as follows: '' Hydrogen peroxide is highly reactive and short lived because of the inherent instability of the peroxide bond (i.e., the O-O bond). Agitation or contact with rough surfaces, sunlight, organics and metals accelerates decomposition. The instability of hydrogen peroxide to exist as itself, along with detoxifying enzymes found in cells (e.g. catalase, glutathione peroxidase), makes it very difficult to find any residues in or on foods (at proposed use levels) by conventional analytical methods.''

C. Mammalian Toxicological Profile

BioSafe Systems proposes products containing 27% hydrogen peroxide by weight. In all cases the product is diluted with water at a rate of 1:50, 1:100 or 1:300, which results in a concentration of 0.25% to 1.50% hydrogen peroxide in the product that is applied. BioSafe Systems has cited open literature with respect to toxicity data which shows that hydrogen peroxide is toxic at high levels; that at a 1.5% concentration it has no impact on human skin, eyes or respiratory system; that the concentrate has a pH of 1.05 and thus has been categorized in Toxicity Category I for skin and eye irritation; that for the oral route of exposure, a concentration of 0.5% hydrogen peroxide was determined not to present a possible adverse effect due to the fact that hydrogen peroxide at concentrations of 0.04 and 0.05% has been classified as GRAS by FDA and USDA for use as a food additive, toothpaste or mouthwash. Biosafe summarized open literature pertaining to toxicology as follows:

Solutions containing 6% hydrogen peroxide have an acute oral LD_{50} >5,000 milligram/kilogram (mg/kg) in rats (Toxicity Category III), an acute dermal LD_{50} > 10,000 mg/kg in rabbits (Toxicity Category IV), and an inhalation LC_{50} of 4 mg/l (Toxicity Category IV). Such solutions are mild irritants to rabbit skin and cause severe, irreversible corneal injury in half of the exposed rabbits (Toxicity Category I).

Solutions containing 50% hydrogen peroxide have an acute oral LD_{50} > 500 mg/kg in rats (Toxicity Category II) and an acute dermal LD_{50} >1,000 mg/kg in rabbits (Toxicity Category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC_{50} is 4 mg/l (2,000 ppm). Solutions containing 50% hydrogen peroxide are also extremely irritating (corrosive) to rabbit eyes (Toxicity Category I).

D. Aggregate Exposure

1. *Dietary exposure— Food*. BioSafe has asserted that dietary exposure from use of hydrogen peroxide, as proposed is minimal since hydrogen peroxide reacts rapidly on contact with surfaces such as food and degrades into oxygen and water, neither of which are of toxicologial concern.

2. *Drinking water*. BioSafe states that the proposed use may result in the transfer of minor amounts of residues to potential drinking water sources, however there is no concern for exposure due to the fact that the residues of hydrogen peroxide are oxygen and water, neither of which are of toxicological concern. Biosafe quotes the existing exemption'' the EPA Office of Water indicates that when used for potable disinfection, no residues of hydrogen peroxide are present by the time the water is pumped through a distribution system.'' 40 CFR 180.1197.

3. *Non-dietary exposure*. BioSafe states that the potential for non-dietary exposure to the general population including infants and children is unlikely as the proposed use sites are commercial, agricultural and horticultural settings and that non-dietary exposures would not be expected pose any quantifiable risk due to lack of residues of toxicological concern.

E. Cumulative Exposure

BioSafe states that it is not expected that, when used as proposed, hydrogen peroxide would result in residues that would remain in human food items since hydrogen peroxide reacts on contact and degrades rapidly into compounds that are not of toxicological concern.

F. Safety Determination

1. *U.S. population*. Biosafe quotes from the established exemption from the requirement of a tolerance that EPA has concluded that no endpoint exists to suggest any evidence of significant toxicity from acute, short-term or intermediate-term exposures from the proposed food contact uses of hydrogen peroxide''. BioSafe states that since hydrogen peroxide degrades rapidly on contact into residues that are not of toxicological concern, chronic risk from dietary exposure is not anticipated and since residues of hydrogen peroxide are not expected on agricultural commodities, exposure to the general U.S. population from the proposed uses is not anticipated.

2. *Infants and children*. BioSafe states that, as mentioned above, residues of hydrogen peroxide are not expected on agricultural commodities and that hydrogen peroxide degrades rapidly on contact into residues that are of no toxicological concern and that there is a reasonable certainty of no harm for infants and children from exposure to hydrogen peroxide from the proposed uses.

G. Effects on the Immune and Endocrine Systems

BioSafe has cited open literature in that weak direct mutagenicity responses were seen for hydrogen peroxide in Ames tests with *Salmonella typhimurium* strains TA97, TA98, TA102, and TA1537 in a 20 minute preincubation test and in a liquid incubation modification using strain TA1537. Biosafe states that there is additional information regarding immunotoxicity, developmental toxicity and chronic toxicity in the open literature.

