

aggregate exposure to combined residues of fenpyroximate.

F. International Tolerances

Codex Maximum Residue Levels (MRLs) have been established for residues of fenpyroximate and z-isomer on apples in Brazil at 0.1 ppm, France 0.2 ppm, Japan 1.0 ppm, Spain (pome fruits) 0.3 ppm, and Switzerland 0.2 ppm. Codex MRLs have been established on grapes in France at 0.2 ppm, Japan 2.0 ppm, Spain 0.3 ppm, and Switzerland 0.2 ppm.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0230; FRL-7316-1]

2-Ethylhexyl-L-Lactate; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP-2003-0230, must be received on or before August 11, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

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 111)
- Animal production (NAICS 112)

- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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 Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2003-0230. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing 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.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets.

Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are

submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2003-0230. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID number OPP-2003-0230. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and

made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2003-0230.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP-2003-0230. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 30, 2003.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the

pesticide chemical residues or an explanation of why no such method is needed.

I. PURAC America, Inc.

PP OF6179

EPA has received a pesticide petition (PP OF6179) from PURAC America, Inc., 111 Barclay Boulevard, Lincolnshire Corporate Center, Lincolnshire, IL 60069 proposing, pursuant to section 408(d) of FFDCFA, 21 U.S.C. 346a(d), to amend 40 CFR 180.950 to establish an exemption from the requirement of a tolerance for 2-ethylhexyl-L-lactate, when used in accordance with good agricultural or manufacturing practice. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCFA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Toxicological Profile

1. *Acute toxicity.* The oral LD₅₀ of 2-ethylhexyl-L-lactate in rats is greater than 2,000 mg/kg (per Organization for Economic Cooperation and Development (OECD) Guideline No. 401). In the acute oral study, 5 rats per sex, per group were used. The test substance was diluted with water (20% (w/v) and given by gavage at a dose of 10 milligrams/kilogram (mg/kg). Clinical observations, mortality, body weights and gross pathological changes were recorded during a 14-day observation period. Piloerection was seen for up to 4 hours after treatment, but no gross necropsy changes were noted.

2. *Genotoxicity.* Ames testing of a similar lactate, ethyl-L-lactate did not show any activity.

3. *Reproductive and developmental toxicity.* The embryotoxicity and teratogenicity of aerosolized 2-ethylhexyl lactate at 200 and 600 mg/m³ was studied. Only minor developmental effects, most attributable to the stress conditions, and no teratogenic effects were observed.

4. *Subchronic toxicity.* Subacute inhalation studies have been conducted at concentrations up to 600 mg/m³. For aerosol exposure, 2-ethylhexyl-L-lactate was noted to cause minimal damage, the vapor being slightly less toxic than the aerosol. Lactates do not appear to cause systemic toxicity, except at very high concentration (1,800 mg/m³ or higher). These systemic effects may be

secondary to severe irritation seen at high doses.

5. *Animal metabolism.* The *in vitro* hydrolysis of lactate esters (methyl, ethyl, butyl, pentyl, isoamyl, isopropyl, isobutyl, 2-ethylhexyl) in rat olfactory epithelium homogenate has been evaluated. In general, of the eight lactates evaluated, the rat nasal epithelium showed increased capacity to hydrolyze the lactates and increased affinity with increasing molecular weight (increase in alcohol chain length). Based on the similarity of effects and kinetic parameters, it appears that lactic acid is most likely the cause of the lactate toxicity. The *in vitro* hydrolysis of 2-ethylhexyl lactate and di-(2-ethylhexyl)-phthalate by homogenates of rat liver, small intestinal mucosa, blood, skin and caecum content was investigated. The study concluded that 2-ethylhexyl-lactate will be effectively hydrolysed before, during or rapidly after absorption. Results showed the most rapid hydrolysis was in the intestinal mucosa, followed in decreasing order by the liver, caecum, blood, and skin.

6. *Metabolite toxicology.* 2-Ethylhexyl-L-lactate is rapidly hydrolyzed in the body and environment to lactic acid and 2-ethylhexanol (both are listed as exempt from requirements for a tolerance under 40 CFR 180.1001). Lactic acid is a metabolic break down product of all lactates. It is a normal metabolite in humans and is found in or added to foods (21 CFR 172.515). Endogenous production of L(+) lactate in a resting human is 100–124 grams per day. Lactic acid oral LD₅₀ in rats is 3,730 mg/kg. It is not active in mutagenic tests. It will produce skin and eye irritation at high concentrations. The 2-ethylhexanol has an exemption from tolerance under 40 CFR 180.1001 with no limit on use as a cosolvent, defoamer or solvent for all pesticides used before crop emerges from soil and in herbicides before or after crop emergence.

B. Aggregate Exposure

Non-dietary exposure. 2-Ethylhexyl-L-lactate will be used at an application rate of between 0.4 and 1.7 lb/acre as part of the emulsion concentrate or as a solvent for herbicides, fungicides, insecticides, and, other pesticide formulations. The low vapor pressure would tend to keep airborne exposure low.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0227; FRL-7315-8]

Lactic Acid, n-Butyl Ester and Lactic Acid, Ethyl Ester; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP-2003-0227, must be received on or before August 11, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

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:

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- Pesticide manufacturing (NAICS code 32532)

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