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Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

Bureau of Chemical Safety
Food Directorate, Health Canada
251 Sir Frederick Banting Drwy
Postal Locator: 2201C
Ottawa, Ontario, K1A 0K9, Canada

June 6, 2018

Our file: IP12100101

X-ref: IS12053002 & IS12090601

Teri Dickinson Jenner
Manager, Regulatory Affairs Group
Dell Tech Laboratories Ltd.
100 Collip Circle, Suite 220
London, ON N6G 4X8

Dear Ms. Dickinson Jenner,

RE: Lotus PRO LQFC425K and Lotus PRO LQFC825K

This is in response to your e-mail of March 26, 2018, wherein you submitted additional information and clarification on the subject products for use ozonated solutions in food processing establishments on behalf of Tersano Inc.

The subject Lotus PRO devices are used to produce ozonated solution to make up to **2 ppm** ozone to sanitize food contact surfaces in food processing establishments.

Based on the submitted and above-mentioned information, we see no reason to object to the use of the **ozonated solution** to sanitize hard food contact surfaces in food processing establishments, provided that:

- a) the units are installed, applied by qualified personnel and used as directed by the manufacturer of the ozone generating devices at the concentration up to 2 ppm of ozone in the water;
- b) prior the sanitizing process, food contact surfaces are pre-cleaned by ozonated water and wiped with microfiber cloth (or paper towel) to remove visible residues, as stated on the label;
- c) the surfaces are hard and non-porous in nature and thoroughly drained prior to being loaded with food to maintain the residual amount of ozone on food contact surfaces to a *negligible* level;
- d) prior to application (spraying) of the sanitizer in food handling areas, all food should either be removed from the vicinity or otherwise protected from the spray;
- e) this is used under well-ventilated conditions in the plant where there will be no accumulation of ozone in food processing areas; and
- f) regular inspection/monitoring should be put in place to ensure that the ozone-emitting device must not generate ozone in the air, incidental to their normal operation, at a maximum level of 0.05 ppm, and no extraneous emissions of an undesirable nature are being released into the food-processing environment.

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Concerning the submitted label, we recommend the following information to be added to the label:

- The maximum concentration of ozone in ozonated solution produced by the devices.
- A cautionary statement such as “Avoid contamination of food during application and storage”.

As the submitted label contains microbiological claims against *E. coli*, etc., please note that our review relating to the use of these products in food packaging applications has a food safety focus only, and this letter is not an opinion regarding the antimicrobial efficacy related to the products, and it is not an opinion regarding the acceptability of the products and their use with respect to occupational health and safety, which, in general, is subject to provincial and territorial oversight.

The hazard associated with the human exposure to ozone is under the jurisdiction of the provincial authority concern. For workplace health and safety in Ontario you intend to notify the Ontario provincial health authorities about the proposed application of ozone.

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

Yours truly,

A handwritten signature in blue ink, appearing to read 'E. Emelianova', written in a cursive style.

Elena Emelianova, Ph.D.
Scientific Evaluator
Food Packaging Materials and
Incidental Additives Section
Chemical Health Hazard Assessment Division