

and the level of cucurbitacin would be 0.88951 gram per pound. A gram of "straightneck" squash contains 0.00139 gram cucurbitacin per gram of squash. Thus, consumption of a pound of treated corn would add less cucurbitacin to the diet than a gram serving of squash. To have consumed the sufficient amount of the most toxic cucurbitacin, LD<sub>50</sub>=5 mg/kg body weight, a 50 kg human would have to eat over 400 pounds of the treated corn.

i. *Drinking water.* Most cucurbitacins are insoluble in water and transfer of these cucurbitacins to ground water is unlikely. The glycosylated forms which are more water soluble are less toxic to humans. No uses are registered for application to bodies of water and none are anticipated.

2. *Non-dietary exposure.* Registered uses are limited to agricultural crops.

#### D. Cumulative Effects

Exposure through other pesticides and substances with the common mode of toxicity as this compound. No information indicates that toxic effects would be cumulative with any other compounds. Further, no other pesticides or substances are registered with this mode of action.

#### E. Safety Determination

1. *U.S. population.* The fact that cucurbitacins are ubiquitous in many plants regularly consumed by the general public, the maximum projected additional exposure to these compounds is significantly less than that from a normal serving of these plants, and the previously granted temporary exemption for buffalo gourd root powder as a specific source of cucurbitacins (55 FR 49700, November 30, 1990), and a permanent exemption from the requirement of a tolerance (57 FR 40128, September 2, 1992), later amended to include zucchini juice (63 FR 43085, August 12, 1998), (FRL-6017-5) support an amendment to the existing tolerance exemption.

2. *Infants and children.* The use sites of the cucurbitacins are all agricultural for the control of Diabrotina beetles. Therefore, non-dietary exposure to infants and children is not expected. The limited application rate and correspondingly low maximum residue requiring that a 1 kg child would have to consume almost 10 pounds of corn in a single meal to obtain a LD<sub>50</sub> dose and that the aggregate exposure and cumulative exposure pose little, if any, risk all; all provide reasonable certainty that no harm will result to infants and children from exposure to residue of the cucurbitacins.

#### F. International Tolerances

There are no international tolerances or tolerance exemptions for cucurbitacins. However, prior EPA findings of significant relevance to this petition include a temporary exemption from the requirements of a tolerance for residues of the buffalo gourd (*Cucurbita foetidissima*) root powder as source of cucurbitacins in or on the raw agricultural commodity field corn for the control of adult corn rootworms (55 FR 49700, November 30, 1990).

In addition, the Agency established a permanent exemption from the requirement of a tolerance for residues of buffalo gourd root powder when used as an inert ingredient (gustatory stimulant) in pesticide formulations applied to growing crops only (57 FR 40128, September 2, 1992).

In 1998 EPA amended the permanent exemption from the requirement of a tolerance to add the residues of zucchini juice (*Cucurbita pepo*) to the list of "inert ingredients" (63 FR 43085, August 12, 1998).

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### ENVIRONMENTAL PROTECTION AGENCY

[PF-881; FRL-6090-8]

#### Ecolab Inc.; 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 a pesticide petition 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-881, must be received on or before October 1, 1999.

**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" section. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-881 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Amelia M. Acierto, Registration Support Branch, Registration Division

(7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308-8375; and e-mail address: acierto.amelia@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	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 in the "FOR FURTHER INFORMATION CONTACT" section.

###### 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-881. 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 (CM #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-881 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, 401 M St., SW., 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, CM #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](mailto: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 5.1/6.1 or ASCII file format. All comments in electronic form must be identified by docket control number PF-881. 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 in the "FOR FURTHER INFORMATION CONTACT" section.

### 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 a pesticide petition 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 Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains 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 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: August 23, 1999.

### James Jones,

Director, Registration Division, Office of Pesticide Programs.

## Summaries of Petitions

### 1. PP 9E5081

#### Summary of Petitions

EPA has received a pesticide petition (PP 9E5081) from Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102 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 hydroxyethylidene-1,1-diphosphonic acid (HEDP) in or on the raw agricultural commodities, in processed commodities, and in or on meat and meat byproducts of cattle, sheep, hogs, goats, horses, and poultry, milk, and dairy products, eggs, seafood and shellfish, and fruit and fruits and vegetables when such residues result from the use of HEDP as a component of a food contact surface sanitizing solution up to 34 parts per million (ppm) for use in food handling establishments. 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. Residue Chemistry

1. *Analytical method.* Because Ecolab Inc. is petitioning for an exemption from the requirement of a tolerance, an enforcement method for HEDP is not needed.

