Excellent Pharma Consulting
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April 23, 2020

Sharon Carlisle
U.S. Environmental Protection Agency
Office of Pesticides Programs
Division Mail Code
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

RE: Intent to Market Product Using EPA Exemption (Title 40 Part 152.10, Subpart A, §152.10(a)

Ms. Carlisle,

Excellent Pharma Consulting is the Registered Agent for Aphex BioCleanse Systems, Inc.. They have developed a product called VegAphex Fruit and Vegetable Wash which is a liquid post-harvest spray to remove waxes, pesticides, and agricultural debris from fruits and vegetables. In accordance with Title 40 CFR Part 152 Subpart A §152.10 - *Products That Are Not Pesticides Because They Are Not Intended for a Pesticidal Purpose (a) Deodorizer, bleaches, and cleaning agents*, Aphex™ BioCleanse Systems hereby provides notice of our intent to market VegAphex Fruit and Vegetable Wash.

We believe the product meets the criteria of EPA Exemption Title 40 CFR Part 152 Subpart A §152.10 because it is strictly intended to be used as a wash for produce (§152.10 *(a) Deodorizer, bleaches, and cleaning agent)*. The product is intended for final retailers and their customers.

Included you will find information to support that the product meets the aforementioned exemption.

- Information About Product / Notifier
- Draft labeling

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- Reference Documents

Excellent Pharma Consulting appreciates the Agency's consideration of this request. If I can be of further assistance, please contact me at (847) 922-2673 or via email at vgalliani@comcast.net

Regards,

Victoria Galliani

Victoria Galliani
Registered Agent for Aphex BioCleanse Systems, Inc

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Information About the Product

The product is a liquid post-harvest spray to remove waxes, pesticides, and agricultural debris. It makes no claim to treat or prevent a disease, nor does it make any germicidal claim. The product is intended for final retailers and their customers.

The composition of VegAphex is 99% electrolytic water (about 80% H_5O_2, 15% H_7O_5, 5% H_3O). The requirements for making an electrolytic solution is to use a highly dissociative chemical reactant such as a strong acid, a strong base or the salt of one of these acids or bases. This is added to an electrolytic solvent such as water which must be pure (DI, RO) so there are no contaminants or precipitates coming out of the solution. The importance of water as an active solvent is in reducing the strong attractive forces that hold solid salts and molecules together. Once the ions are released, they are stabilized by interactions with the solvent molecules.

The proprietary manufacturing process for making VegAphex is the utilization of sulfuric acid (GRAS) as an accelerant to the reaction with water. This acid-base reaction (water is the base) produces ionized (electrolytic) water, more specifically 80% H_5O_2, 15% H_7O_5, and 5% H_3O (trace amount of hydrogen sulfate) and once reacted sulfuric acid is not detectable in the final solution. The water molecule has a polar triangle structure with covalent bonding of two hydrogen atoms to one oxygen atom. Water is one of the most polar molecules known in nature. The polarity of water underlines its chemistry and thus the chemistry of life. Polar molecules interact with one another through attraction. This weak attraction is called a hydrogen bond. Since it is basically an activated form of water, it will not alter the appearance, flavor, or taste of any food. It is not a color or food additive nor is there any nutritional claims for the product.

Sulfuric acid (used in accordance with 21 CFR §184.1095) was chosen as the reactant because it is specifically listed by EPA and FDA for uses such as in the production of caramel, modified hop extract, and modified food starch, and is also prescribed as part of an approved sanitizing solution formulation (hydrogen peroxide,

peroxyacetic acid, acetic acid, sulfuric acid, and 2,6-pyridinedicarboxylic acid) for use on food-processing equipment and utensils.

Information About Notifier

The contact information for Aphex is as follows

David J. Weaver
President & CEO
585-798-7775
Aphex BioCleanse Systems, Inc.
15 Fishers Road Suite 111
Pittsford, New York 14534

Draft Label

For your convenience a copy of the label for the 8 oz product is presented. Other sizes will be available with no changes to labelling except for product volume.

