and reproductive studies were 6 to 65 times higher than the NOAEL used to establish the PAD. Further, the combined TMRC values for all current and pending dimethomorph tolerances will utilize less than 100% of the PAD for each of these subgroups. Therefore, the registrant believes that the results of the toxicology and metabolism studies support both the safety of dimethomorph to humans based on the intended use as a fungicide on imported grapes and raisins and the granting of the requested tolerances

F. International Tolerances

There are no Codex tolerances established for dimethomorph.

[FR Doc. 00–8959 Filed 4–11–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–929; FRL–6498–8]

Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket control number PF–929, must be received on or before May 12, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–929 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Indira Gairola, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–6379; e-mail address: gairola.indira@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–929. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–929 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: *''opp-docket@epa.gov,''* or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–929. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control 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 pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

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

Dated: April 3, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the view of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summaries announce 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.

1. LignoTech USA, Inc.

6E4705

EPA has received a pesticide petition (6E4705) from LignoTech USA, Inc., 100 Highway 51 South, Rothschild, WI 54474–1198 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for residues of humic acid, sodium salt when used as an inert ingredient in pesticide formulations applied to growing crops, raw agricultural commodities (RAC) after harvest, or to animals. 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. Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, LignoTech USA, Inc. has submitted the following information, data and arguments in support of their petition.

A. Product Identity

1. *Product chemistry*. Humic substances are ubiquitous in the environment, including soils, fresh water and oceans. Humic acid, sodium salt (synonym: sodium humate) has been defined as the portion of soil organic matter that is soluble in base and insoluble in mineral acid or alcohol. A variety of brown materials, not occurring in soil, have also, been designated humic acids. Two examples of the latter are the dark-colored substances from coal and from marine sediment.

Humic acid (CAS No. 68131–04–4) is a hydrophilic, reversible colloid whose molecular weight ranges from 2,000 daltons for the more soluble form to 500,000 daltons for the less soluble form. The average molecular weight for humic acids is in the 20,000–50,000 daltons range. Chemically, humic acids are complex, polymeric polyhydroxy acids formed by the process of degradation of organic matter under the action of soil microorganisms and ground worms.

Most humic acids of commercial use are produced by extraction of naturally occurring lignite and brown coals with alkali. The sodium salt of humic acid is produced by extraction of Leonardite with sodium hydroxide.

2. *Proposed use practice*. Humic acid, sodium salt is proposed for use as an inert ingredient in pesticide formulations that would typically be applied to growing crops. Humic acid, sodium salt has been used safely in commercial agriculture for many years, and is generally applied via tank mixing with fertilizers, and/or pesticides, or as granules. Humates such as humic acid, sodium salt are beneficial to growing plants, and are reported to affect germination speed, nutrient uptake, promote root and plant growth, and increase pesticide effectiveness. Use levels of humic acid, sodium salt are anticipated to be in the range of 5 to 50% by weight of the product formulation, with the typical use level expected to be in the 5 to 10% use range. It is anticipated that humic acid, sodium salt would be added directly to the pesticide active ingredient at the time of manufacture/formulation, or it would be tank-mixed with the pesticide at the time of application.

3. *Magnitude of residues*. It is not expected that, when used as proposed, humic acid, sodium salt would result in residues that would remain in human food items.

B. Toxicological Profile

1. *Acute toxicity*. Humic acid, sodium salt is ubiquitous in the environment, and is derived from soil or soil deposits. Sodium humates and humic acids are generally recognized as having low mammalian, aquatic and avian toxicity. Toxicity testing of LignoTech USA, Inc.'s humic acid, sodium salt product (trade name: Lignosol UVB; code number: D–1109) indicated an acute oral toxicity of LD_{50} > 5,000 milligrams/kilograms (mg/kg) Toxicity Category IV, no primary skin irritation Toxicity Category IV, and mild eye irritation Toxicity Category III. The results of these acute toxicity studies indicate Toxicity Category III or IV, which pose

no significant human health risks. Published literature reports that humic acid is nongenotoxic, nonteratogenic and nonmutagenic to test animals. There are no reports in the literature of humic acid, sodium salt causing disease or injury to man or other animals. No incidents of hypersensitivity have been reported in the published literature by researchers, manufacturers or users.

2. *Genotoxicty*. A study published on the *in vivo* cytogenic effects of natural humic acid determined that ''humic acid has not been demonstrated to be genotoxic either *in vitro* or *in vivo*.''

3. *Endocrine disruption*. To date there is no evidence to suggest that humic acid, sodium salt functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

C. Aggregate Exposure

1. *Dietary exposure*. Dietary exposure from use of humic acid, sodium salt in pesticide formulations is minimal. Even if exposure occurred, the lack of reports of disease in man or animals indicates there is no risk for these exposures.

i. *Food*. Dietary exposure from use of humic acid, sodium salt in pesticide formulations is minimal. Residues of humic acid, sodium salt are not expected on agricultural commodities. Humic substances are ubiquitous in nature and have been used for many years in commercial agriculture without adverse effect.

ii. *Drinking water*. Humic substances are ubiquitous in nature, including soils, fresh water and oceans. Increased drinking water exposure from use of humic acid, sodium salt in pesticide formulations would not be expected. Humic acid, sodium salt has been widely used in commercial agriculture for many years without adverse effect.

