BNC HAND SANITIZER ANTISEPTIC- alcohol gel BNC KOREA CO., Ltd.

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

Alcohol 80% v/v.

Purpose

Antiseptic

Uses

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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

Directions

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

Other information

Store between 15-30 $^{\circ}$ C (59-86 $^{\circ}$ F) Avoid freezing and excessive heat above 40 $^{\circ}$ C (104 $^{\circ}$ F)

Inactive ingredients

Aloe vera leaf, Butylene glycol, Carbomer, Glycerin, 1,2-hexanediol, Purified water USP, Trolamine **Questions?** CALL 213-462-9955

Package Label - Principal Display Panel

Label 100 mL

BnC

Hand Sanitizing Antiseptic Gel With Moisturizing Formula



Label 300 mL



Label 500 mL



BNC HAND SANITIZER ANTISEPTIC

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78419-002	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
GLYCERIN (UNII: PDC6A3C0OX)			
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
TROLAMINE (UNII: 9O3K93S3TK)			
1,2-HEXANEDIO L (UNII: TR0 46 Y3K1G)			

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:78419-002- 01	100 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2020		
2	NDC:78419-002- 02	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020		
3	NDC:78419-002- 03	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/01/2020		

Labeler - BNC KOREA CO., Ltd. (694074732)

Establishment					
Name	Address	ID/FEI	Business Operations		
BNC KOREA CO., Ltd.		694074732	manufacture(78419-002)		

Revised: 6/2020 BNC KOREA CO., Ltd.