Reference Document

- FDA and EPA Certifications of Electrolyzed Water.
- 21 CFR 184.1095 – Sulfuric Acid (GRAS)

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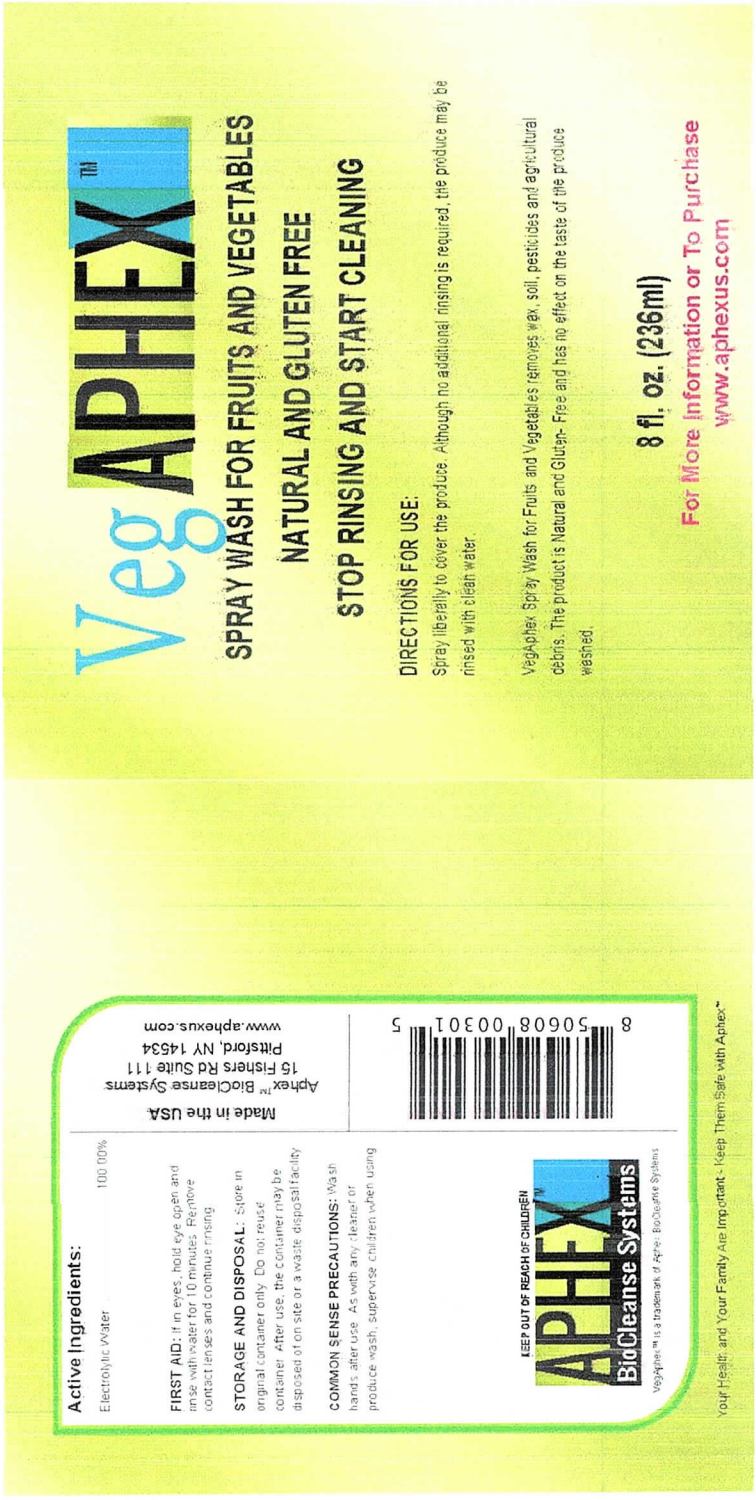
Draft Label for 8 oz. VegAphex



