

HAND SANITIZER- alcoholgel gel
Campari Science & Technology (Suzhou) 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.

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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.

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Directions

- 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 to avoid swallowing.

Other information

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

Inactive ingredients

WATER □ GLYCERIN □ JOJOBA OIL PEG-150 ESTERS □ ALOE BARBADENSIS EXTRACT □
TOCOPHEROL □ PANTHENOL □ LONICERA JAPONICA (HONEYSUCKLE) FLOWER EXTRACT □
CHRYSANTHEMUM INDICUM FLOWER EXTRACT □ SOPHORA ANGUSTIFOLIA ROOT
EXTRACT □ MENTHA PIPERITA (PEPPERMINT) LEAF EXTRACT □ SCUTELLARIA
BAICALENSIS ROOT EXTRACT □ ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER □
TRIETHANOLAMINE

Active Ingredient(s)

Alcohol [Vol.%]63%-77%

Package Label - Principal Display Panel



HAND SANITIZER

alcoholgel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54837-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	350 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
PANTHENOL (UNII: WV9CM0O6Z)	
WATER (UNII: 059QF0KO0R)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CHRYSANTHEMUM INDICUM FLOWER (UNII: I6OER6U04L)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	Leedun
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54837-003-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/15/2020	

Labeler - Campari Science & Technology (Suzhou) Co., Ltd. (548374083)

Establishment

Name	Address	ID/FEI	Business Operations
Campari Science & Technology (Suzhou) Co., Ltd.		548374083	manufacture(54837-003)

Revised: 5/2020

Campari Science & Technology (Suzhou) Co., Ltd.