2. *Magnitude of residues.* The residues which transfer from the sanitized dish or utensil to food are not of toxicological significance.

#### B. Toxicological Profile

1. *Acute toxicity.* This material has been reviewed by the EPA as an inert ingredient in antimicrobial pesticide

formulations used in or on raw agricultural commodities. The summary that follows is from the May 22, 1998 **Federal Register** Final Rule ((63 FR 28253), (FRL-5790-1)). The rat acute oral lethal dose (LD)<sub>50</sub> is 2,400 milligrams/kilograms (mg/kg).

2. *Genotoxicity.* HEDP was reported to be non-mutagenic in a Salmonella/Mammalian microsome test or in a L5178Y TK mouse lymphoma cell point mutation assay, with and without mammalian microsomal activation.

3. *Reproductive and developmental toxicity.* In a combined 2-generation reproduction/developmental toxicity study, rats (22 rats/sex/dose) were administered HEDP at doses of 0, 0.1, and 0.5% in the diet. The no observable adverse effect level (NOAEL) for developmental and reproductive findings was 50 mg/kg/day (0.1% in the diet) and the lowest observable adverse effect level (LOAEL) was 250 mg/kg/day (0.5% in the diet) based on reduced litter size in the first litter (F1a) and an increase in stillborn pups in the second litter (F1b). These effects occurred in the absence of maternal toxicity and were seen in both reproductive litters of the first generation. In a developmental toxicity study, rabbits were administered HEDP at doses of 0, 25, 50 and 100 mg/kg/day, either incorporated into feed or by gavage with water. The NOAEL for both systemic and developmental effects was 50 mg/kg/day and the LOAEL was 100 mg/kg/day by gavage based on decreased maternal weight gain/ food consumption and decreased fetal body weights.

4. *Subchronic toxicity.* —i. *Dogs.* In a subchronic feeding study in beagle dogs (4 dogs/sex/dose), HEDP was administered via the diet at 0, 1,881, 3,881, or 10,881 ppm for 90 days. The NOAEL was 10,881 ppm (250 mg/kg/day).

ii. *Rats.* In a subchronic feeding study in rats, Sprague-Dawley strain rats were fed HEDP at dietary concentrations of 0, 3,881, 10,881 and 30,881 ppm for 90 days. The NOAEL was 10,881 ppm (approximately 500 mg/kg/day) and the LOAEL was 30,881 ppm (approximately 1,500 mg/kg/day) based on decreased body weight decreased food consumption, slight anemia, and decreased heart, liver, and kidney weights.

5. *Chronic toxicity.* Chronic exposure to HEDP is not expected to demonstrate any additional toxicity beyond what was noted in subchronic toxicity tests. Since this compound is not considered to be genotoxic and is not structurally similar to known carcinogens, it is not likely to be carcinogenic.

6. *Endocrine disruption.* To the best of our knowledge, nothing in the literature suggests HEDP is an endocrine disruptor. HEDP does not act like hormones or inhibit hormonal activity.

#### C. Aggregate Exposure

1. *Dietary exposure.* Acute: There are no acute toxicological concerns for HEDP, therefore, an acute dietary risk assessment is not required.

i. *Food.* Chronic: Indirect using the worst case scenario of HEDP in a sanitizing solution at the maximum proposed level of 34 ppm, in a restaurant where all food consumed by an individual in a single day has contacted sanitized dishes and food preparation surfaces, and there is 100% transference of the sanitizer from the surface to the food, the exposure would be 0.002 mg/kg/day for a 70 kg person (adult) and 0.0025 mg/kg/day for a 28 kg person (child). Chronic: Direct Antimicrobial fruit and vegetable wash exposure calculated to be 0.88104 mg/kg/day for a 70 kg person and 0.8811 mg/kg/day for a 28 kg person (see **Federal Register** May 22, 1998 (63 FR 28253)).

ii. *Drinking water.* Acute: Since there are no acute toxicological concerns for HEDP, an acute drinking water risk assessment should not be required. Chronic: Not expected to exceed 0.8817 mg/kg/day for adults and 0.0025 mg/kg/day for children (see **Federal Register** May 22, 1998 (63 FR 28253)).

2. *Non-dietary exposure.* Acute: Since there are no acute toxicological concerns for HEDP, an acute non-dietary risk assessment should not be required. Chronic: Not expected to exceed 0.0049 mg/kg/day for adults and 0.0204 mg/kg/day for children (see **Federal Register** May 22, 1998 (63 FR 28253)).

