

DR. ALPHA HAND CLEANER- alcohol gel
EVESEL 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.

Dr. Alpha hand cleaner 75% Evesel

Active Ingredient(s)

Ethyl Alcohol 75% 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.

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


Inactive ingredients

Alcohol, Water, Butylene Glycol, Carbomer, Triethanolamine, perfume, Polysorbate 60, DL-Panthenol

Package Label - Principal Display Panel

칼선

265*110



Dr. ALPHA
Hand Cleaner


Rinse-free antibacterial cleaning gel

<input checked="" type="checkbox"/> Alcohol Antiseptic 75%	<input checked="" type="checkbox"/> Non-sterile Solution
<input checked="" type="checkbox"/> Topical Solution	<input checked="" type="checkbox"/> Improved Formula
<input checked="" type="checkbox"/> Effective Inhibition	<input checked="" type="checkbox"/> Anti-germs

Suitable For External Use Only
1000 ml / 33.81 fl. oz.


ALCOHOL
75%

DRUG FACTS	
<i>Active ingredient</i>	<i>Purpose</i>
Ethyl Alcohol 75% v/v.....	Antiseptic
<i>Use[s] :</i> Hand Cleaner 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 until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.	
Other information • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients Water, Butylene Glycol, Carbomer, Triethanolamine, perfume, Polysorbate 60, DL-Panthenol	



MANUFACTURED BY
EVESEL
Pharmaceutical

MANUFACTURED BY EVESEL CO., LTD
27, Gongdan 1-daero 90beon-gil, Sicheung-si,
Gyeonggi-do, Korea



8 85981 28049301 >
Made in Korea

45파이 (155*134)

ALCOHOL
75%



Dr. ALPHA Hand Cleaner

Rinse-free antibacterial cleaning gel

- Alcohol Antiseptic 75%
- Non-sterile Solution
- Topical Solution
- Improved Formula
- Effective Inhibition
- Anti-germs


Suitable For External Use Only
120 ml / 4.06 fl. oz.



DRUG FACTS	
Active ingredient Ethyl Alcohol 75% v/v.....	Purpose Antiseptic
Use[s]: Hand Cleaner 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 until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.	
Other information • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients Water, Butylene Glycol, Carbomer, Triethanolamine, perfume, Polysorbate 60, DL-Panthenol	

MANUFACTURED BY
EVESEL
 EVESEL CO., LTD
 27, Gongdan 1-daero 80beon-gil,
 Sijeung-e, Gyeonggi-do, Korea
 Made in Korea

175*70



Dr. ALPHA
Hand Cleaner

Rinse-free antibacterial cleaning gel


<input checked="" type="checkbox"/> Alcohol Antiseptic 75%	<input checked="" type="checkbox"/> Non-water Solution
<input checked="" type="checkbox"/> Topical Solution	<input checked="" type="checkbox"/> Improved Formula
<input checked="" type="checkbox"/> Effective Inhibition	<input checked="" type="checkbox"/> Anti-germs

ALCOHOL
75%


DRUG FACTS

Active ingredient Ethyl Alcohol 75% w/v	Purpose Antiseptic
Use(s) Hand Cleaner 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 see a doctor if irritation or rash occurs. There 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. - Superior to other hand sanitizers for use in children under 6 years of age when using this product to avoid swallowing.	
Other information - Store between 15-20°C (59-68°F) - Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients Water, Butylene Glycol, Carbomer, Triethanolamine, perfume, Polyacrylate G1, DL-panthothenol	

Suitable For External Use Only
300 ml / 10.14 fl. oz.



MANUFACTURED BY EVEEHI CO., LTD
27, Gongsin 1-dong, Bosa-gu, Seoul
Gyeonggi-do, Korea

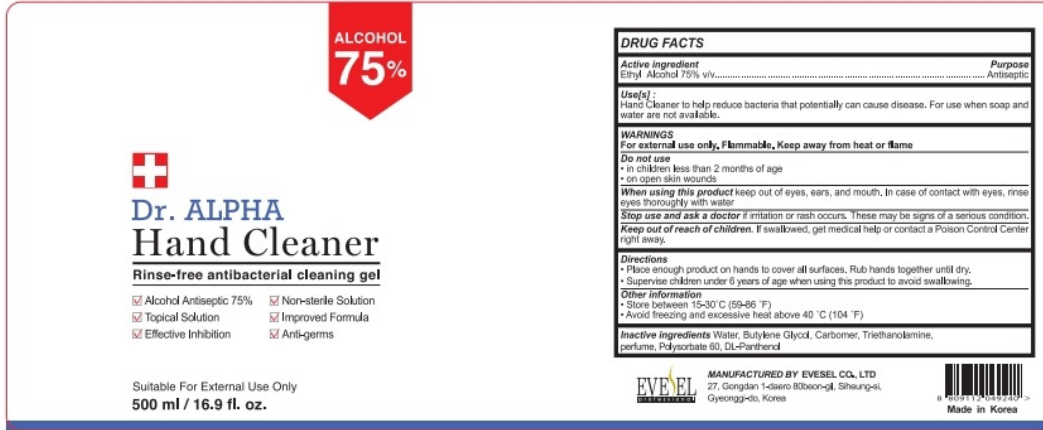


Made in Korea

50*75



220*90



DR. ALPHA HAND CLEANER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78 146-756
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	0.2 mL in 100 mL
BUTANEDIOL (MIXED ISOMERS) (UNII: TMS4MGA0H4)	1 mL in 100 mL
CARBOMER 980 (UNII: 4Q93RCW27E)	0.45 mL in 100 mL
PANTHENOL (UNII: WV9CM0O67Z)	0.01 mL in 100 mL
POLYSORBATE 60 (UNII: CAL22UVI4M)	0.05 mL in 100 mL
WATER (UNII: 059QF0KO0R)	23.2 mL in 100 mL

CARBOMER HOMO POLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)	0.03 mL in 100 mL
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78 146-756-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
2	NDC:78 146-756-10	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
3	NDC:78 146-756-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
4	NDC:78 146-756-12	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
5	NDC:78 146-756-30	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
6	NDC:78 146-756-11	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/11/2020	

Labeler - EVESEL CO., LTD (689533479)

Establishment

Name	Address	ID/FEI	Business Operations
EVESEL CO., LTD.		689533479	manufacture(78 146-756)

Revised: 1/2021

EVESEL CO., LTD