



August 25, 2004

Food and Drug Administration
Rockville MD 20857

Mr. Michael Harvey
Enviro Tech Chemical Services, Inc.
500 Winmoore Way
Modesto, CA 95358

RE: Food Contact Notification No. 000447

Dear Mr. Harvey:

This is in reference to Food Contact Notification (FCN #000447) for the Food Contact Substance (FCS) and use described as follows:

Food Contact Substance

An aqueous mixture of peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), sulfuric acid (CAS Reg. No. 7664-93-9), and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP)(CAS Reg. No. 2809-21-4)

Notifier

Enviro Tech Chemical Services, Inc.

Manufacturer/Supplier

Enviro Tech Chemical Services, Inc.

Intended Use

To control microbial growth in wash water that contacts fruits and vegetables that are not raw agricultural commodities.

Limitations/Specifications

The additive will be used in process water such that the level of hydrogen peroxide will not exceed 120ppm, and the levels of peroxyacetic acid and HEDP will not exceed the limits specified in 21 CFR 173.315(a)(5).

This is to inform you that on October 14, 2004, FCN 000447 will become effective. The above description will be used by FDA to describe your notification. It will be added to the list of effective notifications for food contact substances available on the agency's Internet site at <http://www.cfsan.fda.gov/~dms/opa-fcn.html>.

The agency has determined under 21 CFR 25.32(q) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

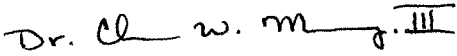
This effective notification is applicable only to the FCS described above, manufactured by Enviro Tech Chemical Service, Inc., limited to the above use and whose manufacture, identity, specifications and conditions of use conform to the information submitted in the notification upon which the determination of safety is based. You should inform the agency of any modification in the FCS limitations/specifications or conditions of use given in the notification or of any alteration in the manufacturing process that would result in a change in the impurities in the FCS. Such changes may require submission of a new notification.

The existence of an effective notification for an FCS does not relieve use of the subject substance from compliance with any other provision of the Federal Food, Drug, and Cosmetic Act or with 21 CFR 174.5 General provisions applicable to indirect food additives. For example, in accordance with section 402(a)(3) of the Act, use of the additive should not impact odor or taste to food rendering it unfit for human consumption.

If new data or information becomes available to FDA demonstrating that the intended use of the FCS is no longer safe, the agency will inform you of its determination that the intended use of the FCS is no longer safe. In addition, if you become aware of data that raise questions about the safety of the intended use of the FCS, you should notify the agency immediately and be prepared to supply data necessary to resolve the questions.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Handwritten signature of Clarence W. Murray, III in cursive script.

Clarence W. Murray, III, Ph.D.
Division of Petition Review, HFS-265
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

[Code of Federal Regulations]
 [Title 21, Volume 3]
 [Revised as of April 1, 2001]
 From the U.S. Government Printing Office via GPO Access
 [CITE: 21CFR173.315]

[Page 130-132]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 173--SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION--Table

Subpart D--Specific Usage Additives

Sec. 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetab

Chemicals may be safely used to wash or to assist in the peeling of fruits and vegetables in accordance with the following conditions:

- (a) The chemicals consist of one or more of the following:
 - (1) Substances generally recognized as safe in food or covered by prior sanctions for use in washing fruits and vegetables.
 - (2) Substances identified in this subparagraph and subject to such limitations as are provided:

[[Page 131]]

Substances	Limitations
A mixture of alkylene oxide adducts of alkyl alcohols and phosphate esters of alkylene oxide adducts of alkyl alcohols consisting of: <greek-a>-alkyl (C<INF>12</INF>-C<INF>18</INF>)-omega-hydroxy-poly (oxyethylene) (7.5-8.5 moles)/poly (oxypropylene) block copolymer having an average molecular weight of 810; <greek-a>-alkyl (C<INF>12</INF>-C<INF>18</INF>)-omega-hydroxy-poly (oxyethylene) (3.3-3.7 moles) polymer having an average molecular weight of 380, and subsequently esterified with 1.25 moles phosphoric anhydride; and <greek-a>-alkyl (C<INF>10</INF>-C<INF>12</INF>)-omega-hydroxypoly (oxyethylene) (11.9-12.9 moles)/poly (oxypropylene) copolymer, having an average molecular weight of 810, and subsequently esterified with 1.25 moles phosphoric anhydride.	May be used at a level not to exceed 0.2 percent in lye-peeling solution to assist in the lye peeling of fruit and vegetables.
Aliphatic acid mixture consisting of valeric, caproic, enanthic, caprylic, and pelargonic acids.	May be used at a level not to exceed 1 percent in lye peeling solution to assist in the lye peeling of fruits and vegetables.
Polyacrylamide.....	Not to exceed 10 parts per million in wash water. Contains not more than 0.2 percent acrylamide monomer. May be used in the washing of fruits and vegetables.
Potassium bromide.....	May be used in the washing or

	to assist in the lye peeling of fruits and vegetables.
Sodium n-alkylbenzene-sulfonate (alkyl group predominantly C<INF>12</INF> and not less than 95 percent C<INF>10</INF> to C<INF>16</INF>).	Not to exceed 0.2 percent in wash water. May be used i washing or to assist in t lye peeling of fruits and vegetables.
Sodium dodecylbenzene-sulfonate (alkyl group predominantly C<INF>12</INF> and not less than 95% C<INF>10</INF> to C<INF>16</INF>).	Do.
Sodium 2 ethyl-hexyl sulfate.....	Do.
Sodium hypochlorite.....	May be used in the washing or to assist in the lye peeling of fruits and vegetables.
Sodium mono- and dimethyl naphthalene sulfonates (mol. wt. 245-260).	Not to exceed 0.2 percent in wash water. May be used in the washing or to assist in the lye peeling of fruits and vegetables.