#### D. Cumulative Effects

*Chronic drinking water:* Not to exceed 0.8817 mg/kg/day adults and 0.0025 mg/kg/day children (see **Federal Register** May 22, 1998 (63 FR 28253)).

Chronic dietary: Previous clearance as a component of an antimicrobial formulation for use on fruit and vegetables resulted in an overestimation of 0.88104 mg/kg/day for adults and 0.8811 mg/kg/day for children (see **Federal Register** May 22, 1998 (63 FR 28253)). The proposed use as a component of a food contact surface sanitizer is not to exceed 0.002 mg/kg/day for adults and 0.0025 mg/kg/day for children. Non-dietary exposure: Not to exceed 0.0049 mg/kg/day for adults and 0.0204 mg/kg/day children.

#### E. Safety Determination

1. *U.S. population.* Using the extremely conservative exposure assumptions described above, the aggregate exposure to HEDP from all uses, including the proposed use will not exceed 0.0076 mg/kg/day for adults and 0.0255 mg/kg/day for children.

2. *Infants and children.* Nothing in the available literature indicates that infants or children are more sensitive to the effects of this compound. Exposure of this inert ingredient (from the use proposed in this petition) should not pose a health risk to the U.S. population subgroup of infants and children.

#### F. International Tolerances

No Codex maximum residue levels have been established for HEDP.

## 2. PP 9E5086

#### Summary of Petition

EPA has received a pesticide petition (PP 9E5086) from Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102 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 acetic acid in or on the raw agricultural commodities, in processed commodities, and in or on meat and meat byproducts of cattle, sheep, hogs, goats, horses, and poultry, milk, and dairy products, eggs, seafood and shellfish, and fruit and fruits and vegetables when such residues result from the use of acetic acid as a component of a food contact surface sanitizing solution for use in food handling establishments. The request is for an unlimited clearance. 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. Residue Chemistry

1. *Analytical method.* Because Ecolab Inc. is petitioning for an exemption from the requirement of a tolerance, an enforcement method for acetic acid is not needed.

2. *Magnitude of residues.* The residues which transfer from the sanitized dish or utensil to food are not of toxicological significance.

#### B. Toxicological Profile

1. *Acute toxicity.* Acetic acid is a direct food additive. It is considered

generally recognized as safe by the Food and Drug Administration and is a normal constituent in the human diet. Acetic acid is allowed under 40 CFR 180.1001(c) as an inert ingredient in pesticide formulation applied to growing crops or to raw agricultural commodities after harvest without limit in the formula. Acute oral lethal dose (LD<sub>50</sub>) (rat): 3310 3530 milligrams/kilograms (mg/kg); Acute oral LD<sub>50</sub> (mouse): 4960 mg/kg; Inhalation LC<sub>50</sub> (mouse): 5620 parts per million (ppm)/1 hour(s); Dermal LD<sub>50</sub> (rabbit): 1060 mg/kg.

2. *Genotoxicity.* Nothing in the available literature indicates that acetic acid is a genotoxic or mutagenic compound. It is generally recognized as safe and is a normal constituent in the human diet.

3. *Reproductive and developmental toxicity.* Nothing in the available literature indicates that acetic acid is a developmental or reproductive toxin. It is generally recognized as safe and is a normal constituent in the human diet.

4. *Subchronic toxicity.* Nothing in the available literature indicates long term exposure to acetic acid produces any adverse toxicological effects unless it is ingested at a concentration where it produces corrosive or other effects on the gastric mucosa. There are no studies indicating that prolonged exposure to acetic acid produces cumulative toxicity since acetic acid is a normal constituent of cellular metabolism. Acetic acid is a catabolic breakdown product of fatty endogenous acid metabolism and is also used in the synthesis of lipids. Estimated daily intakes of acetic acid/acetate ion are in the range of 2 grams per day for an adult. As a normal constituent of the human diet, there are no toxicological concerns with acetic acid.

5. *Chronic toxicity.* Chronic exposure would not produce any additional effect beyond what is noted in subchronic exposure, therefore, no additional concerns are warranted. Nothing in the literature indicates that acetic acid may be carcinogenic.

6. *Animal metabolism.* Acetic acid and its derivatives are used in the metabolism fatty acids. It is a normal constituent of mammalian metabolism, therefore, a discussion of acetic acid metabolites is not relevant.

7. *Metabolite toxicology.* "Metabolites" of acetic acid are used in several processes of cellular metabolism. These metabolites are normal constituents of the cell, therefore a discussion of metabolite toxicity of acetic acid is not relevant.

