

HAND SANITIZER - alcohol liquid
Ningbo Kleen Products 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.

Label Content

Active Ingredient: Ethyl Alcohol 62%

Purpose: Antiseptic

Uses: To decrease bacteria on the skin that could cause disease

Warnings: For external use only-hands. Flammable. Keep away from heat and flame.

When using this product. Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest

Stop use and see a doctor if skin irritation develops.

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

Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water

Other Information

Do not store above 105F

May discolor some fabric

Harmful to wood finishes and plastics

Directions: Wet hands thoroughly with products and allow to dry without wiping. For children under 6 use only under adult supervision. Not recommended for infants

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Drug Facts	Active ingredient	Purpose	Control Center right away. Directions: Wet hands thoroughly with product and allow to dry without wiping • For children under 6 use only under adult Supervision. • Not recommended for infants. Other Information: Do not store above 105°F. • May discolor some fabrics. • Harmful to wood finishes and plastics. Inactive ingredients: Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water. Distributed by: Polyconcept, Miami, Fl 33169 • 1-800-749-7367
	Ethyl Alcohol 62%	Antiseptic	
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Stop use and ask a doctor if skin irritation develops.			
Keep out of reach of children. If swallowed, get medical help or call a Poison			

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52174-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	36.43 g in 100 g
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.02 g in 100 g
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	0.2 g in 100 g
TROLAMINE (UNII: 9O3K93S3TK)	0.2 g in 100 g

GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 100 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.5 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52174-002-01	10 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/08/2010	

Labeler - Ningbo Kleen Products Co., Ltd. (529352816)

Registrant - Ningbo Kleen Products Co., Ltd. (529352816)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Kleen Products Co., Ltd.		529352816	manufacture

Revised: 9/2010

Ningbo Kleen Products Co., Ltd.