

FRESH WATER HAND SANITIZER- alcohol gel
Soleo Cosmetic 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.

Drug Facts

Ethyl Alcohol (Alcohol) 62% (w/w)

Glycerin, Carbomer, Green Tea Extract, Aloe Extract, L-Menthol, Aminomethyl Propanol, Water
Antimicrobial

Hand gel for cleaning and moisturizing the hand

KEEP OUT OF REACH OF THE CHILDREN

Store under 30°C (86°F)

For external use only.

Flammable, keep away from fire or flame.

When using this product keep out of eyes. If contact with eyes occurs, rinse promptly and thoroughly with water.

Stop use and ask a doctor if significant irritation or sensitization develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

- Put enough product in your palm to thoroughly cover your hands
- Rub hands together briskly until dry
- Children under 6 years of age should be supervised when using this product



KUNDAL

**FRESH WATER
HAND SANITIZER+**

Hand Gel for Cleaning and
Moisturizing the Hand

HAND SANITIZER

KILLS 99.9 % OF GERMS

100 ml / 3.38 fl. oz.

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DOUBLE EDITION

순정수 함유 손소독제

주식회사 더 스킨팩토리 THE SKIN		인쇄사양
품목명	룬탈_손소독제(미국ver)_덧방라벨	<input type="checkbox"/> 칼선
수정날짜	2020 / 03 / 10	<input checked="" type="checkbox"/> K100
작성자	컨텐츠팀 류혜진 010-7736-5150	

작업지시사항 HISTORY	
2020-03-10	룬탈_손소독제(미국ver)_덧방라벨_신규

※ 답당은 본 이미지를 사내 폴더에 올렸음을 확인합니다.
 ※ 본 이미지는 사내 폴더에 올린 최종 데이터 이미지와 동일합니다.

규격 : 58 X 92(mm)

Drug Facts	
Active Ingredient	Purpose
Ethyl alcohol 62% w/w	Antimicrobial
Use Hand sanitizer to help reduce bacteria on the skin	
Warnings	
Flammable. Keep away from fire or flame.	
For external use only	
Do not use on the following body parts : ● around the eyes and ears, ● in the mouth, and ● damaged skin. Irritation may occur.	
Stop use and ask a doctor if you notice any of the following hypersensitivity symptoms such as ● rash, ● erythema, ● itching, ● edema, and ● skin irritation.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ● Put enough product in your palm to thoroughly cover your hands	
● Rub hands together briskly until dry	
● Children under 6 years of age should be supervised when using this product	
Other Information Store under 30°C (86°F).	
Inactive Ingredients Glycerin, Carbomer, Green Tea Extract, Aloe Extract(09), L-Menthol, Aminomethyl Propanol, Water (Aqua)	

FRESH WATER HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71693-600
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	62 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
LEVOMENTHOL (UNII: BZ1R15MTK7)	
ALOE (UNII: V5VD430 YW9)	

WATER (UNII: 059QF0KO0R)

GLYCERIN (UNII: PDC6A3C0OX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71693-600-01	2 in 1 PACKAGE	03/01/2020	
1		100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/01/2020	

Labeler - Soleo Cosmetic Co., Ltd. (557829412)

Registrant - THE SKINFACTORY Co., Ltd. (694804099)

Establishment

Name	Address	ID/FEI	Business Operations
Soleo Cosmetic Co., Ltd.		557829412	manufacture(71693-600)

Establishment

Name	Address	ID/FEI	Business Operations
THE SKINFACTORY Co., Ltd.		694804099	label(71693-600)

Revised: 3/2020

Soleo Cosmetic Co., Ltd.