2. EDPOM contains as an integral part of its composition the atomic elements carbon, nitrogen, hydrogen and oxygen.

3. EDPOM does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).

4. EDPOM is not designed, nor is it reasonably anticipated to substantially degrade, decompose or depolymerize prior to, during, or after use.

5. EDPOM is not manufactured or imported from monomers and/or reactants that are not included on the Toxic Substances Control Act (TSCA) substance inventory or manufactured under an applicable TSCA section 5 exemption.

6. EDPOM is not a water absorbing polymer.

7. EDPOM has a minimum-average molecular weight of 25,000. Substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

8. EDPOM has a minimum-average molecular weight of 25,000. EDPOM meets the requirements for molecular weight distribution of oligomer contents of less than 25% with molecular weights below 1,000 and less than 10% with molecular weights below 500.

Ecolab Inc. believes that sufficient information has been submitted to assess the hazards of EDPOM. No toxicology data are being submitted as the Agency does not generally require these data to rule on exemptions from the requirement of a tolerance for an inert ingredient. Because EDPOM conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Ecolab Inc. believes there are no concerns for risks associated with toxicity.

C. Aggregate Exposure

1. Dietary exposure. Acute: Due to the low toxicity, there are no toxicological concerns for EDPOM. An acute dietary risk assessment is not appropriate.

Chronic: Chronic exposure would not produce any effect since it is not absorbed. Therefore, no concerns are warranted.

2. Food. When EDPOM is used as a component of a food contact surface sanitizer, the residue that would be introduced into food will be insignificant. EDPOM is not absorbed from the GI tract. Based on this, there are no toxicological concerns resulting from exposures to residues of EDPOM resulting from the use of sanitizing solutions.

ii. Drinking water. Acute: EDPOM is not expected to be introduced into drinking water, therefore an acute drinking water risk assessment is not required. Chronic: EDPOM is not expected to be introduced into drinking water; therefore, a chronic drinking water risk assessment is not required.

2. Non-dietary exposure. EDPOM is not absorbed from the GI tract or through the skin. The potential for significant additional non-occupational exposure to the general population (including children) is unlikely.

D. Cumulative Effects

The amount of EDPOM exposure resulting from indirect exposure to sanitizing solutions will be miniscule. EDPOM is a high molecular weight alkoxylated amine polymer that is not absorbed by the body. EDPOM in the diet poses no cumulative toxicological risk. Ecolab Inc. believes that sufficient information has been submitted to assess the hazards of EDPOM. Because EDPOM conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Ecolab Inc. believes there are no concerns for risks associated with cumulative effects.

E. Safety Determination

1. U.S. population. There are no adverse toxicological effects resulting from ingestion of trace amounts of EDPOM, so there is no need to determine aggregate risks, or to conduct a safety determination. EDPOM exposure due to its use as an inert ingredient in a food contact surface sanitizer is negligible. Ecolab Inc. believes that sufficient information has been submitted to assess the hazards of EDPOM. Because it conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, there are no concerns for risks associated with any potential exposure to adults.

2. Infants and children. Children are at no greater risk from exposure to EDPOM. Therefore, as with adults, a safety determination is not appropriate. Ecolab Inc. believes that sufficient information has been submitted to assess the hazards of EDPOM. Because it conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, there are no concerns for risks associated with any potential exposure to children.

E. International Tolerances

No Codex Maximum Residue Levels have been established for EDPOM.

[FR Doc. 00–8405 Filed 4–6–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–932; FRL–6499–7]

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–932, must be received on or before May 8, 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–932 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Treva C. Alston, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8373; e-mail address: alston.treva@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:

<table>
<thead>
<tr>
<th>Category</th>
<th>NAICS</th>
<th>Examples of potentially affected entities</th>
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<tbody>
<tr>
<td>Industry</td>
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<td>Pesticide manufacturing</td>
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</table>
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–932. 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, 2121 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–932 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, 2121 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–932. 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 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 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.


James Jones,
Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. 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.

