, was considered to be equivocal and probably secondary to maternal toxicity. The developmental NOAEL is 200 mg/m^3 and the developmental LOAEL is 600 mg/m^3 based on reduced mean fetal body weights.

D. Metabolism

Lactic acid, 2-ethylhexyl ester is formed by combining lactic acid and 2-ethylhexanol. In mammalian metabolism, this process is reversed. Simple esters such as the lactic acid esters undergo hydrolysis yielding lactic acid and the corresponding alcohol. The human body has well-understood pathways for metabolizing ingested lactic acid. Humans also produce lactic acid as an intermediate product of carbohydrate or glucose metabolism. The Food and Drug Administration (FDA) has estimated the lactate turnover rate in man to be of the order of 2 grams/kg/day. The Agency's evaluation of lactic acid has been placed as a support document in the EDOCKET for this final rule.

In the hydrolysis of lactic acid, 2-ethylhexyl ester, the corresponding alcohol would be 2-ethylhexanol. The mammalian body would metabolize 2-ethylhexanol to the corresponding aldehyde, which would then be metabolized to the corresponding carboxylic acid. The mammalian body has well-understood pathways for metabolism of carboxylic acids to carbon dioxide and water.

E. Toxicity of 2-Ethylhexanol

Since 2-ethylhexanol (CAS Reg. No. 104–76–7) is the alcohol formed via hydrolysis, toxicity studies performed using 2-ethylhexanol as the test substance can be used to further understand the toxicity of lactic acid, 2-ethylhexyl ester. Three sources of data are available: Data submitted to the Agency under a Toxic Substances Control Act (TSCA) test rule, the conclusions and recommendations of the Organization for Economic Cooperation and Development (OECD), and the International Uniform Chemical Information Database (IUCLID) submitted by industry to the European

Chemicals Bureau. Taken together these three data sources supply more than adequate information to evaluate the toxicity of 2-ethylhexanol.

Under a TSCA test rule, toxicity studies performed using 2-ethylhexanol were submitted to the Agency's Office of Pollution Prevention and Toxics (OPPT). Reviews of two carcinogenicity studies (mouse and rat) and a dermal developmental toxicity study are posted on the Agency's website (see *http://www.epa.gov/opptintr/chemtest/ethylhex.htm*). The conclusions of the Agency's reviewers were that 2-ethylhexanol is not carcinogenic in the mouse under the conditions of the study, and that there is no evidence of carcinogenicity in the rat at any dose level tested. In the developmental toxicity study there was no evidence of developmental toxicity at any dose level. The dermal developmental NOAEL is therefore equal to or greater than the highest dose tested (HDT), 3.0 milliliter (mL)/kg/day or 2,520 milligram/kilogram/day (mg/kg/day). Maternal effects (reduced weight gain) were noted at the 3.0 mL/kg/day dose level. Exfoliation occurred at the application site at the 1.0 mL/kg/day dose level. The maternal NOAEL is 0.3 mL/kg/day or 252 mg/kg/day.

The agreed upon conclusions and recommendations of the OECD Screening Information Dataset Initial Assessment Profile (SIAP) are available via the internet (see *http://cs3-hq.oecd.org/scripts/hpv/Home.asp*). The SIAP contains summarized results of OECD's review of several 90–day toxicity studies, two carcinogenicity studies, and several developmental toxicity studies. The IUCLID for 2-ethylhexanol was obtained from the European Chemicals Bureau website (see *http://ecb.jrc.it.esis/*). The IUCLID dataset is a compilation of data submitted by the manufacturers of 2-ethylhexanol and is posted as received. By combining these two sources, the Agency was able to obtain more details on certain of the toxicity studies than available in the SIAP.

Results of three 90–day oral toxicity studies are available:

- In a rat feed study, the NOAEL is 57 mg/kg/day and the LOAEL is 282 mg/kg/day based on swelling of the liver and kidney.
- In a rat gavage study the NOAEL is 125 mg/kg/day and the LOAEL is 250 mg/kg/day based on clinical effects: Cyanide insensitive palmitoyl CoA-oxidation in the liver.
- In a mouse gavage study the NOAEL is 125 (male) and 250 (female) mg/kg/day. The LOAEL is 250(M) and 500(F) based on stomach effects.

These results are consistent (the 57 mg/kg/day is an artifact of dose spacing) and indicate that the target organs were the liver, stomach, and kidney.

2-Ethylhexanol was negative in numerous mutagenicity studies. Both the SIAP and the IUCLID indicated that 2-ethylhexanol is not carcinogenic in the rat or mouse.

