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Intellectual Capital Associates

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20 April 2016

Program Manager, USDA/AMS/TM/NOP
Room 4008-So., Ag Stop
1400 Independence Avenue, SW
Washington, DC 20250

Attn: Ms. Jessica Walden

Dear Jessica:

This letter is written in response to your letter dated 18 April 2016 in which the Handling Subcommittee asks for written response to Item B.5 – Manufacturing Process.

1. Q. "The NOSB Handling Subcommittee believes the petition seeks listing of a process, rather than a material. If reviewed as petitioned, the HS would be reviewing several materials: sodium chlorite, zeolite acting as a carrier which is impregnated with sodium chlorite, acidic chlorine dioxide activators and related buffers."

   R. As stated above, Sodium Chlorite is the common denominator material used to generate Chlorine Dioxide. There is always the requirement to ship it to the location wherein ClO_2 is to be generated because ClO_2 cannot be shipped and is always made on site. The generating process can be liquid (using chemical reactors) or, in this case, solid impregnates. No matter the process used to generate Chlorine Dioxide, Sodium Chlorite is used as the stable precursor material and is activated to release Chlorine Dioxide by acidification.

2. Q "The Handling Subcommittee believes a petition considering sodium chlorite for the particular use of gas generation is more consistent with how other sodium chlorite materials have been reviewed. Therefore, the Handling Subcommittee asks that the petition be revised to "sodium chlorite (for generation of chlorine gas)" instead of chlorine dioxide gas. If listed, certifiers and/or material review organizations will review the sodium chlorite product and the attendant components noted above."

   R. Since Sodium Chlorite is the main precursor for the generation of Chlorine Dioxide, and Chlorine Dioxide is generated at the point of application (…it is not shipped or handled prior to that point) ICA agrees that the more appropriate designation for the material being listed would be ***"sodium chlorite for the generation of chlorine dioxide gas"*** [(1)] in lieu of "chlorine

dioxide gas" as currently listed in our application. We hereby request that our application be changed to reflect a request for description of the material to be listed as **"sodium chlorite for the generation of chlorine dioxide gas**". As we understand it, the name for the product being listed would still be "FruitGard®".

3. Q. "Additionally, the Handling Subcommittee requests the following information: As with use of other sodium chlorite materials, does produce treated with chlorine dioxide dry gas require a potable water rinse sufficient that residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act?"

   R. A common post-harvest intervention is to generate Chlorine Dioxide on site, absorb it in water and spray or inject it into produce rinses.

   When applied in water rinses, Chlorine Dioxide acts primarily on organisms and organic material in the water; yielding very little if any reductions on the produce surfaces. The reaction pathway for Chlorine Dioxide in organic laden water is generally thought to be a 1 electron transfer process; thus, very little material participates in the full 5 electron oxidizing capability. Consequently, these water systems will contain unreacted Chlorine Dioxide, chlorite ion and chlorate ion. (This is well documented in the literature regarding potable raw water treatment using chlorine dioxide gas).

   Previously, there was a concern that Chlorine Dioxide and its by-products could persist as residues on produce surfaces when rinsed by treated water. However, subsequent research has shown these by-products were not chemically bound on treated produce, and a simple water rinse could eliminate them - thus assuring compliance with safe drinking water act.

   In the case of direct gas treatment, it has been proven that ClO_2 gas rapidly reacts with produce surfaces and that residues of concern, primarily Chlorine Dioxide, or chlorite ion, do not persist [(2)]. Produce surfaces are naturally rich in reducing matter …a reactive surface that encourages a full 5 electron transfer of Chlorine Dioxide yielding the primary by-product chloride ion. Gas applications are different than water chemistry described above, and so, unlike traditional water interventions, precautionary potable rinses are not required. (see the directions page for EPA Reg. # 79814-5 and FCN 000949 - attached below).

   The unique quality of Chlorine Dioxide gas to condense on produce, kill pathogens or spoilage organisms on those surfaces, and leave behind no residues of concern makes it distinctly different and better than historical rinse methods already listed as GRAS and/or Organic.

ICA appreciates the opportunity apply for this NOP listing. Let me know if you have any questions or need further information.

