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SUPPLEMENTARY INFORMATION:

Electronic Availability:

Internet

Electronic copies of this document and the draft brochure are available from the EPA Home Page at the **Federal Register**--Environmental Documents entry for this document under "Laws and Regulations" (<http://www.epa.gov/fedrgstr/>).

Fax-on-Demand

Using a faxphone call 202-401-0527 and select item 6020 for a copy of the draft brochure entitled "Pesticides on Food: Consumer Information."

I. Background

On August 3, 1996, President Clinton signed into law the Food Quality Protection Act of 1996 (FQPA). FQPA significantly amends the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), the laws governing pesticide regulation. FQPA sets a new health-based safety standard for all pesticide residues in food and requires that all established permissible pesticide residue limits (tolerances) be re-evaluated in accordance with the new standard.

The new law requires EPA to provide information on pesticide residues in or on food to large grocery stores for public display. At a minimum, the Agency must inform the public of the risks and benefits of pesticide use on food; a listing of all pesticides which do not meet the new standard; foods containing residues of these pesticides and foods that may reasonably substitute for these; and ways consumers can reduce their exposure to pesticides.

This effort builds on the Agency's commitment to ensure consumer safety and strengthen its right-to-know efforts to ensure that consumers are provided information which will allow them to make informed and environmentally-conscious decisions. The Agency is exploring additional mechanisms for informing the public about ways to reduce their exposure to pesticides and other chemicals in their diet, homes, workplaces, and schools.

This **Federal Register** Notice announces the availability of the draft brochure entitled "Pesticides on Food: Consumer Information." The draft brochure is available in two formats; the text is identical, but the illustrations differ. EPA is soliciting comments on this draft brochure prior to publication and distribution to large grocery stores for public display.

In developing this draft brochure, EPA has been consulting on a wide

range of issues with key constituencies, primarily through the Pesticide Program Dialogue Committee (PPDC). The PPDC is a permanently chartered Federal advisory committee that plays a key role in the implementation of FQPA. It provides advice and guidance to EPA on regulatory development and reform initiatives as well as public policy and regulatory issues associated with evaluating and reducing risks from pesticide use. In March 1997, the PPDC established a workgroup (29 members) consisting of EPA representatives, industry, the Food and Drug Administration, the United States Department of Agriculture, and environmental and public interest groups. In addition to these constituencies, to ensure that the brochure is understandable and useful, the Agency is conducting consumer research: 48 consumers have been interviewed to determine their knowledge and perceptions of pesticides. This draft brochure and future versions of it also will be evaluated by consumers in focus groups during January, February, and March 1998. Documents relating to the development of the draft brochure are being made available under docket control number OPP-00520.

In addition, EPA, is providing the public with an opportunity to comment on the Agency's interpretation of "public display" as it is used in section 408(o) of the FFDCA. EPA interprets "public display" to mean: to place the brochure in a manner that makes it available and visible to all shoppers, either in the produce department, entrance, or check-out; to make available copies for shoppers to pick up, and to replenish the supply when necessary. The FFDCA allows grocers to determine the manner of public display. However, EPA believes it is important to emphasize that grocers do have an obligation to display the brochure, and that it is necessary and appropriate to define "public display," to ensure that the intent of section 408(o) is effectuated.

II. Public Record and Electronic Submissions

The official record for this document, as well as the public version, has been established for this document under docket control number "OPP-00520" (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday,

excluding legal holidays. The official record is located at the Virginia address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number "OPP-00520." Electronic comments on this document may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Pesticides.

Dated: January 8, 1998.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 98-925 Filed 1-13-98; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-783; FRL-5759-6]

Ecolab Inc.; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the filing of a pesticide petition proposing the exemption from the requirement of a tolerance for residues of peroxyacetic 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 eggs when such residues result from the use of peroxyacetic acid as an antimicrobial agent on fruits, vegetables, tree nuts, cereal grains, herbs, and spices.

DATES: Comments, identified by the docket control number [PF-783] must be received on or before February 13, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132,

CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT:

Dennis H. Edwards, Jr., Chief, Regulatory Management Branch I, Antimicrobials Division (7510W), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, 703-308-6411, e-mail: edwards.dennis@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition [PP 7F4808] from Ecolab Inc. 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 by establishing an exemption from tolerance for residues of peroxyacetic 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 eggs when such residues result from the use of peroxyacetic acid as an antimicrobial agent on fruits, vegetables, tree nuts, cereal grains, herbs, and spices.