H. Existing Tolerances

An exemption from the requirement of a tolerance has been established for residues of hydrogen peroxide up to 120 ppm in or on raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs and spices (40 CFR 180.1197).

I. International Tolerances

There is no Codex Alimentarium Commision Maximum Residue Level (MRL) for hydrogen peroxide.

[FR Doc. 98–25084 Filed 9–22–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–833; FRL–6026–1]

Notice of Filing of Pesticide Petitions

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 the docket control number PF–833, must be received on or before October 23, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7502C), Information Resources and Services Division, Office of Pesticides Programs,

Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow 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. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: The Regulatory Action Leader listed in the table below:

Regulatory Action Leader	Office location/telephone number	Address
Diana Horne	9th Floor, CM #2, 703–308–8367, e-mail: horne.diana@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA
Sheila A. Moats	9th Floor, CM #2, 703–308–1259, e-mail: moats.sheila@epamail.epa.gov.	Do.

SUPPLEMENTARY INFORMATION: 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 petition. Additional data may be needed before EPA rules on the petition.

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–833] (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 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF–833] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: September 8, 1998.

Kathleen D. Knox,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summaries of Petitions

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 views of the petitioners. EPA is publishing the petition summaries verbatim without editing them 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. EDEN Bioscience Corporation

PP 8F4975

EPA has received a pesticide petition (PP) 8F4975 from EDEN Bioscience Corporation, 11816 North Creek Parkway N., Bothell WA 98011-8205, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a temporary tolerance for the biological pesticide Harpin in or on all food commodities. Harpin will be utilized on under the conditions of Experimental Use Permit 69834-EUP-R.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, EDEN Bioscience Corporation has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by EDEN Bioscience Corporation and EPA has not fully evaluated the merits of the petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary was not clear that it reflected the conclusion of the petitioner and not necessarily EPA.

A. Proposed Use Practices

The proposed experimental program will be conducted in Alabama, Arkansas, Arizona, California, Connecticut, Florida, Georgia, Iowa, Idaho, Illinois, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Montana, North Carolina, North Dakota, New Jersey, New Mexico, New York, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Virginia, and Washington. The following crops are to be treated: tomatoes (fresh market and processing), peppers (bell and chile), cotton, cucurbits (cucumbers, squash, and melons), rice, ornamental roses, ornamentals (greenhouse foliage and bedding plants), strawberries, tobacco (burley and flue-cured), small grains (winter or spring wheat and barley), peanuts, conifer seedlings, alfalfa, potatoes, grapes (wine and table varieties), turf (lawn and garden), apples, citrus (oranges, grapefruit, lemons, limes, tangerines, and tangelos), soybeans (dry), blueberry, cranberry, raspberry, corn, sweet corn, and sugar cane. The proposed experimental program would utilize 559.98 pounds of

active ingredient per year on 4,997 acres during 1998-2000. Harpin will be applied by various methods at a maximum rate of 0.06 pounds to 0.39 pounds active ingredient per acre per site during the season, depending on the crop. For tomatoes and peppers, which represent the majority of the acreage to be treated, all plants will be treated once or twice prior to transplanting to the field, minimizing any potential environmental impact of product application in the field. Application methods may include seed treatments by soaking or dusting, root or seedling drenches, drenches at transplanting and foliar sprays during the growing season, with emphasis on pre-flowering applications. Standard spray equipment is appropriate for foliar applications.

B. Product Identity/Chemistry

Harpin is a bacterial protein product that is produced by fermentation. The harpin protein confers systemic resistance to multiple diseases in numerous crops. The dried formulated product containing harpin is Messenger™. In addition to broad-spectrum control of diseases caused by bacteria, fungi, and some viruses, Messenger™ also provides enhanced plant growth in many crops. Such enhancements include improved germination, increased overall plant vigor, accelerated flowering and fruit set, advanced maturity, and increased yield and quality of the final harvest. Messenger™ may enhance plant growth in the absence of detectable plant disease. Finally, treatment with Messenger™ provides substantial tolerance to certain soil-borne plant pathogens, reducing the need for toxic, conventional chemical means of control.

An analytical method for residues is not applicable, since the petitioner has requested an exemption from the requirement of a tolerance.

C. Mammalian Toxicological Profile

Harpin is a naturally occurring protein derived from the plant pathogenic bacterium, *Erwinia amylovora*, the causative agent for fire blight disease. Because of its role in plant host-parasite relationships, harpin is presumed to have been present in *E. amylovora* for as long as the bacterium has been involved in the fire blight disease. As such, harpin protein has been constantly produced and secreted by *E. amylovora* on or in edible fruits such as apple or pear with no apparent adverse effects on humans.

