



Part IV Section B: ENVIRONMENTAL ASSESSMENT

1. Date:

September 29, 2004

2. Name of Notifier:

Lonza Inc.

3. Address:

Lewis & Harrison, 122 C Street, NW Suite 740, Washington, DC 20001

4. Description of the Proposed Action:

This Food-Contact Substance (FCS) Notification requests the use of benzethonium chloride used as an antibacterial agent in no-rinse antimicrobial hand sanitizers that are used by food handlers. The benzethonium chloride will be added to hand sanitizer formulations at a minimum application rate of 0.2%.

The benzethonium chloride will be used throughout the United States by formulators of antimicrobial no-rinse antimicrobial hand sanitizers. The no-rinse hand sanitizers containing benzethonium chloride will be used nationwide by food-handling establishments.

5. Identification of the Food-Contact Substance:

Chemical Name

- Diisobutyl(phenoxy)ethoxy)ethyl)dimethylbenzylammonium

Common/Trade Name

- Benzethonium Chloride USP

CAS Registry Number

- 121-54-0

Molecular Weight

- 448.1

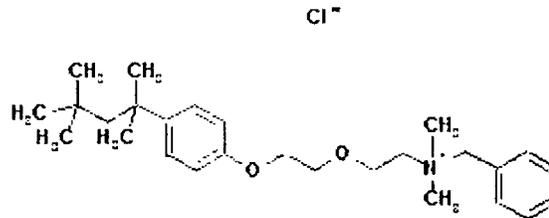
Chemical Formula

- C₂₇H₄₂ClNO₂

Impurities



Structure



Chemical/Physical Properties

Properties	Values
Specific gravity	1.25 @ 25 °C
Solubility	135 g/L (Very soluble in water giving
pH	6.0 – 7.5
Stability	Stable
Physical State	Solid (Powder)
Color	White
Melting Point	164-166 °C (hot stage)

6. Environmental Consequences of the Proposed Action:

a. Production of the food contact substance

This information is not being provided since there are no extraordinary circumstances that apply to the manufacture of benzethonium chloride.

b. Use and disposal of the food contact substance

The action involves a component of no-rinse antimicrobial hand sanitizers, at less than 0.2% by weight of the finished product. The no-rinse antimicrobial hand sanitizers are applied directly to the hands of workers in food-handling establishments prior to any contact with food items. The transfer rate of benzethonium chloride from the hands to the food during contact is calculated to be $4.16 \mu\text{g}/\text{cm}^2 \text{ hr}$. When used as intended in no-rinse antimicrobial hand sanitizers, benzethonium chloride would, therefore, have a negligible release to the environment. The only routes of possible environmental introduction of benzethonium chloride would be: (1) some portion of the food-contact substance and its degradation products would stay on the hands and at some point the hands would be washed, causing the food-contact substance to go to the wastewater treatment plant; (2) some of the food contact substance and its degradation products would transfer to the food and would subsequently be washed away or consumed with the food; and, (3) some amount of the food-contact substance and its degradation products would transfer to the food-contact materials which may be disposed of in municipal solid waste combustors or in landfills. These three routes would introduce only a negligible amount of food-contact substance and its degradation products into the environment. These disposal routes are also governed by EPA regulations in 40 CFR Parts 60 (for combustors) and Part 258 (for landfills). Based on the negligible levels of benzethonium chloride on the food packaging material, the introduction of combustion products or introductions at landfill sites are not environmentally significant. Therefore, we do not expect that any limited increases in environmental introductions resulting from the proposed action will threaten a violation of EPA's regulations governing combustors and landfills or have any other adverse environmental effect.

Benzethonium chloride concentrate is also registered with the U.S. Environmental Protection Agency (USEPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Lonza, Inc. is the registrant, and the USEPA Registration Number is 6836-97. According to the label approved under FIFRA, the product is intended for the formulation of antimicrobial products for many uses, including food handling/storage establishment premises. The label also states, "Do not discharge effluent containing this product into waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority."

7. Alternatives to the Proposed Action:

Alternatives to the proposed action need not be considered because no potential adverse effects have been identified.

8. List of Preparers:

This EA was prepared for Lonza Inc. by Wendy McCombie of Lewis & Harrison. Ms. McCombie has a B.S. degree in Biology from the Gettysburg College and over twelve years of experience in the regulatory field.

9. Certification:

The undersigned official certifies that the information presented is true, accurate, and complete to the best knowledge of Lonza Inc.

Name: Eliot I. Harrison

Title: Agent for Lonza, Inc.

Signature:

Date: September 29, 2004