BATHEAL HAND SANITIZER- hand sanitizer gel SUNJU CORPORATION

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)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic

Use(s)

To help reduce bacteria and germs on the skin.

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 briskly until dry.
- Supervise children 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, Sodium Hyaluronate, Glycerin, Lemon Oil, Carbormer, Tromethamine, Fragrance

Package Label - Principal Display Panel

500mL NDC: 75272-001-10



Drug Facts

Active ingredient[s]

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Avoid freezing and excessive heat above 40°C(104°F)

Inactive ingredients Water, Sodium Hyaluronate, Glycerin, Lemon Oil, Carbomer, Tromethamine, Fragrance

www.sunju.co.kr

BATHEAL HAND SANITIZER

hand sanitizer gel

Product Information

HUMAN OTC DRUG NDC:75272-001 Product Type Item Code (Source)

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength ALCOHOL ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) 70 mL in 100 mL

Inactive Ingredients

Ingredient Name					
GLYCERIN (UNII: PDC6A3C0OX)					
LEMON OIL (UNII: 19 GRO 8 2 4 L L)					
WATER (UNII: 059QF0KO0R)					
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)					
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)					
TROMETHAMINE (UNII: 023C2WHX2V)					

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:75272-001- 10	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/24/2020				
Marketing Information							
	Marketing Categ	ory Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
0	TC monograph not	final part333A	04/24/2020				
-	8 F	F					

Labeler - SUNJU CORPORATION (694816019)

Establishment								
Name	Address	ID/FEI	Business Operations					
INNOSKIN CO., LTD.		695625879	manufacture (75272-001)					

Revised: 5/2020 SUNJU CORPORATION