

UPW 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.

80138-203

ACTIVE INGREDIENT

Alcohol 58%

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 from heat or flame

Do not use

- on infants less 2 months 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°C(33.8~86°F)
- Avoid freezing and excessive heat above 40°C(104°F)

INACTIVE INGREDIENTS

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

PACKAGE LABEL

Bacteria & Virus
99.999% Sanitize

Bacteria ZERO Premium

UPW HAND SANITIZER +

200ml e 6.76 fl.oz.

DRUG FACTS

Activ ingredient[s]	Purpose
Alcohol 58% v/v	Antiseptic

USE[s]

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 from 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°C(33.8~86°F)
- Avoid freezing and excessive heat above 40°C(104°F)

INACTIVE INGREDIENTS

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

MANUFACTURER

KUMSUNG ENC CO., LTD. +82-1577-4546
44 mokane-ro, Danwon-gu, Ansa-si, Gyeonggi-do, South Korea
www.ksenc.co.kr

8 801989 195105

Bacteria & Virus
99.999% Sanitize

Bacteria ZERO Premium

UPW HAND SANITIZER +

500ml e 16.90 fl.oz.

DRUG FACTS

Activ ingredient[s]	Purpose
Alcohol 58% v/v	Antiseptic

USE[s]

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 from 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°C(33.8~86°F)
- Avoid freezing and excessive heat above 40°C(104°F)

INACTIVE INGREDIENTS

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

MANUFACTURER

KUMSUNG ENC CO., LTD. +82-1577-4546
44 mokane-ro, Danwon-gu, Ansa-si, Gyeonggi-do, South Korea
www.ksenc.co.kr

8 801989 195105

UPW HAND SANITIZER

alcohol gel

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		TOPICAL	NDC:80138-203	
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	58 mL in 100 mL
Inactive Ingredients				
Ingredient Name				Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)				
TROLAMINE (UNII: 9O3K93S3TK)				
WATER (UNII: 059QF0K00R)				
GLYCERIN (UNII: PDC6A3C0OX)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80138-203-01	200 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/11/2020	
2	NDC:80138-203-02	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/11/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	09/11/2020	

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(80138-203)