

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 FFDCA, 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 FFDCA; 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:

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