Results of developmental toxicity studies via the oral and inhalation routes of exposure performed using 2-ethylhexanol were reported in the SIAP and IUCLID.

- For the rat oral (gavage) study the maternal NOAEL is 130 mg/kg/day and the maternal LOAEL is 650 mg/kg/day. The developmental NOAEL is 130 mg/kg/day, and the developmental LOAEL is 650 mg/kg/day based on slightly reduced mean fetal body weights and increased frequency of fetuses with skeletal variations and retardations.
- In a mouse oral (gavage) developmental toxicity study both the maternal and the developmental NOAEL are equal to or greater than 191 mg/kg/day, the HDT.
- In a single dose rat developmental inhalation toxicity study, maternal feed consumption was reduced, but no fetal malformations were noted. The maternal NOAEL would be less than or equal to 0.850 mg/m^3. The developmental LOAEL would be equal to or greater than 0.850 mg/m^3.

Metabolism studies performed using 2-ethylhexanol indicate that after oral administration, 2-ethylhexanol is rapidly excreted in respiratory carbon dioxide, feces, and urine. Elimination is essentially complete by 28 hours after administration. Only 3% of the administered 2-ethylhexanol is excreted unchanged.

The SIAP conclusions called for additional testing with the metabolite of 2-ethylhexanol, which is 2-ethylhexanoic acid. The rationale for this conclusion was based on the results of several oral studies conducted at time-frames of less than two weeks duration. The IUCLID indicated that these studies were conducted at high dose levels ranging from over 300 to 1,500 mg/kg/day. Alterations in testicular weights were consistently noted at 1,000 and 1,500 mg/kg/day. Alterations in testicular weights were not consistent at dose levels in the 300's mg/kg/day. However, the testicular effects were not noted in the 90–day oral toxicity studies even at dose levels up to 500 mg/kg/day.

F. Conclusions

Acute toxicity studies indicate that lactic acid, 2-ethylhexyl ester is of low to moderate acute oral toxicity, and is irritating to the eye. The database supplied by the petitioner, most specifically the 28–day study, indicate that lactic acid, 2-ethylhexyl ester is irritating to the lung and respiratory tract. Irritation effects such as these are handled through the use of personal protective equipment as determined by the end-product acute toxicity testing not through the establishment of tolerance exemptions.

Of significant note for dietary exposure, chemical substances such as lactic acid esters hydrolyze in the mammalian body to lactic acid and the corresponding alcohol (2-ethylhexanol). The human body has well-understood pathways for metabolizing such chemicals. Given the relationship of 2-ethylhexanol as a metabolite of the mammalian body's metabolism of lactic acid, 2-ethylhexyl ester, data on 2-ethylhexanol is useful for understanding the toxicity of lactic acid, 2-ethylhexyl ester. Data on 2-ethylhexanol can be used to judge that lactic acid, 2-ethylhexyl ester is not a carcinogen.

The Office of Pesticide Programs has reviewed and evaluated a developmental inhalation toxicity study conducted with lactic acid, 2-ethylhexyl ester. OPPT has reviewed and evaluated a dermal developmental toxicity study conducted with 2-ethylhexanol. The SIAP and IUCLID provided information on another developmental inhalation toxicity study conducted with 2-ethylhexanol. None of these studies are the route of exposure most appropriate for evaluating dietary exposure; however, there are in these studies no indications of any increased susceptibility.

For evaluating dietary exposure the oral developmental and 90–day studies conducted using 2-ethylhexanol provide the most appropriate information for assessing the toxicity of lactic acid, 2-ethylhexyl ester. These studies consistently demonstrate NOAELs greater than 100 mg/kg/day.

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).

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

1. *Food*. The Agency has developed a screening-level model for predicting dietary exposure to inert ingredients. The results of this model are considered to over-estimate exposure to an inert ingredient in a pesticide product. The modeled chronic dietary exposure for the U.S. population for an inert ingredient is 0.12 mg/kg/day. This is well-below the dose levels (discussed above) at which an adverse effect is expected from exposure to lactic acid, 2-ethylhexyl ester.

The Agency must also consider the potential for exposure to lactic acid as a result of application of a pesticide product containing a lactate ester. Lactic acid occurs naturally in meats, fruits, tomato juice, beer, wine, molasses, sour milk, yogurt and cottage cheese. Lactic acid has been added to commercially prepared foods since the 1940-1950s. The FDA has estimated a per capita daily intake for lactic acid of 15 mg. Given the existing and wide-spread presence of lactic acid in the food supply, the amount of lactic acid that could be present as a result of an application of a pesticide product containing lactic acid or a lactate ester is expected to be a very small proportion.