8. *Endocrine disruption.* Acetic acid does not act like hormones or inhibit

hormonal activity. It is not structurally related to any known endocrine disruptor. Nothing in the literature suggests that it is an endocrine disruptor or possesses intrinsic hormonal activity.

#### C. Aggregate Exposure

1. *Dietary exposure.* Acute: There are no acute toxicological concerns for acetic acid, an acute dietary risk assessment is not required. Chronic Indirect: Using a worst-case scenario, the additional exposure from food contact surface sanitizers would be 0.03 mg/kg/day for a 70 kg person (adult) and 0.04 mg/kg/day for a 28 kg person (child).

i. *Food.* Chronic Direct: A typical adult ingests approximately 2 grams (2000 mg) of acetic acid/acetate per day via the diet. The incremental increase in exposure as a result of the use in food contact surface sanitizing solutions is negligible.

ii. *Drinking water.* Acute: Since there are no acute toxicological concerns for acetic acid, an acute drinking water risk assessment should not be required. Chronic: There is no concern about the potential for transfer of acetic acid residues to human drinking water. It is essentially impossible that residues from the proposed use will transfer acetic acid residues to any sources of human drinking water.

2. *Non-dietary exposure.* The potential for significant additional non-occupational exposure under the use proposed to the general population (including children) is unlikely.

#### D. Cumulative Effects

Well over 99% of the exposure to acetic acid will be via the diet. Most of this exposure will be through ingestion of "vinegar" in the diet. Small amounts of acetic acid exposure will be the result of non-food uses. The amount of acetic acid exposure resulting from indirect exposure to sanitizing solutions will be virtually zero. Since acetic acid in the diet poses no toxicological risk, the cumulative toxicity resulting from this additional exposure is negligible.

#### E. Safety Determination

1. *U.S. population.* Since there are not adverse toxicological effects resulting from normal dietary concentrations of acetic acid, there is no need to determine aggregate risks, or to conduct a safety determination. Acetic acid is generally recognized as safe and the incremental exposure due to its use as an inert in a food contact surface sanitizer is negligible.

2. *Infants and children.* As in adults, infants and children use acetic acid as a basic constituent of cellular

metabolism. Children are at no greater "risk" from exposure to acetic acid. Therefore, as with adults, a safety determination is not appropriate.

#### F. International Tolerances

No Codex maximum residue levels have been established for acetic acid.

### 3. PP 9E6014

#### Summary of Petition

EPA has received a pesticide petition (PP 9E6014) from Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55120 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 phosphoric acid in or on raw agricultural commodities, in processed commodities, and in or on meat and meat byproducts of cattle, sheep, hogs, goats, horses, and poultry, milk, and dairy products, eggs, seafood and shellfish, and fruit and fruits and vegetables when such residues result from the use of phosphoric acid as a component of a food contact surface sanitizing solution for use in food handling establishments. The request is for an unlimited clearance. 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. Residue Chemistry

1. *Analytical method.* Because Ecolab Inc. is petitioning for an exemption from the requirement of a tolerance, an enforcement method for phosphoric acid is not needed.

2. *Magnitude of residues.* The residues which transfer from the sanitized dish or utensil to food are not of toxicological significance.

#### B. Toxicological Profile

1. *Acute toxicity.* Phosphoric acid is a direct food additive. It is considered generally recognized as safe by the Food and Drug Administration and is a normal constituent in the human diet. Phosphoric acid is allowed under 40 CFR 180.1001(c) as an inert ingredient in pesticide formulation applied to growing crops or to raw agricultural commodities after harvest without limit in the formula. From the Reregistration Eligibility Decision (RED) document for Mineral Acids: Acute oral lethal dose

(LD<sub>50</sub>): 1530 milligrams/kilograms (mg/kg); Dermal LD<sub>50</sub>: 2740 mg/kg.

2. *Genotoxicity.* Nothing in the available literature indicates that phosphoric acid or phosphate ion are considered to be genotoxic or mutagenic.

3. *Reproductive and developmental toxicity.* Nothing in the available literature indicates that phosphoric acid or phosphate ion are developmental or reproductive toxins. They are generally recognized as safe and are normal constituents in the human diet.

4. *Subchronic toxicity.* Nothing in the available literature indicates long-term exposure of phosphoric acid/phosphate ion produces any adverse toxicological effects unless it is ingested at a concentration where it produces corrosive or other effects on the gastric mucosa. There are no studies that indicate that prolonged exposure to low concentrations of phosphoric acid/phosphate ion produce cumulative toxicity since they are normal constituents of cells.