2. *Non-dietary exposure*. The potential for non-dietary exposure to the general population, including infants and children, is unlikely as the proposed use sites of pesticide formulations that would contain humic acid, sodium salt are commercial, agricultural and horticultural settings. However, non-dietary exposures would not be expected to pose any quantifiable risk due to a lack of residues of toxicological concern. In addition, the personal protective equipment required for use of most pesticide formulations mitigates the potential for exposure to applicators and handlers of the proposed products, when used in commercial, agricultural and horticultural settings.

D. Cumulative Effects

It is not expected that, when used as proposed, humic acid, sodium salt would result in residues that would remain in human food items. Data on humic acid, sodium salt has shown a lack of toxicity to humans or other animal species, as well as no information in the literature indicating a cumulative effect with any other compound. A cumulative risk assessment is therefore, not necessary.

E. Safety Determination

1. *U.S. population*. Humic substances are ubiquitous in the environment. Based on known acute toxicity studies, humic acid, sodium salt is not toxic to humans. There have been no reports of toxins or secondary metabolites associated with humic acid, sodium salt, and the acute toxicity studies conducted have shown that it is nontoxic and nonirritating to test animals. Published literature reports that humic acid is nongenotoxic, nonteratogenic and nonmutagenic to test animals. Residues of humic acid, sodium salt are not expected on agricultural commodities, and therefore, exposure to the general U.S. population, from the proposed uses, is not anticipated.

2. *Infants and children*. Residues of humic acid, sodium salt, when used in pesticide formulations, are not expected on agricultural commodities. There is a reasonable certainty of no harm for infants and children from exposure to humic acid, sodium salt from the proposed use.

F. International Tolerances

There are no international tolerances or tolerance exemptions for humic acid, sodium salt. No CODEX maximum residue levels have been established for humic acid, sodium salt.

2. PURAC America Inc.

5E4510

EPA has received a pesticide petition (15E4510) from PURAC America Inc., Barclay Boulevard, 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 to establish an exemption from the requirement of a tolerance for ethyl lactate when used as an inert ingredient in pesticide formulations applied to growing crops, RAC's after harvest or animals . 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 LD_{50} of butyl lactate in rats is greater than 2,000 mg/kg (top dose tested-per OECD Guideline No. 401). No mortality or macroscopic effects were noted. The (inhalation) LC_{50} for butyl lactate is 5,140 mg/kg (top aerosol concentration generated). It is known that lactates hydrolyze to lactic acid and the corresponding alcohol. No mortality or macroscopic effects at autopsy were noted. All animals gained weight during the 14–day observation period. The only clinical signs noted were decreased breathing frequency and wet head or fur during exposure and shortly after.

2. *Genotoxicity*. Ames testing of similar lactate (ethyl lactate) did not show any activity. Butyl lactate should give similar results in these tests.

3. *Reproductive and developmental toxicity*. Developmental and mutagen testing has not been conducted on butyl lactate, but ethyl lactate a similar lactate, has been evaluated. Dermal developmental testing of ethyl lactate in rats day 6–15 of gestation did not produce any developmental effects or other signs of toxicity in the dams or fetus other than skin irritation in the dams at the top dose (3.619 grams/kilograms (g/kg)).

4. *Subchronic toxicity*. Subacute inhalation studies have been conducted on two similar lactates (ethyl, isobutyl), but not on butyl lactate. Degenerative changes in the nasal cavity were noted in both studies. For ethyl lactate the effects were noted at 600 mg/m^3 and higher, primarily in the olfactory epithelium. In the case of isobutyl lactate, effects were seen at 400 mg/m^3 and above, but less severe than ethyl lactate at the same concentrations. The affected areas tended to be more respiratory than olfactory epithelium for isobutyl lactate. The no observed adverse effect level (NOAEL) in both studies is 200 mg/m^3. Based on the similarity of effects and kinetic parameters it appears that lactic acid is most likely the cause of the lactate toxicity. Butyl lactate would be expected to give similar results in a subacute inhalation test.

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). The *in vitro* hydrolysis kinetic parameters were similar for ethyl and isobutyl lactate (Kmax 1. 11 0. 7 mM, Vmax 70 and 180 nmol/min/mg respectively).