(3) Sodium mono- and dimethyl naphthalene sulfonates (mol. wt. 245-260) may be used in the steam/scald vacuum peeling of tomatoes at a level not to exceed 0.2 percent in the condensate or scald water.

(4) Substances identified in this paragraph (a)(4) for use in flume water for washing sugar beets prior to the slicing operation and subject to the limitations as are provided for the level of the substances in the flume water:

Substance	Limitations
<greek-a>-Alkyl-omega-hydroxypoly-(oxyethylene) produced by condensation of 1 mole of C<INF>11</INF>-C4863<INF>15</INF> straight chain randomly substituted secondary alcohols with an average of 9 moles of ethylene oxide.	Not to exceed 3 ppm.
Linear undecylbenzenesulfonic acid.....	Do.
Dialkanolamide produced by condensing 1 mole of methyl laurate with 1.05 moles of diethanolamine.	Not to exceed 2 ppm.
Triethanolamine.....	Do.
Ethylene glycol monobutyl ether.....	Not to exceed 1 ppm.
Oleic acid conforming with Sec. 172.860 of this chapter.	Do.
Tetrapotassium pyrophosphate.....	Not to exceed 0.3 ppm.
Monoethanolamine.....	Do.
Ethylene dichloride.....	Not to exceed 0.2 ppm.
Tetrasodium ethylenediaminetetraacetate...	Not to exceed 0.1 ppm.

(5) Substances identified in this paragraph (a)(5) for use on fruits and vegetables that are not raw agricultural commodities and subject to the limitations provided:

Substances	Limitations
Hydrogen peroxide.....	Used in combination with acetic acid to form peroxyacetic acid. Not to exceed 59 ppm in wash water.
1-Hydroxyethylidene-1,1-diphosphonic acid	May be used only with peroxyacetic acid. Not to exceed 4.8 ppm in wash

Peroxyacetic acid..... water.
 Prepared by reacting acetic acid with hydrogen peroxide.
 Not to exceed 80 ppm in wash water.

(b) The chemicals are used in amounts not in excess of the minimum required to accomplish their intended effect.

(c) The use of the chemicals listed under paragraphs (a)(1), (a)(2), and (a)(4) is followed by rinsing with potable water to remove, to the extent possible, residues of the chemicals.

(d) To assure safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the

[[Page 132]]

act, the name of the additive or a statement of its composition.

(2) The label or labeling of the additive container shall bear adequate use directions to assure use in compliance with all provisions of this section.

[42 FR 14526, Mar. 15, 1977, as amended at 42 FR 29856, June 10, 1977; 42 FR 32229, June 24, 1977; 43 FR 54926, Nov. 24, 1978; 61 FR 46376, 46377, Sept. 3, 1996; 63 FR 7069, Feb. 12, 1998; 64 FR 38564, July 19, 1999]

[Code of Federal Regulations]
[Title 40, Volume 20]
[Revised as of July 1, 2001]
From the U.S. Government Printing Office via GPO Access
[CITE: 40CFR180.1197]

[Page 547-548]

TITLE 40--PROTECTION OF ENVIRONMENT

CHAPTER I--ENVIRONMENTAL PROTECTION
AGENCY--(Continued)

PART 180--TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN FOOD--Tabl

Subpart D--Exemptions From Tolerances

Sec. 180.1197 Hydrogen peroxide; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial treatment in solutions containing a diluted end-use concentration of hydrogen peroxide up to 120 ppm per application on fruits,

[[Page 548]]

vegetables, tree nuts, cereal grains, herbs, and spices.

(b) An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on all food commodities at the rate of less than or equal to 1% hydrogen peroxide per application on growing crops and post harvest potatoes when applied as an algaecide, fungicide and bactericide.

(c) An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide, in or on all raw and processed food commodities when used in sanitizing solutions containing a diluted end-use concentration of hydrogen peroxide up to 1,100 ppm, and applied to tableware, utensils, dishes, pipelines, tanks, vats, fillers, evaporators, pasteurizers, aseptic equipment, milking equipment, and other food processing equipment in food handling establishments including, but not limited to dairies, dairy barns, restaurants, food service operations, breweries, wineries, and beverage and food processing plants.

[65 FR 75179, Dec. 1, 2000]

[Code of Federal Regulations]
[Title 40, Volume 20]
[Revised as of July 1, 2001]
From the U.S. Government Printing Office via GPO Access
[CITE: 40CFR180.1196]

[Page 547]

TITLE 40--PROTECTION OF ENVIRONMENT

CHAPTER I--ENVIRONMENTAL PROTECTION
AGENCY--(Continued)

PART 180--TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN FOOD--Tabl

Subpart D--Exemptions From Tolerances

Sec. 180.1196 Peroxyacetic acid; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for residues of peroxyacetic acid in or on raw agricultural commodities, in processed commodities, when such residues result from the use of peroxyacetic acid as an antimicrobial treatment in solutions containing a diluted end use concentration of peroxyacetic acid up to 100 ppm per application on fruits, vegetables, tree nuts, cereal grains, herbs, and spices.

(b) An exemption from the requirement of a tolerance is established for residues of peroxyacetic acid, in or on all raw and processed food commodities when used in sanitizing solutions containing a diluted end-use concentration of peroxyacetic acid up to 500 ppm, and applied to tableware, utensils, dishes, pipelines, tanks, vats, fillers, evaporators, pasteurizers, aseptic equipment, milking equipment, and other food processing equipment in food handling establishments including, but not limited to dairies, dairy barns, restaurants, food service operations, breweries, wineries, and beverage and food processing plants.

[65 FR 75173, Dec. 1, 2000]