

HAKU GARDENIA HAND SANITIZER- ethyl alcohol gel
SRC Company 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

Ethyl alcohol 70%

INACTIVE INGREDIENTS

Water, Carbomer, Glycerin, Propylene Glycol, Triethanolamine, Polysorbate 80, Aloe barbadensis leaf extract, Fragrance

PURPOSE

ANTISEPTIC

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.

Uses

- Hand sanitizer to help reduce bacteria that potentially can cause disease.
- Recommended for repeated use.

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.
- Not recommended for infants

Other Information

- Store between 1°-30° (33.8°-86°)
- Avoid freezing and excessive heat above 40° (104°)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

HAKUTM

**GARDENIA
HAND
SANITIZER**

2.02 fl. oz (60mL)

Drug Facts	
Active ingredients Ethyl alcohol 70%	Purpose ANTISEPTIC
Uses - Hand sanitizer to help reduce bacteria that potentially can cause disease. - Recommended for repeated use.	
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.	
Directions - Place enough product on hands to cover all surfaces. Rub hands together until dry. - Supervise children under 8 years of age when using this product to avoid swallowing. - Not recommended for infants	
Other information - Store between 1°C-30°C (33.8°F-86°F) - Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients Water, Carbomer, Glycerin, Propylene Glycol, Triethanolamine, Polysorbate 80, Aloe barbadensis leaf extract, Fragrance	
Distributor: SRC Company Co., Ltd. 15 Nonhyeon-ro 150-gil, Gangnam-gu, Seoul, Republic of Korea	

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12M Other

HAKU GARDENIA HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78857-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	42 mL in 60 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78857-080-01	60 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/01/2020	

Labeler - SRC Company Co., Ltd. (694702525)**Registrant** - SRC Company Co., Ltd. (694702525)**Establishment**

Name	Address	ID/FEI	Business Operations
C&N COSMETICS CO.,LTD		688853696	manufacture(78857-080)

Revised: 6/2020

SRC Company Co., Ltd.