The proposed analytical method is titration. Pursuant to the section 408(d)(2)(A)(i) of the FFDCA, as amended, Ecolab Inc. has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Ecolab Inc. and EPA has not fully evaluated the merits of the petition. EPA edited the summary to clarify that the conclusions and arguments were the petitioner's and not necessarily EPA's and to remove certain extraneous material.

I. Petition Summary

This section has been arranged to provide a justification for this tolerance exemption and a summary of available data.

The request is to exempt from the requirement of a tolerance, residues of peroxyacetic 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 eggs when such residues result from the use of peroxyacetic acid as an antimicrobial agent on fruits, vegetables, tree nuts, cereal grains, herbs, and spices.

The residues which do remain are not of toxicological significance.

A. Residue Chemistry

Residues of peroxyacetic acid are not expected because peroxyacetic acid reacts rapidly on contact with materials such as food and is degraded to moieties which present no toxicological concern (Reregistration Eligibility Decision, Peroxy Compounds. U.S. EPA. EPA 738-R-93-030). The degradation products of peroxyacetic acid are acetic acid (which is generally regarded as safe in food up 0.15%, 21 CFR 184.1005), water, oxygen and hydrogen peroxide (H₂O₂). The degradation products of peroxyacetic acid are not of significant toxicological concern.

Adequate analytical methodology is available through titration to determine the amounts of peroxyacetic 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 eggs.

B. Toxicological Profile

Peroxyacetic acid is a moderately acutely toxic material with an oral LD₅₀ of approximately 1,540 mg/kg in rats (1993 RED). The toxicity is highly dependent on the concentration of the solution administered. In concentrated solutions, systemic toxicity may occur, but the hazard is more likely to be due to the corrosivity. At lower concentrations of peroxyacetic acid the lethal dose may be significantly higher due to the lack of the corrosive effects. At these concentrations peroxyacetic acid would produce primarily an irritant effect, especially following repeated doses.

No reliable long term toxicological data is available on this material. Structurally, this molecule resembles H₂O₂ with the presence of an acetyl group. Although peroxyacetic acid is a stronger oxidizing agent than H₂O₂, the

mechanism of biocidal and toxicological action of peroxyacetic acid is anticipated to be similar to that of H₂O₂ and other peroxides. By this mechanism, the toxicological effects of peroxyacetic acid would likely resemble that of H₂O₂.

In chemical reactions, the degradation products of peroxyacetic acid are acetic acid, water, oxygen and H₂O₂. Acetic acid, water and oxygen are not a toxicological concern and H₂O₂ is not considered toxicologically significant at low concentrations.

H₂O₂ is a moderately toxic material with an oral LD₅₀ of approximately 2,000 mg/kg (1993 RED). The toxicity is highly dependent on the concentration of the solution administered. At concentrations in the range of 30% or higher, systemic toxicity may occur, but the hazard is more likely to be due to the corrosivity. At lower concentrations of H₂O₂ the lethal dose of H₂O₂ may be significantly higher due to the lack of the corrosive effects. At concentrations in the range of 3%, and below, H₂O₂ produces primarily an irritant effect, especially following repeated doses.

Few chronic studies suitable for toxicological evaluation have been conducted. In one study, approximately 100 mice per group were given 0, 0.1% or 0.4% H₂O₂ in their drinking water for 100 weeks. At the conclusion of the study, there was one adenoma of the duodenum in controls, six adenomas and one carcinoma of the duodenum in the low dose, and two adenomas and five carcinoma of the duodenum in the high dose. The incidence was significantly higher in the treated animals, however this may reflect a corrosive effect of the test material leading to a hyperplastic response rather than genotoxic effect.

In another study mice were given 0.4% H₂O₂ (4,000 ppm) in drinking water for 108 weeks. Results from interim sacrifices demonstrated gastric irritation and "erosion" was evident throughout the course of the study. This is expected based on the long term exposure. Duodenal and gastric hyperplastic nodules were noted in treated animals at all interim sacrifices from day 90 to the end of the study. There was a 5% incidence in duodenal carcinoma compared to 0% in the controls. Again, this may reflect a corrosive effect of the test material leading to a hyperplastic response rather than genotoxic effect. Since only one treatment group was used, this provides only limited evidence of the oncogenicity of this material. In a follow-up experiment, mice were given 0.4% H₂O₂ in drinking water for up to 180 days followed by a recovery period

of up to 30 days. The stomach lesions regressed completely but a few of the duodenal lesions persisted. This further demonstrated the corrosivity of the test material.