5. *Chronic toxicity.* Chronic exposure would not produce any additional effect over what is noted in subchronic exposure, therefore, no additional concerns are warranted. Nothing in the literature indicates that phosphoric acid may be carcinogenic.

6. *Animal metabolism.* Phosphoric acid is a normal constituent of cells. It is used for many purposes including buffering of the blood, high energy bonds, DNA synthesis, etc. A discussion of the metabolism is not relevant.

7. *Metabolite toxicology.* Phosphoric acid and phosphate are not metabolized by the body, but rather serve as major components in cellular structure and processes. A discussion of metabolite toxicity is not relevant.

8. *Endocrine disruption.* A review of information from the Agency for Toxic Substances and Disease Registry indicates that potential endocrine effects from exposure to phosphoric acid or phosphate ion have not been studied. To the best of our knowledge, nothing in the available literature suggests that phosphoric acid acts as an endocrine disrupter or that it possesses intrinsic hormonal activity.

#### C. Aggregate Exposure

1. *Dietary exposure.* Acute: There are no acute toxicological concerns for phosphoric acid, therefore, an acute dietary risk assessment is not required. Chronic Indirect: Using a worst-case scenario, the exposure would be 0.0065 mg/kg/day for a 70 kg person (adult) and 0.008 mg/kg/day for a 28 kg person (child).

i. *Food.* Chronic Direct: A typical adult ingests approximately one to two grams of phosphoric acid/phosphate per day as phosphorus via the diet. Following ingestion, it is absorbed by the gastrointestinal tract. In the plasma and in intra and extracellular fluid, the pH is such that the phosphoric acid exists in its ionized form, phosphate. The approximate concentration of phosphate in the plasma is 4 mg/100 milliliters (mls). Phosphate serves many biological purposes including buffering the blood, serving as a constituent of cell membranes, providing high energy phosphate bonds for cellular energy demands, maintaining DNA structure and many other functions. Phosphate is also a major constituent of the skeletal system. It is excreted in the urine and needs to be replenished on an ongoing basis. The normal human diet contains significant quantities of phosphate. Phosphate is also derived from phosphoric acid as a consequence of its direct addition to food, as approved under 21 CFR 582.1073. When used as a food contact surface sanitizer, the residue that would be introduced into food will be insignificant compared to the normal dietary intake of phosphoric acid/phosphate ion. Based on this, there are no toxicological concerns resulting from exposures to residues of phosphoric acid resulting from the use of sanitizing solutions.

ii. *Drinking water.* Acute: Since there are no acute toxicological concerns for phosphoric acid, an acute drinking water risk assessment should not be required. Chronic: There are no toxicological concerns about the exposure of low concentrations of phosphate ion in the drinking water. Although it is possible that trace amounts of phosphates used as a sanitizer may ultimately get into drinking water, no adverse health effects would result. The amount of "naturally occurring phosphate" in water will greatly exceed the amount derived from sanitizing solutions.

2. *Non-dietary exposure.* The exposure phosphoric acid/phosphates in non-occupational settings is minimal. Phosphates may be present in some products including general purpose cleaners, soaps, etc. however, dermal absorption would be insignificant. Since phosphate is a relatively significant constituent of the diet, non-occupational exposure will be small by comparison.

#### D. Cumulative Effects

Over 99% of the exposure to phosphoric acid/phosphates is expected to be via the diet. Small amounts of phosphoric acid/phosphate exposure

will be the result of non-food uses. The amount of phosphoric acid/phosphate exposure resulting from indirect exposure to sanitizing solutions will be virtually zero. Since phosphoric acid/phosphate in the diet poses no toxicological risk, the cumulative toxicity resulting from this additional exposure is negligible.

#### E. Safety Determination

1. *U.S. population.* Since there are not adverse toxicological effects resulting from normal dietary concentrations of phosphoric acid/phosphate ion, there is no need to determine aggregate risks, or to conduct a safety determination. Phosphoric acid is generally recognized as safe and the incremental exposure due to its use as an inert in a food contact surface sanitizer is negligible.

2. *Infants and children.* As in adults, infants and children use phosphoric acid as a basic constituent of cellular metabolism, energy production and cell structure. Children are at no greater "risk" from exposure to phosphoric acid. Therefore, as with adults, a safety determination is not appropriate.

#### F. International Tolerances

No Codex maximum residue levels have been established for phosphoric acid.

[FR Doc. 99-22747 Filed 8-31-99; 8:45 am]  
BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[PF-885; FRL-6096-8]

### Notice of Filing Pesticide Petitions 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-885], must be received on or before October 1, 1999.

**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** section. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-885 in the subject line on the first page of your response.