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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: October 10, 2003.

Debra Edwards,

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 summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position 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.

PURAC America, Inc.

PP OF6180

EPA has received a pesticide petition (OF6180) from PURAC America, Inc., 111 Barclay Blvd., Lincolnshire Corporate Center, Lincolnshire, IL 60069 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance exemption for n-propyl-S-lactate, also known as n-propyl-L-lactate, under 40 CFR 180.950, 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.* No mortality in either male or female rats occurred during the 14-day observation period, setting the oral lethal dose (LD)₅₀ greater than 2,000 milligrams/kilogram (mg/kg) for n-propyl lactate. In the acute oral study, five rats per sex per group were used. The test substance was undiluted and given by gastric lavage at a dose of 2 milliliter/kilogram (mL/kg) body weight (bwt). Clinical observations, mortality, body weights, and gross pathological changes were recorded during a 14-day observation period. All animals gained weight. There were no

gross pathological changes at the end of the study.

Lactate esters generally have an inhalation lethal concentration (LC)₅₀ above 5,000 milligrams/meters³ (mg/m³).

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

3. *Reproductive and developmental toxicity.* No evidence of teratogenicity or maternal toxicity was observed in an inhalation study of a related lactate, 2-ethylhexyl-L-lactate or in a dermal study of ethyl-L-lactate.

4. *Subchronic toxicity.* Subacute inhalation studies have been conducted at concentrations up to 600 mg/m³ or higher on four lactate esters (ethyl, n-butyl, isobutyl, and 2-ethylhexyl-L-lactate). Degenerative and regenerative changes in the nasal cavity were noted in all studies. The no observed adverse effect level (NOAEL) in ethyl, n-butyl, and isobutyl-L-lactate vapor studies was 200 mg/m³. 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.

6. *Metabolite toxicology.* n-Propyl-L-lactate is rapidly hydrolyzed in the body and environment to lactic acid and n-propanol (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 n-propanol has an exemption from the requirement of a tolerance under 40 CFR 180.1001 with no limit on use as a solvent for all pesticides applied to growing crops or to raw agricultural commodities after harvest.