In mutagenicity studies equivocal and conflicting results were found. H₂O₂ was mutagenic to strain TA92. Positive and negative results have been demonstrated in other *Salmonella* assays. Overall, there is limited evidence that H₂O₂ is mutagenic.

C. Aggregate Exposure

1. *Dietary exposure.* There are no established U.S. food tolerances for peroxyacetic acid. According to the 1993 RED, peroxyacetic acid is used in dairy/cheese processing plants, on food-processing equipment and in pasteurizers in breweries, wineries and beverage plants. While some contact may occur between treated equipment and food, no residues are expected since only trace amounts would come in contact with food having contacted treated equipment and the compound degrades rapidly (in air) primarily to acetic acid (which is generally regarded as safe in food up 0.15%, see 21 CFR 184.1005), oxygen, water and H₂O₂. In addition, peroxyacetic acid may be safely used on food-processing equipment, utensils, and other food-contact articles according to the Food and Drug Administration (21 CFR 178.1010, *Sanitizing Solutions*).

Dietary exposure from these uses is possible; however, peroxyacetic acid reacts instantly upon contact with materials such as food and degrades to moieties which present no significant toxicological concern. The addition to dietary aggregate exposure of peroxyacetic acid as described in this petition is minimal.

2. *Drinking water exposure.* There is no concern about the potential for transfer of peroxyacetic acid residues (both the parent pesticide and any degradates) to human drinking water because the use sites for peroxyacetic acid listed in the 1993 RED include indoor food, indoor non-food, indoor medical, and indoor residential. Peroxyacetic acid is proposed for use as an antimicrobial agent on fruits, vegetables, tree nuts, cereal grain, herbs, and spices. It is unlikely that residues from these uses will transfer peroxyacetic acid residues (both the parent and any degradates) to any sources of human drinking water. In addition, the degradation products of peroxyacetic acid in aqueous solutions are acetic acid (which is generally regarded as safe in food up 0.15%, see 21 CFR 184.1005), water and oxygen.

These degradation products are not of toxicological concern.

Because of the physical chemistry of this pesticide, it is unlikely that any States are conducting water monitoring programs for peroxyacetic acid.

3. *Non-occupational exposure.* The estimated non-occupational exposure to peroxyacetic acid has been evaluated based on its proposed use pattern.

According to the 1993 RED, the compound, in the form of a soluble concentrate/liquid, is used in industrial and commercial settings.

Peroxyacetic acid is highly reactive and short-lived because of the inherent instability of the peroxide bond (O-O bond) and, because the peroxide bond is weak, transformation to acetic acid, water, oxygen and peroxide is very highly favored thermodynamically (1993 RED). The degradation products of peroxyacetic acid in aqueous solutions are acetic acid (which is generally regarded as safe in food up 0.15%, see 21 CFR 184.1005), water, oxygen and H₂O₂. The generation of H₂O₂ is the only potential degradate of concern.

H₂O₂ use in homes is medicinal and exposures are expected to be infrequent and at extremely short topical duration; however, it is important to put into perspective the typical medicinal dose of H₂O₂ versus a biocidal dose. Commercially available 3% H₂O₂ (30,000 ppm) can be purchased for use as a topical and oral disinfectant. When using this product as a oral cavity disinfectant, a typical use scenario would be rinsing the mouth three times a day. In a typical mouth rinse application, some of the rinsing agent is normally ingested; a conservative estimate of 3 ml is used in the following example. Assuming that a 70 kg person ingests only 3 ml. of the H₂O₂ solution during each rinse, he will be exposed to approximately 3.9 mg/kg H₂O₂ in a single day. This treatment has been done millions of times without any adverse effects with the possible exception of slight irritation to the oral cavity.

The potential for significant non-occupational exposure to peroxyacetic acid under the use proposed in this petition to the general population (including children) is unlikely. Peroxyacetic acid is proposed in this petition to be used only at commercial establishments (including farms) and is not to be used in or around the home.

D. Cumulative Effects

When used as proposed, peroxyacetic acid dissipates quickly; there is no reasonable expectation that residues of these compounds will remain in human

food items in accordance with 40 CFR 180.3. The mode of action of this pesticide is oxidation. Other chemicals that may fall into this category are H₂O₂ acid and potassium peroxymonosulfate sulfate as listed in the 1993 RED. Combining exposures to these compounds is appropriate; however, each degrades rapidly (due to the peroxy bond, the O-O bond) into compounds that are not toxicologically significant (including water, oxygen, and carbon dioxide).

