

**D.THERAPINO ONE STEP HAND SANITIZER- alcohol gel**

**David 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.*

-----

**Drug Facts**

alcohol

water, aloe extract, carbomer, menthol, triethanolamine, butylene glycol, 1,2-hexanediol

**KEEP OUT OF REACH OF THE CHILDREN**

hand sanitizer to help reduce bacteria that potentially can cause disease

for use when soap and water are not available

hand sanitizer to help reduce bacteria that potentially can cause disease

for use when soap and water are not available

For external use only.

Flammable, keep away from fire or flame.

When using this product keep out of eyes. If contact with eyes occurs, rinse promptly and thoroughly with water.

Stop use and ask a doctor if significant irritation or sensitization develops.

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

for external use only

# D.therapino One Step Hand Sanitizer

**alcohol 70%**

<b>Drug Facts</b>	1gal
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 70% v/v .....	Antiseptic
<b>Use[s]</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. these may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>• Supervise children under 6years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>• Store between 15-30C (59-86F)</li> <li>• Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b>	
water,carbomer,triethanolamine,aloe barbadensis leaf extract,menthol	

**DAVID COSMETIC CO., LTD.**  
14, Dodam 8-ro, Seo-gu, Incheon  
**MADE IN KOREA**



## D.THERAPINO ONE STEP HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58241-0008
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 g in 100 mL	
<b>Inactive Ingredients</b>				
		<b>Ingredient Name</b>	<b>Strength</b>	
		MENTHOL (UNII: L7T10EP3A)		
		CARBOMER 940 (UNII: 4Q93RCW27E)		
		TROLAMINE (UNII: 9O3K93S3TK)		
		WATER (UNII: 059QF0K00R)		
		ALOE VERA LEAF (UNII: ZY81Z83H0X)		
		1,2-HEXANEDIOL (UNII: TR046Y3K1G)		
		BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58241-0008-1	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2020	
2	NDC:58241-0008-2	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2020	
3	NDC:58241-0008-3	110 mL in 1 TUBE; Type 0: Not a Combination Product	06/13/2020	
<b>Marketing Information</b>				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	06/13/2020	

**Labeler** - David Cosmetic Co Ltd (695697845)

**Registrant** - David Cosmetic Co Ltd (695697845)

### Establishment

Name	Address	ID/FEI	Business Operations
David Cosmetic Co Ltd		695697845	manufacture(58241-0008) , label(58241-0008)