



Health
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Santé
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Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

Bureau of Chemical Safety
251 Sir Frederick Banting Driveway
Postal Locator: 2201C
Ottawa, Ontario
K1A 0K9

November 26, 2013

Our Files: IS13041201/02, IS13041209
to IS13041216 & IP13101701

RE: **Viriditec Sanitation Solution – VSS 1.0**
Viriditec Sanitation Solution – VSS 3.0
Viriditec Sanitation Solution – VSS 3.1
Viriditec Sanitation Solution – OSS 1.0
Viriditec Sanitation Solution – VIS Industrial System
Viriditec Sanitation Solution – OSS Industrial System
Viriditec Sanitation Solution – VSS Sterilant Cabinet
Viriditec Sanitation Solution – Maid Cart
Viriditec Sanitation Solution – Environmental Cart
Viriditec Sanitation Solution – ADU

This is in reference to your submissions dated October 12, 2012 sent to the Canadian Food Inspection Agency (CFIA) wherein you are seeking the acceptability of the subject products to be used as ozone generating devices to ozonate water for the purpose of sanitizing and disinfecting hands and hard food contact surfaces in Federally Registered Food Establishments. The CFIA has forwarded your submissions to our Bureau on April 8, 2013 and requested us to assess the safety of these products. This is also in reference to your status requests dated May 23 and November 13, 2013 and to the letter of Robert de Valk of October 15, 2013 wherein he provided additional information for our evaluation.

Please be advised that the Additives and Contaminants Section of this Division will send their comments to your office separately regarding the use of these products on food surfaces (Fruits and vegetables, poultry, red meat carcass, fish and shell eggs).

For the use of the subject products as incidental additives and specific to the applications listed below, our comments are:

General Cleaners
Drain Cleaners

Based on the information provided, we can advise that we see no reason to object to the use of products to clean food contact surfaces in food plants provided that:

- a) They are used as directed by the manufacturer of the ozone generating device at a maximum level of 2.5ppm of ozone in the water;
- b) Prior to cleaning with the ozonated water, surfaces are cleaned with an acceptable detergent and thoroughly rinsed with a potable water rinse; and
- c) After use, hard surfaces are thoroughly rinsed with potable water before their re-use.

Sanitizers of packaging materials
Microbial control agents for use Can Cooling Water

Based on the information on hand, we can advise that we have no reason to object to the use of the ozonated water to sanitize food packaging materials and cans provided that:

- a) They are used as directed by the manufacturer of the ozone generating device at a maximum level of 2.5ppm of ozone in the water; and
- b) Treated surfaces are thoroughly drained in order to maintain the amount of residual ozone to a negligible level.

Deodorizers for food handling environment
General use Disinfectants
General use Sanitizers

As a general rule, a good sanitation and disinfection must always begin with an effective cleaning of the surface to be treated followed by a thorough potable water rinse; as the presence of organic deposits from food residues (oils, grease and proteins) can lower the effectiveness of any disinfectant or sanitizer.

Because, ozone is a very strong oxydizing agent and the presence of organic matter may generate unwanted by-products with undesirable health effect. Therefore, food contact equipment and other hard food contact surfaces must be cleaned first and rinsed with potable water before the ozonated water sanitation or disinfection can proceed.

Based on the information on hand, we can advise that we have no reason to object to the use of the ozonated water to sanitize and disinfect hard food contact surfaces provided that:

- a) They are used as directed by the manufacturer of the ozone generating device at a maximum level of 2.5ppm of ozone in the water;
- b) Prior to treatment, hard food contact surfaces are cleaned with an acceptable detergent and thoroughly rinsed with a potable water rinse; and

- c) Treated surfaces are thoroughly drained prior to re-use in order to maintain the amount of residual ozone to a negligible level.

Notwithstanding the above, as a disinfectant claim is made regarding these products, your company must contact the Office of submission and Intellectual Property for DIN registration of these products at the following address.

Office of Submission and Intellectual Property
Therapeutic Products Programme
Health Canada
A.L. #0201A1
Finance Building
Tunney's Pasture
Ottawa, Ontario
K1A 1B9
Tel: (613) 941-0838 or (613) 941-0839
Fax: 613-941-0825

Hand Disinfectants
Hand dip sanitizers
Hand Sanitizers

Based on the information on hand, we can advise that we have no reason to object to the use of the ozonated water to sanitize and disinfect hard food contact surfaces provided that:

- a) They are used as directed by the manufacturer of the ozone generating device at a maximum level of 2.5ppm of ozone in the water;
- b) Prior to treatment, hands are cleaned with an acceptable detergent and thoroughly rinsed with a potable water rinse; and
- c) Treated hands are thoroughly drained and dried prior to handling food in order to maintain the amount of residual ozone to a negligible level.

Because of their therapeutic effects on skin (preventing or controlling diseases by reduction of organisms on skin), your company must contact the Therapeutic Products Directorate (TPD) to ensure the safety and efficacy of antiseptic products. The TPD is responsible for the mandatory pre-market assessment of human-use antiseptic products.

Please find their address below.

Manager
Non-prescription Drug Evaluation Division
Therapeutic Drug Directorate (TPD)
101 Tunney's Pasture Driveway
Address Locator: 0201A1
Ottawa, Ontario
K1A 0K9

Fax: (613) 941-0825
email: sipd-submissions@hc-sc.gc.ca

Hand Cleaners

Based on the information provided, we can advise that we see no reason to object to the use of products to clean the hands of the employees handling food products in food plants provided that:

- a) They are used as directed by the manufacturer of the ozone generating device at a maximum level of 2.5ppm of ozone in the water;
- b) Prior to cleaning with the ozonated water, hands are cleaned with an acceptable detergent and thoroughly rinsed with a potable water rinse;
- c) After use, hands are thoroughly rinsed with potable water before handling food in the plant.; and
- d) As the subject products have a human skin application, your company receives a favourable opinion from the Cosmetic Division, Consumer Product Safety Bureau of Health Canada for cosmetic notification to ensure the safety of the products on the skin. Please find their address below:

Notification Officer
Cosmetics Division
Consumer Product Safety Bureau
A.L. # 3504D
123 Slater Street,
Ottawa, ON, K1A 0K9
Fax: 613-952-3039

Non-food handling areas cleaners

Personal Hygiene Cleaners

Water treatment compounds (where the treated water or the steam produced will not come in direct contact with food products)

The above-noted applications of the products fall within the exempted products as listed in the Food Directorate Guidelines (No.4) for Incidental Additive Submissions. Therefore, they do not require our evaluation for use as proposed in food processing plants.

Although these exempted products are not subject to our review, it is expected that:

- a) the products are properly labelled;
- b) the products will not be used and stored in food handling areas; and
- c) the use of the product will not directly or indirectly contaminate food products during their uses.

We trust that the foregoing will be of use to you.

Yours truly,

A handwritten signature in blue ink, appearing to read "Amina Badar". The signature is stylized with a large initial "A" and a long horizontal stroke.

Amina Badar
Scientific Evaluator
Food Packaging Materials and
Incidental Additives Section
Chemical Health Hazard Assessment Division

cc. CFIA