

HAND SANITIZER- hand sanitizer gel
Ningbo Meiteli Cosmetic 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.

Advanced Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 75%

Purpose

Antimicrobial

Use

Hand Sanitizer to help reduce bacteria on the skin.

Warning

Flammable. Keep away from heat or flame

For external use only.

Do not use near eyes

In case of contact rinse eyes thoroughly with water.

Stop use

Stop use and see a doctor if irritation or rash appears and lasts

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a poison control Center right away.

Directions

Put enough sanitizer in your palm to cover both hands, Rub hands together briskly until dry, Children under six should be supervised

Other

- Store below 110F(43C)
- May discolor some fabrics or surfaces

Inactive ingredients

Water(Aqua). Glycerin, Acrylatewc10-30 Alkyl CateCrosspolymer, Aloe Barbadensis Leaf Extract, Triethanolamine

Package Label - Principal Display Panel

<p style="font-size: 8px;">*when used as directed</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Drug Facts</td> <td style="width: 50%;"></td> </tr> <tr> <td>Active Ingredient Ethyl Alcohol 75% v/v.....</td> <td style="text-align: right;">Purpose Antimicrobial</td> </tr> <tr> <td colspan="2">Use Hand sanitizer to help reduce bacteria on the skin.</td> </tr> <tr> <td colspan="2">Warnings Flammable. Keep away from fire or flame.</td> </tr> <tr> <td colspan="2">For external use only</td> </tr> <tr> <td colspan="2">When using this product do not use it in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts.</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2">Directions Place enough product in your palm and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.</td> </tr> <tr> <td colspan="2">Other Information Store below 110°F (43°C) - May discolor certain fabrics</td> </tr> <tr> <td colspan="2">Inactive Ingredients: Water (Aqua), Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbardensis Leaf Extract, Triethanolamine</td> </tr> </table> <p style="font-size: 8px;">©2020 Eden Products, LLC, Lakewood, NJ 07037 Eden's hand[®] hand sanitizer is alcohol based and made with aloe to help soothe and calm your skin. In short, it's thoughtfully made with all the good stuff. All rights reserved. Trade Dressing ©2020 Eden Products, LLC. All rights reserved. NDC2252441</p>	Drug Facts		Active Ingredient Ethyl Alcohol 75% v/v.....	Purpose Antimicrobial	Use Hand sanitizer to help reduce bacteria on the skin.		Warnings Flammable. Keep away from fire or flame.		For external use only		When using this product do not use it in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts.		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		Directions Place enough product in your palm and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.		Other Information Store below 110°F (43°C) - May discolor certain fabrics		Inactive Ingredients: Water (Aqua), Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbardensis Leaf Extract, Triethanolamine		<div style="background-color: #004a7c; color: white; padding: 10px; text-align: center;"> <p style="writing-mode: vertical-rl; transform: rotate(180deg); font-weight: bold;">eden's hand[®]</p> <h1 style="margin: 0;">hand sanitizer</h1> <p style="font-size: 12px;">instantly kills 99.9% of germs*</p> <p style="font-size: 10px;">2 FL.OZ (60mL)</p> </div>	<p style="font-size: 8px;">eden's hand[®] hand sanitizer is alcohol based and made with aloe to help soothe and calm your skin. In short, it's thoughtfully made with all the good stuff.</p> <p style="font-size: 8px; text-align: right;">eden's hand[®] hand sanitizer</p>
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HAND SANITIZER				
hand sanitizer gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75541-006	
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)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
ALOE (UNII: V5VD430YW9)				
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75541-006-02	119 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
2	NDC:75541-006-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
3	NDC:75541-006-04	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
4	NDC:75541-006-03	178 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
5	NDC:75541-006-05	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
6	NDC:75541-006-07	948 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
7	NDC:75541-006-06	476 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/21/2020		

Labeler - Ningbo Meiteli Cosmetic Co., Ltd. (546624772)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Meiteli Cosmetic Co., Ltd.		546624772	manufacture(75541-006)

Revised: 5/2020

Ningbo Meiteli Cosmetic Co., Ltd.