2. *Drinking water exposure*. When released to the environment, lactic acid, 2-ethylhexyl ester will be present predominantly in the dissolved phase surface and ground water. The chemical is soluble in water (0.3 g/liter). Once lactic acid, 2-ethylhexyl is in the water, it is expected that at neutral pH degradation would begin immediately via hydrolysis. Lactic acid, 2-ethylhexyl ester would also degrade rapidly via biodegradation. The estimated half-life of lactic acid, 2-ethylhexyl ester in soil is 17 days. Based on information submitted by the petitioner and estimates from the Agency's PBT profiler (*http://www.pbt.profiler.net*) lactic acid, 2-ethylhexyl ester should completely degrade to water and carbon dioxide in days. Given the rapid biodegradation (i.e. lack of persistance) significant concentrations of lactic acid, 2-ethylhexyl ester are very unlikely in either ground or surface water used as sources of drinking water.

B. Other Non-Occupational Exposure

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.

VI. 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.''

Unlike other pesticide chemicals for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to lactic acid, 2-ethylhexyl ester. The lactate esters are a structurally-related group of chemicals that all hydrolyze to lactic acid, which is not a toxic metabolite. 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

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 database unless EPA concluded that a different margin of safety will be safe for infants and children. Lactic acid, 2-ethylhexyl ester has been tested in an inhalation developmental toxicity study in which there were no indications of increased susceptibility. The hydrolysis product of lactic acid, 2-ethylhexyl ester is 2-ethylhexanol. Developmental toxicity studies conducted using 2-ethylhexanol as the test substance have been performed via the oral, dermal, and inhalation routes of exposure. The results of these studies also do not indicate any increased susceptibility. A safety factor analysis has not been used to assess the risk of lactic acid, 2-ethylhexyl ester. 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, and Infants and Children

Based on the available toxicity data on lactic acid, 2-ethylhexyl ester and on its metabolites lactic acid and 2-ethylhexanol, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of lactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9) and lactic acid, 2-ethylhexyl ester, (2S)- (CAS Reg. No. 186817–80–1). EPA finds that establishing exemptions from the requirement of a tolerance for lactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9) and lactic acid, 2-ethylhexyl ester, (2S)- (CAS Reg. No. 186817–80–1) will be safe for the general population including infants and children.

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, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9) and lactic acid, 2-ethylhexyl ester, (2S)- (CAS Reg. No. 186817–80–1) for endocrine effects may be required.

B. Analytical Method

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 forlactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9) and lactic acid, 2-ethylhexyl ester, (2S)- (CAS Reg. No. 186817–80–1).

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for lactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9) and lactic acid, 2-ethylhexyl ester, (2S)- (CAS Reg. No. 186817–80–1) 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, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9) and lactic acid, 2-ethylhexyl ester, (2S)- (CAS Reg. No. 186817–80–1) are to be classified as List 4B inert ingredients. This classification is due to the Toxicity Category II determination for the acute eye irritation study and the lung irritation effects in the 28–day study. Tolerance exemptions for lactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9) and lactic acid, 2-ethylhexyl ester, (2S)- (CAS Reg. No. 186817–80–1) are established in 40 CFR 180.910 and 180.930 instead of 40 CFR 180.950 as requested by the petitioner PURAC.

X. Conclusions

Accordingly, exemptions from the requirement of a tolerance are established for lactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9) and lactic acid, 2-ethylhexyl ester, (2S)- (CAS Reg. No. 186817–80–1).

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–2003–0230 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 October 31, 2005.

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 issue(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 14th 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. *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–2003–0230, 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*. 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 issue(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 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 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: August 23, 2005.

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 ingredients 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, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9).	.....	Solvent
Lactic acid, 2-ethylhexyl ester, (2S)-(CAS Reg. No. 186817–80–1).	.....	Solvent
* *	*	* *

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

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

* * * * *

Inert Ingredients	Limits	Uses
* *	*	* *
Lactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9).	.....	Solvent
Lactic acid, 2-ethylhexyl ester, (2S)-(CAS Reg. No. 186817–80–1).	.....	Solvent
* *	*	* *

[FR Doc. 05–17360 Filed 8–30–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0326; FRL–7716–1]

S-metolachlor; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues (free and bound) of S-metolachlor in or on certain commodities as set forth in Unit II. of the **SUPPLEMENTARY INFORMATION**. The Interregional Research Project Number 4 (IR–4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), on behalf of the registrant, Syngenta Crop Protection, Swing Road, Greensboro, NC 276419.

DATES: This regulation is effective August 31, 2005. Objections and