ZETTA ULTRA-GEL HAND SANITIZER- alcohol gel DBK 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.

Zetta Ultra-gel Hand Sanitizer

Active Ingredient(s)

Alcohol 79% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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.

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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

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Carbomer 940, Trolamine, Glycerin, Butylene Glycol, Aloe, Dexpanthenol, Alpha-tocopherol,

185x90



500 mL NDC: 74170-003-01

ZETTA ULTRA-GEL HAND SANITIZER alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74170-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	79 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
TROLAMINE (UNII: 9O3K93S3TK)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
WATER (UNII: 059QF0KO0R)		
CARBOMER 940 (UNII: 4Q93RCW27E)		

GLYCERIN (UNII: PDC6A3C0OX)		
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)		
ALOE (UNII: V5VD430 YW9)		
DEXPANTHENOL (UNII: 106C93RI7Z)		
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0 FE3FX)		
HYALURO NIC ACID (UNII: S270 N0 TRQY)		

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:74170-003- 01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/09/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	06/09/2020		

Labeler - DBK Korea Co., Ltd. (687907394)

Registrant - DBK Korea Co., Ltd. (687907394)

Establishment				
Name	Address	ID/FEI	Business Operations	
DBK Korea Co., Ltd.		687907394	manufacture(74170-003)	

Revised: 6/2020 DBK Korea Co., Ltd.