EDEN has conducted studies to evaluate the mammalian toxicology of the harpin protein. The results of these studies indicate that harpin is a Toxicity Category III or IV substance and that it poses no significant human health risks. No toxicity was observed in either of the acute oral toxicity studies conducted with the harpin technical grade active ingredient (TGAI) or a concentrated harpin TGAI. Acute oral LD_{50} values for both harpin protein technical and concentrated harpin protein technical were greater than 2,000 mg/kg in the rat (Toxicity Category IV). The 4-hour LC_{50} for harpin was determined to be greater than 2 mg/L in an acute inhalation study with rats. EDEN has not observed any incidents of harpin-induced hypersensitivity in individuals exposed to harpin during research, production, and/or field testing. The harpin end product produced minimally and mildly irritating results in the eye irritation and dermal irritation studies, respectively.

The proteinaceous nature of harpin, in combination with its lack of acute toxicity, lends an additional measure of safety because when proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (LDLs) (Sjoblad, Roy D., et al. ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' *Regulatory Toxicology and Pharmacology* 15, 3-9). Therefore, because no significant adverse effects were observed, even at the limit doses, harpin is not considered to be an acutely toxic protein.

D. Aggregate Exposure

1. *Dietary exposure— Food*. Because of the low rate of application and rapid degradation of harpin in the environment, residues of harpin in or on treated raw agricultural commodities are expected to be negligible. Moreover, because harpin exhibits no mammalian toxicity, any dietary exposure, if it occurred, would not be harmful to humans.

2. *Drinking water*. Residues of harpin are unlikely to occur in drinking water, due to the low application rate of the product and its rapid degradation in soil and water and on foliar surfaces.

3. *Non-dietary exposure*. Increased non-dietary exposure of harpin via lawn care, topical insect repellents, etc., is not applicable to this EUP application.

E. Cumulative Exposure

Consideration of a common mode of toxicity is not appropriate, given that there is no indication of mammalian toxicity of harpin protein and no information that indicates that toxic effects would be cumulative with any other compounds. Moreover, harpin does not exhibit a toxic mode of action in its target pests or diseases.

F. Safety Determination

1. *U.S. population*. Harpin's lack of toxicity has been demonstrated by the results of acute toxicity testing in mammals in which harpin caused no adverse effects when dosed orally and via inhalation at the limit dose for each study. Thus, the aggregate exposure to harpin over a lifetime should pose negligible risks to human health. Based on lack of toxicity and low exposure, there is a reasonable certainty that no harm to adults, infants, or children will result from aggregate exposure to harpin residue. Exempting harpin from the requirement of a tolerance should pose no significant risk to humans or the environment.

2. *Infants and children*.

See Unit F.1. above.

G. Effects on the Immune and Endocrine Systems

EDEN Bioscience Corporation has no information to suggest that harpin will adversely affect the immune or endocrine systems.

H. International Tolerances

EDEN Bioscience Corporation is not aware of any tolerances, exemptions from tolerance, or MRL's issued for harpin outside of the United States.

2. Stoller Enterprises, Inc.

PP 8F4960

EPA has received a pesticide petition (PP 8F4960) from Stoller Enterprises, Inc., 8580 Katy Freeway, Suite 200, Houston, Texas 70024, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the biochemical pesticide, salicylic acid, in or on all raw agricultural commodities.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Stoller Enterprises, Inc. has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Stoller Enterprises, Inc. and EPA has not fully evaluated the merits of the petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary was not clear that it reflected the conclusion of the petitioner and not necessarily EPA.

A. Product Name and Proposed Use Practices

Salicylic acid will be incorporated into the end-use product, Adjust I, as an active ingredient. Adjust I is proposed

for use on a variety of agricultural, horticultural, and floricultural applications to enhance plant defense against pathogens.

Depending on the crop, the first application of Adjust I is made at the 3-5 leaf stage or other prescribed growth stage. Subsequent applications may be made at 12-day intervals. The rate is 2 quarts of formulated product/acre per treatment. This equates to the application of 20 grams/acre salicylic acid.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* Salicylic acid is a phenolic acid found in insects and plants as free acid or bound. The biochemical is a white, practically odorless, free-flowing crystalline powder. It is slightly soluble in water, forming acidic solutions.

2. *Magnitude of the residue at time of harvest and method used to determine residue.* An analytical method using High Performance Liquid Chromatography (HPLC), UV spectrophotometery, and Gas Chromatography for determining salicylic acid content in Adjust I is available.

