

HANDSOAP- benzalkonium chloride liquid
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.

Active Ingredient(s)

BENZALKONIUM CHLORIDE 0.45%□CHLORHEXIDINE DIGLUCONATE 0.20%

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

Inactive ingredients

WATER□COCAMIDOPROPYL BETAINE□DECYL GLUCOSIDE□GLYCERIN□
COCAMIDOPROPYLAMINE OXIDE□SODIUM CITRATE□ARTEMISIA ARGYI LEAF EXTRACT□
SODIUM HYDROXIDE□PARFUM

Package Label - Principal Display Panel

230x90mm

Leedun

HAND SOAP

Hand Soap kills 99.9% of germs, take care of your hands. This moisturising formula is gentle for skin, safe and convenient with no sticky residue. Suitable for children, office, home and at school.

INSTRUCTIONS: Wet hands, Press down pump, Squeeze liquid and rub with hands until rich foam, then rinse with water.

FULL INGREDIENTS: WATER, COCAMIDOPROPYL BETAINE, DECYL GLUCOSIDE, GLYCERIN, BENZALKONIUM CHLORIDE, CHLORHEXIDINE DIGLUCONATE, COCAMIDOPROPYLAMINE OXIDE, SODIUM CITRATE, ARTEMISIA ARGYI LEAF EXTRACT, SODIUM HYDROXIDE, PARFUM.

CAUTION: FOR EXTERNAL USE ONLY. KEEP OUT OF REACH OF CHILDREN. Avoid contact with eyes. Not to be taken internally.

FIRST AID: For advice, contact a Poisons Information Centre or a Doctor at once. If swallowed contact a Doctor. If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre or a Doctor, or for at least 15 minutes.

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HAND SOAP

GENTLE CLEANING
FRESH .NO STICKY

KILLS 99.9% of GERMS

500ml e 16.9 FL OZ

FORMULA DEVELOPED IN COLLABORATION WITH FRENCH LABORATORY CISCO
MANUFACTURER: Campari Science & Technology (Suzhou) Co., Ltd
ADDRESS: Taiping Industrial Park, Xiangcheng District, Suzhou City
TEL: (0086) 400-088-2658
Made in China L2009

500ml e 16.9 FL OZ

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HANDSOAP

benzalkonium chloride liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54837-002 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------|-------------------------|-------------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 2.25 mg in 500 mL |
| CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L) | CHLORHEXIDINE GLUCONATE | 1 mg in 500 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------------------------|----------|
| COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ARTEMISIA ARGYI LEAF (UNII: 2JYC99Q0WZ) | |
| DECYL GLUCOSIDE (UNII: Z17H97EA6Y) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:54837-002-01 | 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 | part333A | 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(54837-002) |

Revised: 4/2020

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