

HAND SANITIZER- hand sanitizer gel Shantou Shengmei Biotechnology 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.

Hand Sanitizer

Alcohol 75% v/v. Purpose: Antiseptic

Antiseptic, Hand Sanitizer

Hand sanitizer to help reduce bacteria on the skin. Recommend for repeated use. For use when soap and water are not available.

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.

Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

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.

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.

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

This product can effectively kill 99.99% Escherichia coli, Staphylococcus aureus, Candida albicans, Pseudomonas aeruginosa under experimental conditions. The results are for reference only.

Aqua, Hydrolyzed Jojoba Esters, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Aloe Barbadosis Leaf Juice Powder, Citric Acid

55450-004-01 500mL



HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55450-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR64JW8W)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55450-004-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/17/2020	

Labeler - Shantou Shengmei Biotechnology Co., Ltd. (554528509)

Establishment

Name	Address	ID/FEI	Business Operations
Shantou Shengmei Biotechnology Co., Ltd.		554528509	manufacture(55450-004)

Revised: 4/2020

Shantou Shengmei Biotechnology Co., Ltd.