KOSETTE CARE HAND SANITIZER ALCOHOL-FREE- benzalkonium chloride gel Innovation Labs, Inc.

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.

Kosette CARE Hand Sanitizer 65 mL

Active Ingredient

Benzalkonium Chloride 0.11%

Purpose

Antimicrobial

Uses

- To decrease bacteria on skin when soap and water is not available.
- Recommended for repeated use.

Warnings

- For external use only.
- **When using this product** avoid contact with eyes. In case of contact with eyes, flush thoroughly with water.
- **Stop use and ask a doctor if** skin irritation or redness develops and lasts.
- **Keep out of reach of children**. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product in your palm to thoroughly cover your hands. Rub hands together until dry.
- Children under 6 years should be supervised when using this product.

Other information

- Read the directions and warnings before use.
- Store in a cool, dry and well-ventilated place.

Inactive ingredients

water(aqua), butylene glycol, propanediol, acrylates/c10-30 alkyl acrylate crosspolymer, caprylhydroxamic acid, caprylyl glyceryl ether, polyglyceryl-4 caprate, polyglyceryl-6 caprylate, potassium hydroxide, maltodextrin, moringa oleifera seed extract, frangrance(parfum)

Package Label - Principal Display Panel

Kosette

CARE

HAND SANITIZER

KILLS 99.9% OF GERMS

ALCOHOL-FREE

Safe for all, our gentle formula effectively disinfects hands while retaining skin's natural moisture leaving it soft and smooth.

2.2 fl.oz / 65 ml





Drug Facts (continued)

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Warnings For external use only.

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Directions

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Other Information

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Inactive Ingredients

Water(Aqua), Butylene Glycol, Propanediol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Caprylhydroxamic Acid, Caprylyl Glyceryl Ether, Polyglyceryl-4 Caprate, Polyglyceryl-6 Caprylate, Potassium Hydroxide, Maltodextrin, Moringa Oleifera Seed Extract, Fragrance(Parfum)



www.KosetteCare.com

KOSETTE CARE HAND SANITIZER ALCOHOL-FREE

benzalkonium chloride gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:73284-420 Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength BENZALKO NIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM UNII:7N6 JUD5X6 Y) BENZALKONIUM CHLORIDE 0.0011 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
CAPRYLHYDRO XAMIC ACID (UNII: UPY805K99W)		
MORINGA OLEIFERA SEED OIL (UNII: REM6 A5QMC0)		
CAPRYLYL GLYCERYL ETHER (UNII: MI97BW74XZ)		

POLYGLYCERIN-6 (UNII: M51422LRAM)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
WATER (UNII: 059QF0KO0R)	
PROPANEDIOL (UNII: 5965N8W85T)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
POTASSIUM HYDRO XIDE (UNII: WZH3C48 M4T)	
POLYGLYCERYL-4 CAPRATE (UNII: 3N873UN885)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	

Packaging				
# Item Cod	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:73284-4	0- 65 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	07/01/2020				

Labeler - Innovation Labs, Inc. (117109069)

Establishment					
Name	Address	ID/FEI	Business Operations		
Innovation Labs, Inc.		117109069	manufacture(73284-420)		

Revised: 7/2020 Innovation Labs, Inc.