AMERICAN HAND SANITIZER- benzalkonium chloride spray American Hand Sanitizer, 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.

Benzalkonium Chloride 0.13%

Anitseptic

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 eye contact, flush eyes with water.

Stop it and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.

Keep out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Read the entire label before using this product.

Pump a small amount of liquid into palm of hand.

Rub thoroughly over all surfaces of both hands for 15 seconds.

Glycerin, Hydrogen Peroxide, Water

Ouestions?

1-866-443-4509



AMERICAN HAND SANITIZER

benzalkonium chloride spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79421-001	
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 g in 1 mL		

Inactive Ingredients				
Ingredient Name	Strength			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)				
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:79421-001- 01	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/13/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	05/18/2017			

Labeler - American Hand Sanitizer, LLC (117295138)

Establishment				
Name	Address	ID/FEI	Business Operations	
Denison Pharmaceuticals, LLC		001207208	manufacture(79421-001)	

Revised: 8/2020 American Hand Sanitizer, LLC