1. Ecolab Inc.

**PP 9E6028**

EPA has received a pesticide petition (PP 9E6028) 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 urea in or on raw agricultural commodities, in processed commodities, and in or on meat and meat by products of cattle, sheep, hogs, goats, horses, and poultry, milk, and dairy products, eggs, seafood and shellfish, and fruits and vegetables when such residues result from the use of urea 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 urea 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.** Urea is a direct food additive. Urea in concentrated form is severely irritating to the eyes and slightly irritating to the skin. It is essentially non-toxic for acute oral and dermal effects. From published literature values the acute oral LD₅₀ in rats was determined to be 14,300 milligrams/kilograms (mg/kg). No value is assigned for dermal LD₅₀ since it is essentially non-toxic via the dermal route.
2. **Genotoxicity.** Nothing in the available literature indicates that urea is a genotoxic material. There is no data that would indicate it has carcinogenic properties.
3. **Reproductive and developmental toxicity.** Nothing in the available literature indicates that urea 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 chronic exposure of urea products any adverse toxicological effects unless it is ingested at extremely high doses. Urea has been used as a feed supplement in cattle. Levels of 5% in their diet did not result in adverse effects. At dietary levels approaching 25%, symptoms of ammonia toxicity such as central nervous system (CNS) effects develop. At normal dietary intake levels in the human diet, no adverse effects result. Due to the rapid excretion of urea, prolonged low level exposure does not produce cumulative toxicity. Most of the urea in the body is generated endogenously since urea is the major pathway of nitrogen excretion in man. The typical concentration of urea excreted in the urine is approximately 1,000 mg/deciliter (dl).
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 urea may be carcinogenic.
6. **Animal metabolism.** Urea is a normal constituent of cellular metabolism in man.
7. **Endocrine disruption.** A review of information from the Agency for Toxic Substances and Disease Registry indicates that potential endocrine effects from exposure to urea have not been studied. To the best of our knowledge, nothing in the available literature suggests that urea acts as an endocrine disruptor or that it possesses intrinsic hormonal activity.

**C. Aggregate Exposure**

1. **Dietary exposure— i. Acute.** Due to the low toxicity, there are no toxicological concerns for urea. An acute dietary risk assessment is not appropriated.
   ii. **Chronic.** Chronic exposure would not produce any additional effect beyond what is noted in acute exposure, therefore, no additional concerns are warranted.
   iii. **Food— Chronic direct.** A typical adult ingests significant quantities of urea via the diet. An even larger amount is generated endogenously by the liver as a part of nitrogen excretion. Following ingestion, urea is absorbed by the gastrointestinal tract. The approximate concentration of urea in the plasma is 15 mg/dl. When urea is used as a component of a food contact surface sanitizer, the residue that would be introduced into food will be insignificant compared to the normal dietary intake and endogenous production. Based on this, there are no toxicological concerns resulting from exposures to residues of urea resulting from the use of sanitizing solutions.
2. **Drinking water— i. Acute.** Since there are no acute toxicological concerns for urea, an acute drinking water risk assessment is not required.
   ii. **Chronic.** There are no toxicological concerns about the exposure of low concentrations of urea in the drinking water. Although it is possible that trace amounts of urea resulting from its use as a sanitizer may ultimately get into drinking water, no adverse health effects would result.
3. **Non-dietary exposure.** The potential for significant additional non-occupational exposure to the general population (including children) is unlikely.

**D. Cumulative Effects**

Well over 99% of the exposure to urea is expected to be via natural sources in the diet and through endogenous generation. Potentially small amounts of urea exposure will be the result of non-food uses. The amount of urea exposure resulting from indirect exposure to sanitizing solutions will be miniscule. Since urea 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 no adverse toxicological effects resulting from normal dietary concentrations of urea, there is no need to determine aggregate risks, or to conduct a safety determination. Urea 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 produce urea as a basic process of cellular metabolism. Children are not at greater “risk” from exposure to urea. Therefore, as with adults, a safety determination is not appropriate.

**F. International Tolerances**

No codex maximum residue levels have been established for urea.

