GUARDEX SANITIZING HAND- benzalkonium chloride lotion
Nile Hudson 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.

GUARDEX
2 IN 1 SANITIZING HAND LOTION
ORANGE ZEST

Active Ingredients

Benzalkonium Chloride 0.095%

Purpose

Antiseptic

Uses

For hand cleaning reduce bacteria that potentially can cause disease and moisture your hands.

Warnings

For external use only

Stop use and ask a doctor

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

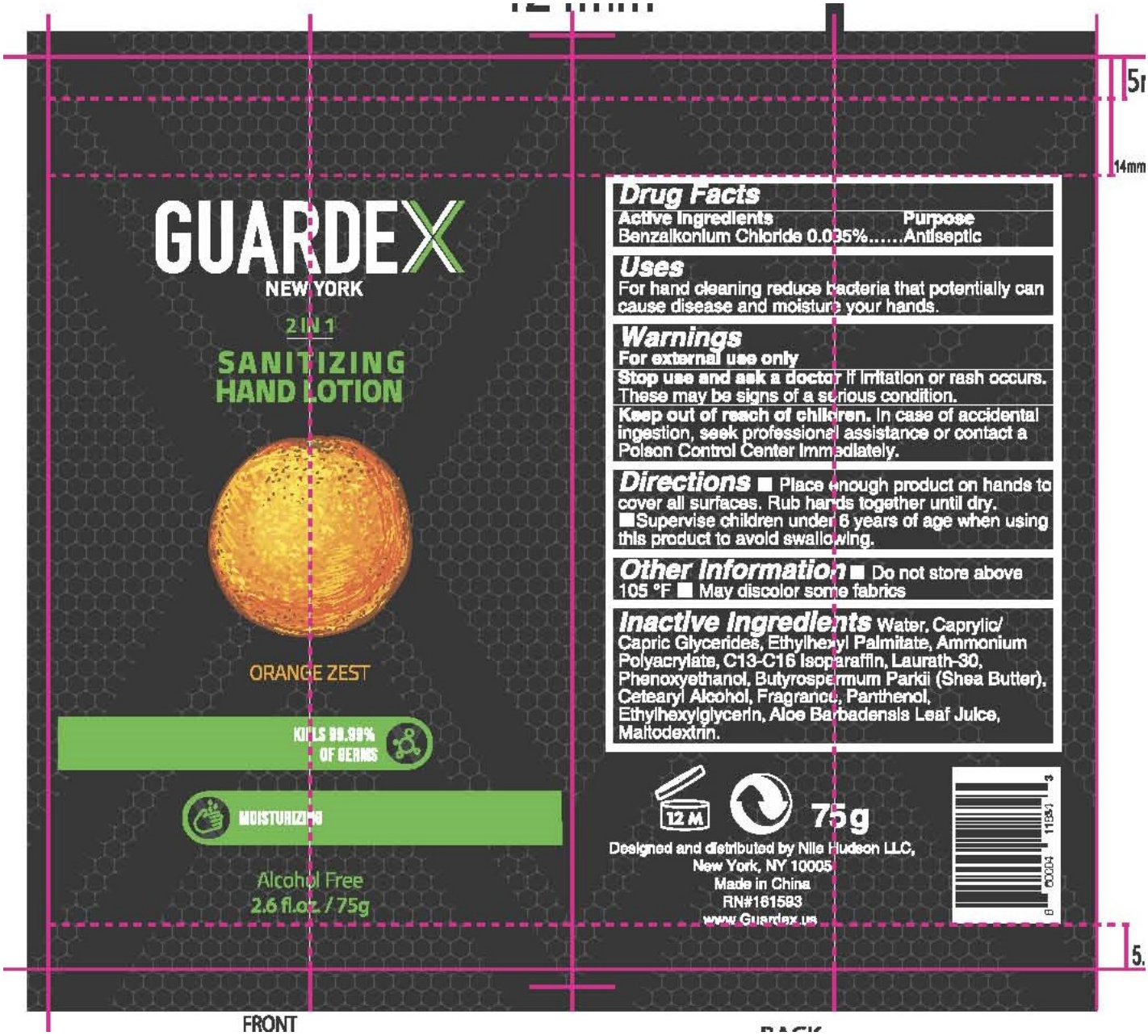
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

- Do not store above 105 °F
- May discolor some fabrics

Inactive Ingredients

Water, Caprylic/Capric Glycerides, Ethylhexyl Palmitate, Ammonium Polyacrylate, C13-C16 Isoparaffin, Laurath-30, Phenoxyethanol, Butyrospermum Parkii (Shea Butter), Cetearyl Alcohol, Fragrance, Panthenol, Ethylhexylglycerin, Aloe Barbadensis Leaf Juice, Maltodextrin.



GUARDEX SANITIZING HAND

benzalkonium chloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81353-026
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.95 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SHEA BUTTER (UNII: K49155WL9Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
LAURETH-30 (UNII: W9D845551A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
C13-16 ISOPARAFFIN (UNII: LED42LZG6O)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PANTHENOL (UNII: WV9CM0O67Z)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81353-026-01	76.89 mL in 1 TUBE; Type 0: Not a Combination Product	12/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/26/2020	

Labeler - Nile Hudson LLC (129371101)

Revised: 12/2020 Nile Hudson LLC