FDA & EPA Certifications of Electrolyzed Water

- FDA approved under 21 CFR 173.315 for direct contact with processed foods.
- FDA approved for several indirect food contact applications under 21 CFR 172.892, 21 CFR 175.105,
- FDA decision #692 allows for vegetable & fruit produce washing using Electrolyzed Water.
- FDA approved for several indirect food contact applications under 21 CFR 176.170 & 21 CFR 177.2800.
- Is an FDA approved sanitizer that meets 21 CFR 178.1010.
- FDA approved under 21 CFR 7120.1 for spray and water treatment for processing of beef, poultry & pork.
- Exempt by the EPA under 40 CFR 180.1054 for washing raw foods that are to be consumed without processing.
- Exempt by the EPA under 40 CFR 180.940 provided that the Electrolyzed Water is applied on a semi-permanent or permanent food-contact surface with adequate draining before contact with food.
- May be applied to food-contact surfaces in public eating places, dairy processing equipment, food-processing equipment and utensils.

Electrolyzed water is approved under 21 CFR 173.315 for direct contact with processed foods.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=173.315

Electrolyzed water is approved for several indirect food contract applications under 21 CFR 172.892

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=172.892

21 CFR 175.105

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=175.105

21 CFR 176.170

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=176.170

21 CFR 177.2800

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=177.2800

It is an approved sanitizer that meets 21 CFR 178.1010.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=178.1010

The EPA has also given approval (40 CFR 180.1054) for washing raw foods that are to be consumed without processing.

40 CFR 180.940. HOCL when used as ingredient in an antimicrobial pesticide formulation may be applied to: **Food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. When ready for use, the end-use concentration of all *Hypochlorous Acid* chemicals in the solution is not to exceed 200 ppm determined as Free Available Chlorine**

The Food Safety and Inspection Service (FSIS) have permitted the use in the following manner:

- Red meat carcasses down to a quarter of a carcass: 20-50 ppm (sprayed on)
- Whole or eviscerated poultry carcasses (not parts): 20-50 ppm (sprayed on)
- In-plant chlorination of water and water for formulation: 1-5 ppm
- Poultry chiller water: Up to 50 ppm (measured in incoming potable water)
- Poultry chiller red water (i.e. re-circulated & reused): Up to 5 ppm
- Reprocessing contaminated poultry carcasses: 20 ppm
- Giblets and salvage parts as influent to a container for chilling not to exceed 20 minutes: 20-35 ppm
- Antimicrobial spray for beef primals: 20 ppm

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GRAS - Sulfuric Acid

Sulfuric acid is specifically listed by FDA for use in the production of caramel, modified hop extract, and modified food starch, and is also prescribed as part of an approved sanitizing solution formulation (hydrogen peroxide, peroxyacetic acid, acetic acid, sulfuric acid, and 2,6-pyridinedicarboxylic acid) for use on food-processing equipment and utensils.

Sulfuric acid, also known as oil of vitriol, is generally recognized as safe (GRAS) when meeting the specifications of and used in accordance with §184.1095. It is used as a pH control agent and processing aid at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level of 0.014% in alcoholic beverages and 0.0003% for cheeses. There is no trace of sulfuric acid in the final solution.

CFR - Code of Federal Regulations Title 21

The information on this page is current as of April 1 2019.

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).[6]

[Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2019]
[CITE: 21CFR184.1095]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 184 -- DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.1095 Sulfuric acid.

(a) Sulfuric acid (H_2SO_4, CAS Reg. No. 7664-93-9), also known as oil of vitriol, is a clear, colorless, oily liquid. It is prepared by reacting sulfur dioxide (SO_2) with oxygen and mixing the resultant sulfur trioxide (SO_3) with water, or by reacting nitric oxide (NO) with sulfur dioxide and water.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 317-318, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.*

(c) The ingredient is used as a pH control agent as defined in 170.3(o)(23) of this chapter and processing aid as defined in 170.3(o)(24) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.014 percent for alcoholic beverages as defined in 170.3(n)(2) of this chapter and 0.0003 percent for cheeses as defined in 170.3(n)(5) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6085, Jan. 25, 1980, as amended at 49 FR 5611, Feb. 14, 1984]

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