E. Safety Determination

1. *U.S. general population.* Peroxyacetic acid naturally degrades to acetic acid (which is generally regarded as safe in food up 0.15%, see 21 CFR 184.1005), water and oxygen which would not pose a health risk to the U.S. general population. These degradation products are not of toxicological concern. Small quantities of H₂O₂ can also be generated.

Residues of peroxyacetic acid are not expected on treated commodities (whether raw agricultural commodities or processed) and the residues are not expected to bioaccumulate in livestock and/or poultry that consume treated feedstuffs because peroxyacetic acid is highly reactive and short-lived due to the inherent instability of the peroxide bond (O-O bond). Because the peroxide bond is weak, transformation to acetic acid, water and oxygen is very highly favored thermodynamically (1993 RED). The degradation of peroxyacetic acid is rapid, therefore, exposure of the pesticide chemical (from the use proposed in this petition) to the U.S. general population should not occur.

2. *Infants and children.* Peroxyacetic acid naturally degrades to acetic acid (which is generally regarded as safe in food up 0.15%, see 21 CFR 184.1005), water and oxygen which would not pose a health risk to the U.S. population subgroup of infants and children. These degradation products are not of toxicological concern.

Residues of peroxyacetic acid are not expected on treated commodities (whether raw agricultural commodities or processed) and the residues are not expected to bioaccumulate in livestock and/or poultry that consume treated feedstuffs because peroxyacetic acid is highly reactive and short-lived due to the inherent instability of the peroxide bond (O-O bond). Because the peroxide bond is weak, transformation to acetic acid, water, oxygen and H₂O₂ is very highly favored thermodynamically (1993 RED). Therefore, exposure of the pesticide chemical (from the use proposed in this petition) to the U.S.

population subgroup of infants and children should not occur.

F. International Tolerances

The petitioner understands that there are no current established Maximum Residue Levels for peroxyacetic acid.

G. Information on Endocrine Effects

Peroxyacetic acid does not act like hormones or inhibit hormonal activity.

II. Public Record and Electronic Submissions

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-783] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF-783] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: December 16, 1997.

Frank Sanders,

Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 98-928 Filed 1-13-98; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-784; FRL-5759-7]

Ecolab Inc.; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the filing of a pesticide petition proposing the exemption from the requirement of a tolerance for residues of hydrogen peroxide (H₂O₂) 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 eggs when such residues result from the use of H₂O₂ as an antimicrobial agent on fruits, vegetables, tree nuts, cereal grains, herbs, and spices.

DATES: Comments, identified by the docket control number [PF-784] must be received on or before, February 13, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Dennis H. Edwards, Jr., Chief, Regulatory Management Branch I, Antimicrobials Division (7510W), Office of Pesticide Programs, U.S.

Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, 703-308-6411. e-mail:

edwards.dennis@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP 7F4834) from Ecolab Inc. 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 by establishing an exemption from tolerance for residues of H₂O₂ 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 eggs when such residues result from the use of H₂O₂ as an antimicrobial agent on fruits, vegetables, tree nuts, cereal grains, herbs, and spices. The proposed analytical method is titration. Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Ecolab Inc. has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Ecolab Inc. and EPA has not fully evaluated the merits of the petition. EPA edited the summary to clarify that the conclusions and arguments were the petitioner's and not necessarily EPA's and to remove certain extraneous material.

I. Petition Summary

This section has been arranged to provide a justification for this tolerance exemption and a summary of available data.

The request is to exempt from the requirement of a tolerance, residues of H₂O₂ 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 eggs when such residues result from the use of H₂O₂ as an antimicrobial agent on fruits, vegetables, tree nuts, cereal grains, herbs, and spices. The residues which do remain are not of toxicological significance.

A. Residue Chemistry

Residues of H₂O₂ are not expected because H₂O₂ reacts on contact with materials such as food and is degraded to moieties which present no toxicological concern (Reregistration Eligibility Decision, Peroxy Compounds, U.S. EPA. EPA 738-R-93-030, the "1993 RED"). The degradation products of H₂O₂ in aqueous solutions are water and oxygen (1993 RED). The degradation products of H₂O₂ are not of toxicological concern.

Because this petition is for an exemption from the requirement of a