STAY SAFE HAND SANITIZER ALCOHOL FREE- benzalkonium chloride gel
Denison Pharmaceuticals, 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.

Active ingredient

Benzalkonium Chloride 0.13%

Purpose

Antimicrobial

Uses:

- For hand sanitizing to decrease bacteria and viruses on the skin
- Recommended for repeated use

Warnings

For external use only

When using this product avoid contact with eyes. In case of contact flush eyes with water.

Stop use or ask a doctor if irritation or redness develops or if condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

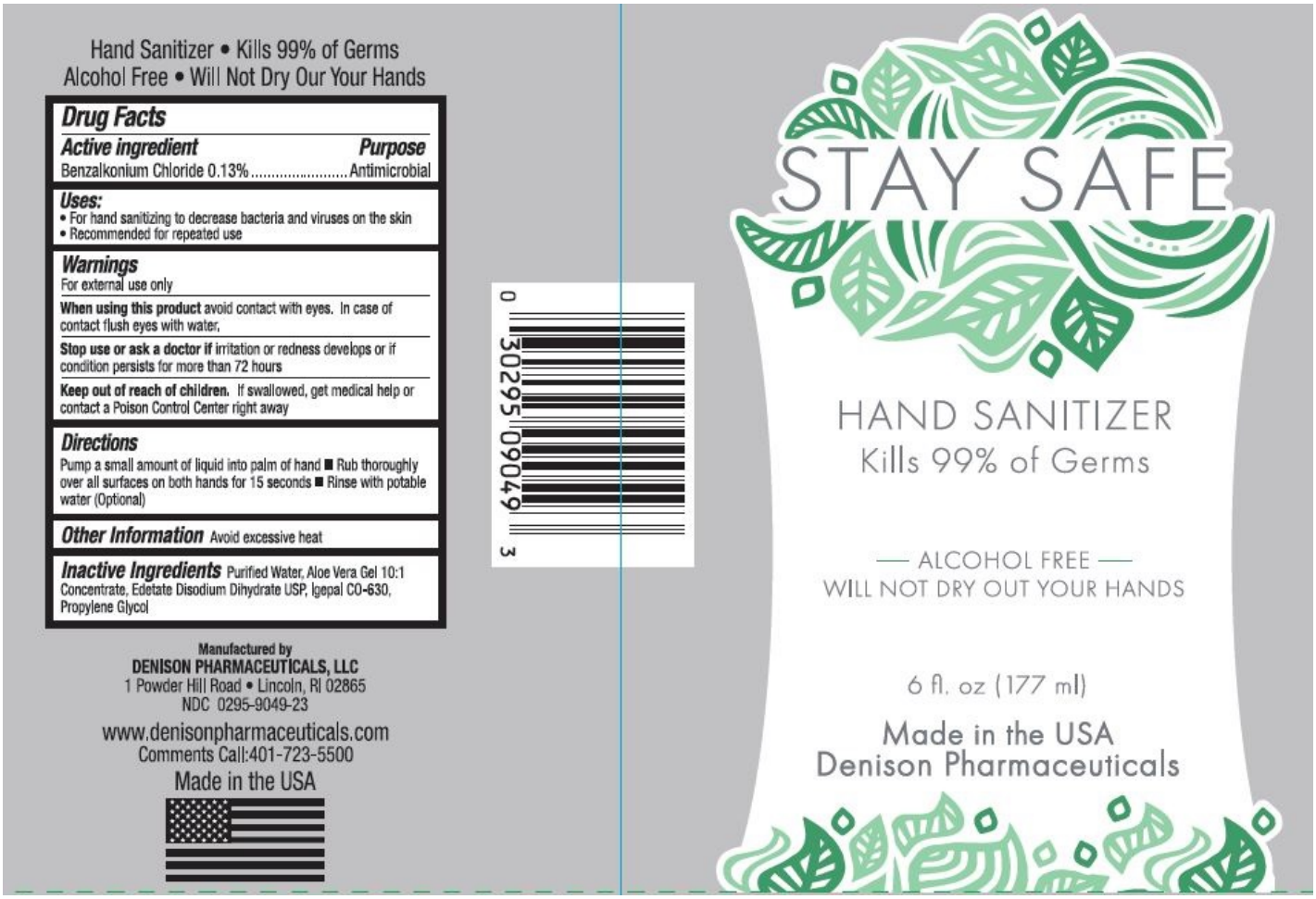
Pump a small amount of liquid into palm of hand • Rub thoroughly over all surfaces on both hands for 15 seconds • Rinse with potable water (Optional)

Other Information

Avoid excessive heat

Inactive Ingredients

Purified water, Aloe Vera Gel 10:1 Concentrate, Edetate Disodium Dihydrate USP, Igepal CO-630, Propylene Glycol



STAY SAFE HAND SANITIZER ALCOHOL FREE

benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0295-9049
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0295-9049-23	177.441 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2020	

Labeler - Denison Pharmaceuticals, LLC (001207208)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	manufacture(0295-9049)

Revised: 4/2020 Denison Pharmaceuticals, LLC