6. *Metabolite toxicology*. Butyl lactate is readily hydrolyzed to lactic acid and N butyl alcohol (both are exempt from requirements for tolerance 40 CFR 180.1001). Lactic acid is a normal metabolite in humans and is found in or added to foods (21 CFR 172.515). Lactic acid oral LD_{50} 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 sodium salt of lactic acid is used in cosmetics as a skin moisturizer and parental solutions in the pharmaceutical industry. Butyl alcohol is found in certain foods and beverages and is used as an approved flavoring agent (21 CFR 172.515). It is used as a solvent in fingernail products. Butyl alcohol oral LD_{50} in rats ranges from 700–2,100 mg/kg. It is not active in mutagenic tests. It will produce skin and eye irritation at high concentrations. It is not a developmental hazard in animals. Its primary effect in man is intoxication and narcosis.

B. Aggregate Exposure

Non-dietary exposure. Butyl lactate will be used in animal, pre- harvest and post-harvest applications as a solvent, diluent, coalescence agent, surfactant and emulsifier at levels up to 50. It will be applied, at a maximum of 2–3 times per crop. The low vapor pressure would tend to keep airborne exposure low.

3. PURAC America Inc.

5E4515

EPA has received a pesticide petition (15E4515) from PURAC America Inc., 111 Barclay Boulevard, 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 to establish an exemption from the requirement of a tolerance for ethyl lactate when used as an inert ingredient in pesticide formulations applied to growing crops, RACs after harvest or animals. 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Toxicological Profile

1. *Acute toxicity*. The oral LD_{50} of ethyl lactate in rats is greater than 2,000 mg/kg (top dose tested-per OECD Guideline No. 401). No mortality or macroscopic effects were noted. All animals gained weight after 3 days. The inhalation LC_{50} for ethyl lactate is 5,400 mg/m^3 (top aerosol concentration generated). It is known that lactates hydrolyze to lactic acid and the corresponding alcohol. No mortality was noted. Macroscopic effects at autopsy revealed pale lungs with dark spots.

2. *Genotoxicity*. A *Salmonella*/Mammalian-Microsome Plate Assay (Ames) of ethyl lactate in five tester strains with and without metabolic activation did not show mutagenic activity.

3. *Reproductive and developmental toxicity*. Dermal developmental testing of ethyl lactate in groups of 25 pregnant rats was conducted at 0, 0.517, 1.551, or 3.619 g/kg/day for day 6–15 of gestation. No developmental effects or other sign of toxicity in the dams or fetus other than skin irritation in the dams at the top dose was observed. The matemal NOAEL (based on skin irritation) is greater than 1.551 g/kg/day. The developmental NOAEL was greater than 3.619 g/kg.

4. *Subchronic toxicity*. Subacute inhalation studies have been conducted on ethyl lactate. Degenerative changes in the nasal cavity were noted in both studies. Groups of rats (5 male and 5 females) were exposed by inhalation for 6 hours/day, 5 days/week for 4 weeks and then held 28 additional days before sacrifice. Exposure was 0, 150, 600, or 2,500 mg/m^3 of ethyl lactate in the first study and 0, 25, 75, or 200 milligram/milliliter (mg/mL) in the second study. For ethyl lactate the effects were noted at 600 mg/m^3 and higher, primarily damage in the olfactory epithelium. The NOAEL was 200 mg/m^3.

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. An *in vivo* absorption and hydrolysis study in rats with ethyl lactate demonstrated 80% hydrolysis in rat plasma in 60 minutes at room temperature. Ethyl lactate was detected in the portal blood indicate partial absorption by the gut.

6. *Metabolite toxicology*. Ethyl lactate is readily hydrolyzed to lactic acid and ethyl alcohol (both which are listed as inert ingredients exempt from requirements for tolerance - 40 CFR 180.1001). These breakdown products are also listed as synthetic flavoring substances (21 CFR 172.515). 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). Lactic acid oral LD_{50} 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 sodium salt of lactic acid is used in cosmetics as a skin moisturizer and parental solutions in the pharmaceutical industry. Ethyl alcohol occurs naturally as a product of fermentation of carbohydrates. It is the primary alcohol in beer, wine and liquor and is found in certain foods and other beverages and is used as a favoring agent (21 CFR 172.515). It is used as a chemical intermediate and as a solvent in perfumers, cosmetics, adhesives, inks and preservatives. Ethyl alcohol oral LD_{50} in rats is 13,700 mg/kg. It is not active in mutagenic tests. It will produce mild skin irritation at high concentrations (dryness). It is a developmental hazard causing fetal alcohol syndrome in humans. Its primary acute effect in man is intoxication and narcosis. It can cause chronic liver damage.

B. Aggregate Exposure

Non-dietary exposure. Ethyl lactate will be used in animal, pre-harvest and post-harvest applications as a solvent, diluent, coalescence agent, surfactant and emulsifier at levels up to 50%. It will be applied, at a maximum of 2–3 times per crop. The low vapor pressure would tend to keep airborne exposure low.

[FR Doc. 00–9099 Filed 4–11–00; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6577–4]

Clean Water Act Section 303(d): Availability of Total Maximum Daily Loads (TMDLs) and Determinations That TMDLs Are Not Needed

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.