



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
Tunney's Pasture
1st floor East, AL: 2201 C
Ottawa, Ontario
K1A 0K9

December 30, 2009

Our file: IS09031302

Your file: K188

Bernard Dallaire
Acting, Technical Program Officer
Canadian Food Inspection Agency
Non-Food Chemicals & Container Integrity
Food Safety Risk Analysis Unit
ADRI – Food Safety Directorate
1400 Merivale Road, P.L. T2-4G
Ottawa, Ontario
K1A 0Y9

JAN 11 2010

Dear Mr. Dallaire:

RE: TidyFoam Antibacterial Hand Soap

This is in reference to your letter of March 2, 2009, concerning a submission made by Kutol Products Company seeking acceptance for use of the subject product in Federally Registered Food Establishments.

Based on additional information submitted on the subject product, we can advise that we see no reason to object to its use as a **hand cleaner** by the employees handling food products in food plants provided that:

- a) there will be no contamination of food as a result of its use;
- b) after use, hands are thoroughly **rinsed with potable water** before handling food in the plant, as specified on the label; and
- c) the product will not leave any residual fragrance on the hands of employees handling food.


We recommend a cautionary statement as in a) above or "Avoid contamination of food during application and storage" to be added to the label of the subject product.

It should be noted that under "Directions" on the labels of these products, it is written that the products are intended to be used "*to decrease bacteria on skin*". According to our current guideline, human-use antiseptic products used in food premises and having therapeutic effect (preventing or controlling diseases by reduction of organisms on skin) is considered to be a drug under *Food and Drugs Act*. Such application is under consideration of the Therapeutic Products Directorate. Therefore, our comments above are only valid if the company contacts the Therapeutic Products Directorate (TPD), Nonprescription Drug Evaluation Division for their evaluation by the following address:

Nonprescription Drug Evaluation Division
Therapeutic Product Directorate (TPD)
101 Tunney's Pasture Driveway
Address Locator: 0202A
Ottawa, Ontario
K1A 0K9
Tel: 613-954-6740 & 613-941-2510
Fax: 613- 946-9614

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

Yours truly,



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