Sincerely,

ICA TriNova, LLC
stevenbeers@icatrinova.com
770.883.6410

(1) In your letter the term “generation of chlorine gas” is used instead of “generation of chlorine **dioxide** gas”.
(2) Smith, *et. al.* (Contained in Exhibit 6b of this submission.)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FruitGard™ is effective for use in controlling microbiological growth such as late blight, brown rot, and others on potatoes during storage and shipment.

The following directions explain the activation and use of these granules for treating potatoes. FruitGard™ is designed to release chlorine dioxide (ClO_2) gas. Treatment **MUST** take place in a suitable enclosed space. Two such treatment sites are Storage Rooms and Shipping Containers. Personnel **MUST** vacate the treatment space during the fumigation process until chlorine dioxide levels are at or below the OSHA 0.1 ppm TWA level.

Prior to application on potatoes, this product must be activated. Acid activation is intended to increase the release rate of chlorine dioxide from the FruitGard™. Activation may be accomplished by adding liquid or solid acid activators. Activate FruitGard™ material only at the point of application.

ACTIVATE IN A WELL-VENTILATED AREA. AVOID BREATHING FUMES.

DO NOT combine or mix acidifiers and FruitGard™ in unapproved or non-vented containers. Trapped chlorine dioxide gas may decompose and overpressure the container or release heat and cause fire.

The amount of FruitGard™ required for a given weight of potatoes can be calculated as follows:

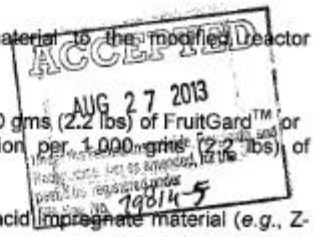
Total wt of Potatoes	Amount FruitGard™ Required
1 kg	1 gm
1 metric ton (1,000 kg)	1 kg
1 cwt (100 lbs)	1.6 oz
1 U.S. ton (2,000 lbs)	32 oz (2 lbs)

Treatment Procedure:

1. Place the required amount of FruitGard™ into a suitable modified reactor. A modified reactor can be the breathable sachets provided with the FruitGard™, or a plastic container (Clamshell, box, pail, *etc.*) with a porous cover (such as Tyvek®) that allows for the release of ClO_2 gas. For very large quantities, use of multiple reactors is recommended.

2. Add the recommended amount of acid activator material to the modified reactor containing the FruitGard™ as shown below:

   a) Liquid food grade acid:
      i. Add 1 once of 50 wt% citric acid solution per 1,000 gms (2.2 lbs) of FruitGard™ or
      ii. Add ½ once of 75 wt% phosphoric acid solution per 1,000 gms (2.2 lbs) of FruitGard™.
   b) Solid Acid Impregnate:
      i. Mix equal amounts of FruitGard™ and the solid acid impregnate material (*e.g.*, Z-Series™ ZF or ZPA).



3. Mix the materials by shaking or stirring gently. FruitGard™ will become active once mixed and begin releasing chlorine dioxide gas.

4. Immediately place reactor vessel / modified reactor in the Storage Container holding the potatoes, preferably on top of the potatoes to be treated. Close the Storage Container.

5. Allow gas to freely migrate across the potatoes' surface for a minimum of 6 hours.

FCN No. 949

ICA TriNova, LLC

According to Section 409(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act, food contact substance notifications (FCNs) are effective only for the listed manufacturer and its customers. Other manufacturers must submit their own FCN for the same food contact substance and intended use.

Food Contact Substance:	Chlorine Dioxide (CAS Reg. No. 10049-04-4).
Notifier:	ICA TriNova, LLC
Manufacturer:	ICA TriNova, LLC
Intended Use:	As an antimicrobial agent for fumigating raw fruits and vegetables
Limitations/Specifications*:	The level of chlorine dioxide in the surrounding air will not exceed 3 ppm. This FCN is not applicable to usage of the FCS in the field, in facilities that only handle raw agricultural commodities, or in transportation from the field to such facilities.
Effective Date:	Mar 2, 2010
National Environmental Policy Act (NEPA) Submission:**	Environmental Assessment (in PDF)[6] (973 kB)
FDA Decision:	Finding of No Significant Impact (FONSI)[7]