V FREE HAND SANITIZER- alcohol gel KUMSUNG ENC 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.

80138-202

Active ingredient

Alcohol 70%

Purpose

Antiseptic

USE

Hand Sanitizer to help reduce bacteria on the skin. For use when soap and water are not available.

WARNINGS

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

Do not use

- on infants less 2months of age
- on open skin wounds

When using this product

keep away from 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 until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

OTHER INFORMATION

- Store between 1~30[(33.8~86[))
- Avoid freezing and excessive heat above 40 (104)

INACTIVE INGREDIENTS

glycerin, 1,3-butylene glycol, carbomer940, triethanol amine, purified water USP

Package Label



DRUG FACTS

Active ingredient[s] Purpose
Alcohol 70% v/v Antiseptic



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INACTIVE INGREDIENTS glycerin, 1,3-butylene glycol, carbomer940, triethanol amine, purified water LISP

MANUFACTURER

KUMSUNG ENC CO., LTD. +82-1577-4546

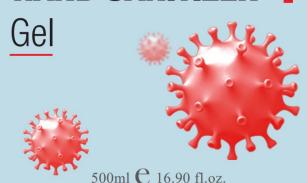
44 mokane-ro, Danwon-gu, Ansna-si, Gyeonggi-do, South Korea







V FREE HAND SANITIZER®—



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V FREE HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80138-202	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
TROLAMINE (UNII: 903K93S3TK)			
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:80138-202- 01	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2020		
NDC:80138-202- 02	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/25/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	08/25/2020		

Labeler - KUMSUNG ENC CO., LTD (688082226)

Registrant - KUMSUNG ENC CO., LTD (688082226)

Establishment				
Name	Address	ID/FEI	Business Operations	
KUMSUNG ENC CO., LTD		688082226	manufacture(80138-202)	

Revised: 8/2020 KUMSUNG ENC CO., LTD