3. *A statement of why an analytical method for detecting the levels and measuring of the pesticide residue is not needed.* Because this phenolic acid is found naturally in plants, residue analysis would not yield meaningful results, i.e., the analysis would not discern whether the salicylic acid source was the plant or from treatment. Additionally, phenolic levels harmful to plants and animals are highly unlikely to occur when the product is applied according to label instructions.

C. Mammalian Toxicological Profile

Salicylic acid is highly regulated in man and other organisms, the mechanisms of which are well understood. Salicylic acid has been administered to numerous species in long term dietary studies without adverse effects at a range of concentrations. The end-use product containing salicylic acid, Adjust I, has been evaluated for acute toxicity. Acute oral toxicity in rats is greater than 3,000 milligrams/kilogram (mg/kg) (Toxicity Category III). Acute dermal toxicity in rabbits is greater than 5,050 mg/kg (Toxicity Category III). In an eye irritation study, there were no signs of irritation following administration of Adjust I (Toxicity Category IV). A rabbit dermal irritation study with Adjust I resulted in no signs of irritation (Toxicity Category IV). There was no indication of dermal sensitization in a guinea pig dermal sensitization study.

Waivers have been requested for genotoxicity, reproductive and developmental toxicity, subchronic toxicity, chronic toxicity, and acute toxicity to nontarget species based on salicylic acid's ubiquity in nature, long history of medicinal uses, favorable toxicological profile in chronic toxicology studies, and inconsequential exposure resulting from label-directed use rates.

D. Aggregate Exposure

1. *Dietary exposure— Food.* Salicylic acid is ubiquitous in nature and is found in lower and higher plant species, insects, cosmetics, over-the-counter medications and natural and processed foods. Many items in the human daily diet contain appreciable quantities of free and bound salicylic acid. Dietary exposure due to topical applications of salicylic acid is difficult to estimate because of the phenolic acid's prevalence in skin care products and over-the-counter medications.

Considering the low dose of salicylic acid required to achieve the desired effect, the levels of salicylic acid found naturally in the diet and the quantity consumed from processed foods, it can be concluded that incremental dietary exposure to salicylic acid resulting from Adjust I applications is negligible.

2. *Drinking water.* The active ingredient, salicylic acid, decomposes readily in water and sunlight. The oxidation reactions of ultraviolet radiation/H_20_2/O_2 with either phenol or salicylic acid successfully degrade those compounds, which are building blocks of aquatic humic substances. Many compounds, including salicylic acid, have been identified by means of spectroscopy and chromatography. The degradation pathway is thought to involve hydroxylation of the aromatic ring and abstraction of a hydrogen atom to form 1,2-benzoquinone, which is cleaved to form muconic acid. The muconic acid is converted to maleic acid, fumaric acid, and oxalic acid. Fumaric and maleic acids eventually become malic acid, and the oxalic acid is degraded to formic acid and then CO_2. These reactions demonstrate how phenolics substances are converted to biodegradable ones.

3. *Non-dietary exposure.* Adjust I is proposed for use on non-residential turf and ornamentals. Exposure from turf grass applications is expected to be minimal because turf users will be protected by shoes and socks. Further, based on the limited frequency of use on turf grass, this non-food use is not likely to result in potential chronic exposure and thus should not be factored into a chronic exposure assessment. Exposures resulting from application to ornamentals is also anticipated to be negligible because consumers normally will not be in contact with treated plants.

E. Cumulative Exposure

Salicylic acid is highly regulated in plants and mammals, the mechanisms of which are well understood. This phenolic acid is not intended for pesticidal use and does not share a common mechanism of toxicity with currently available pesticides, thus Adjust I anticipate no cumulative effects with other substances.

F. Safety Determination

1. *U.S. population.* Because the use of salicylic acid will be delivered at label rates concentrations that are less than or equal to those found in plants, and because the active ingredient has a favorable toxicological profile, the use of the salicylic acid when delivered at label rates poses a negligible, or nonexistent, risk to the U.S. population.

2. *Infants and children.* Salicylic acid and its conjugates, esters, and metabolites are ingested and excreted daily. The compound and its analogs are ubiquitous in the food chain. When used at label rates, the product poses no threat to infants and children. In fact as the product replaces existing fungicides with less favorable toxicological profiles the risk to infants and children will be reduced.

G. Effects on the Immune and Endocrine Systems

There is no literature available to suggest the immune or endocrine systems will be compromised with the use of salicylic acid as an active ingredient at recommended rates.

H. Existing Tolerances

There are no known existing tolerances for the use of salicylic acid for use as a pesticide.

I. International Tolerances

There are no CODEX tolerances or international tolerance exemptions for salicylic acid at this time.

[FR Doc. 98–25315 Filed 9–22–98; 8:45 am]

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