

HAND SANITIZER- hand sanitizer liquid
Fortress Expert 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.

73549-027
HAND SANITIZER

Active ingredient

Ethyl Alcohol 70%

Purpose

Antiseptic

Use

■ For handwashing to decrease bacteria on the skin.

Warnings

For external use only: hands
Flammable, keep away from fire or 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 ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

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

- 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

Water(Aqua), PEG-40 Hydrogenated Castor Oil, Fragrance(Parfum) , Acrylates/ C10-30Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Aloe Barbadensis Extract, Butylene Glycol, 1,2-Hexanediol, Caprylhydroxamic Acid, Citric Acid, Disodium EDTA, Octocrylene, Homosalate, Butyl Methoxydibenzoylmethane, Helianthus Annuus (Sunflower) Seed Oil, Tocopheryl Acetate, Blue 1, Red 33

Package Label

73549-027-01 30ml



30x36mm



outside front panel

1



inside left flap

2



inside center panel

3

(back panel glued to the bottle)



inside right flap

4



outside right panel

5

HAND SANITIZER

hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73549-027
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FRAGRANCE FLORAL ORC0902236 (UNII: R66Z4YW3X0)	
WATER (UNII: 059QF0KO0R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
OCTOCRYLENE (UNII: 5A68WGF6VM)	
AVOBENZONE (UNII: G63QQF2NOX)	
HOMOSALATE (UNII: V06SV4M95S)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73549-027-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/30/2020	

Labeler - Fortress Expert Co., Ltd (543358697)

Establishment

Name	Address	ID/FEI	Business Operations
Fortress Expert Co., Ltd		543358697	manufacture(73549-027)

Revised: 7/2021

Fortress Expert Co., Ltd