2. **Ecolab Inc.**

**PP 9E6029**

EPA has received a pesticide petition (9E6029) from Ecolab Inc., proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the
requirement of a tolerance for nitric 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 fruits and vegetables when such residues result from the use of nitric acid as a component of a food contact surface sanitizing solution for use in food handling establishments at 1,000 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FDCA; 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 nitric 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. Nitric acid (HNO₃) in concentrated form is corrosive to the eyes and corrosive to the skin. In neutral solutions, nitric acid dissociates into nitrate ions (NO₃⁻). Nitrate is a normal constituent of the diet. Nitrate is a chronic toxicant. Residue levels and dietary intake of nitrate account for the vast majority of all nitrate exposure that is a concern, especially in the diet. Nitrate is a common constituent of the human diet. Nitrate is markedly found in green leafy vegetables such as beets (2,400 ppm), celery (2,300 ppm) and turnip greens (6,600 ppm). It is the acute toxicity, not chronic exposure that is a concern, especially in infants (0–3 months). Based on the acute toxicological effects of nitrate, an EPA IRIS oral reference dose (RfD) of 7.0 mg nitrate/kg/day was established. This number assumes that the infant is the most susceptible sub-population and an uncertainty factor of 1, since the results are based on actual human data.

ii. Chronic. Chronic exposure would not produce any additional effect beyond what is noted in acute exposure, therefore, no additional concerns are warranted.

iii. Food. A typical adult ingests significant quantities of nitrate in the diet. A typical adult’s daily intake of nitrate is about 1.3 mg nitrate/kg/day. The dietary intake of nitrate accounts for the vast majority of all nitrate exposure. Using a worst case scenario, exposure to nitrate resulting from the use of nitric acid as a component of a hard surface sanitizer at 1,000 ppm would be 0.057 mg/kg/day for adults. This value is calculated by using standard FDA calculations for exposures to hard surface sanitizers.

2. Drinking water—1. Acute. Nitrate is commonly found in drinking water, most typically in well water. Although there have been several instances of chronic methemoglobinemia reported from people consuming hard surface sanitizers containing high nitrate levels, typically the concentration of nitrate is quite low.
The EPA has set the drinking water equivalent level (DWEL) for nitrate at 10 mg nitrate-nitrogen/L (44 mg nitrate/L).

ii. Chronic. There are no chronic toxicological concerns about the exposure of low concentrations (below 44 mg/L) of nitrate in the drinking water. Although it is possible that trace amounts of nitrate from a sanitizer may ultimately get into drinking water, no adverse health effects would result. The amount of “naturally occurring nitrate” in drinking water (especially well water) will greatly exceed the amount derived from sanitizing solutions. Since only a small fraction of the population drinks well water with elevated concentrations of nitrate, this is not a concern for the general population.

3. 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 nitric acid/nitrate is expected to be via natural sources in the diet and drinking water. Trace amounts of nitric acid/nitrate exposure may result from non-food uses. The amount of nitric acid/nitrate exposure resulting from indirect exposure to sanitizing solutions will be virtually zero. Since nitric acid/nitrate in the diet poses little toxicological risk, the cumulative toxicity resulting from this additional exposure to hard surface sanitizers is negligible.

E. Safety Determination

1. U.S. population. Since there are no adverse toxicological effects resulting from normal dietary concentrations of nitric acid/nitrate ion, and the additional exposure from sanitizers is miniscule, there is no need to determine aggregate risks, or to conduct a safety determination.

2. Infants and children. Infants under 3 months of age are the most susceptible population; however, their diet is unlikely to be in contact with food contact surface sanitizers.

F. International Tolerances

No Codex maximum levels have been established for nitric acid. [FR Doc. 00–8406 Filed 4–6–00; 8:45 am]

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<thead>
<tr>
<th>Cat- egories</th>
<th>NAICS Codes</th>
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<td>Animal production</td>
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<td>311</td>
<td>Food manufacturing</td>
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<td></td>
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2. In person. The Agency has established an official record for this action under docket control number PF–930. 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–930 in the subject line on the first page of your response.

1. By mail. Submit your comments to: Pesticide Information and Records Integrity Branch (PIRIB), Information Resources and Services Division.