

HAND SANITIZER- benzalkonium chloride liquid
Sanit Technologies LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

1000ml Hand Sanitizer Kidney Refill

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antiseptic

Warnings

- **For external use only.**
- **Keep out of eyes. In case of contact, flush eyes with water.**
- **Stop use and consult a doctor** if irritation or redness develops.

Uses

- To decrease bacteria on the skin.

Directions

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

Keep out of reach of children.

- If swallowed, get medical help or contact a Poison Control Center immediately.

Inactive ingredients:

water, cetrimonium chloride, laurtrimonium chloride, dihydroxyethyl cocamine oxide, glycereth-17 cocoate, propylene glycol, diazolidinyl urea, methyl paraben, propyl paraben, citric acid, dihydroxypropyl PEG-5 linoleammonium chloride.

Product Label



7810 25th Court East Unit 106,
Sarasota, Florida 34243
941-351-9114
www.DURISAN.com

Die Line Request
Front - 1000 mL 0.4
Rev. 2020 A
08/14/20

DIE LINE

TEXT AREA

BLEED LINE





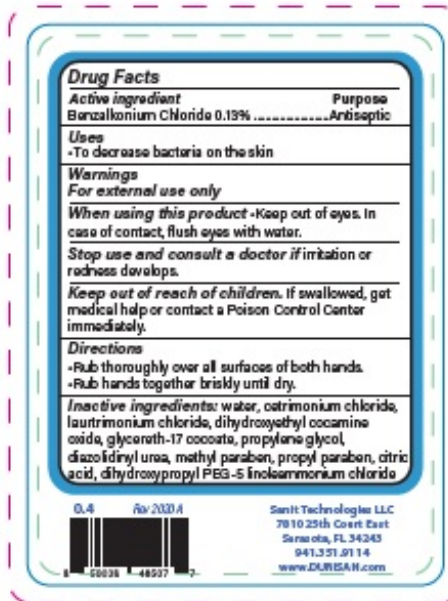
7810 25th Court East Unit 106,
Sarasota, Florida 34243
941-351-9114
www.DURISAN.com

Die Line Request
Back - 1000 mL 0.4
Rev. 2020 A
08/14/20

DIE LINE

TEXT AREA

BLEED LINE



HAND SANITIZER

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71120-113
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
LAURTRIMONIUM CHLORIDE (UNII: A81MSI0FIC)	

DIHYDROXYETHYL COCAMINE OXIDE (UNII: 8AR51R3BL5)	
GLYCERETH-17 COCOATE (UNII: 3057VPT0KC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIHYDROXYPROPYL PEG-5 LINO LEAMMONIUM CHLORIDE (UNII: 0Y0NQR2GH1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71120-113-01	1000 mL in 1 PACKAGE; Type 0: Not a Combination Product	10/06/2020	
2	NDC:71120-113-02	6 in 1 PACKAGE	10/06/2020	
2		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/05/2020	

Labeler - Sanit Technologies LLC (075711022)

Establishment

Name	Address	ID/FEI	Business Operations
Durisan		085479946	manufacture(71120-113)