

GRACE AND STELLA HAND SANITIZER- ethyl alcohol gel

Grace & Stella Inc

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.

grace & stella HAND SANITIZER

Product Facts

Medicinal Ingredient (v/v):

Ethyl alcohol 75%

Purpose

Antiseptic

Non-medicinal ingredients: Water (aqua), Carbomer, Glycerin, Sodium Bicarbonate, Denatonium Benzoate.

Uses: For personal hand hygiene to help prevent the spread of bacteria.

Directions: For occasional personal and domestic use. Place a dime sized drop of product in your palm. Rub thoroughly into hands for at least 30 seconds. Allow to dry. Supervise children when they use this product.

Dosage: Apply as needed.

Warnings: For external use only.

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and consult a health care professional if irritation develops.

Flammability Warning: Keep away from open flame and sources of heat.☐

Security Feature: If the security foil under the cap is missing or damaged do not use the product.

Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.

Other information: Store between 15-30°C (59-86°F). Avoid freezing and excessive heat above 40°C (104°F). May discolour certain fabrics or surfaces.

Topical & Non-Sterile Gel

75% Ethyl Alcohol

KILLS HARMFUL GERMS

Imported by: Grace & Stella Inc.

320 - 425 Carrall St.

Vancouver, BC, V6B 6E3, Canada

Questions?? Call toll free

1-877-30-PAMPER (1-877-307-2673)

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MADE IN CHINA

@GRACEANDSTELLA

GRACEANDSTELLA.COM

Packaging

DRUG FACTS LABEL

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ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76851-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76851-102-06	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/06/2020	
2	NDC:76851-102-10	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/06/2020	
3	NDC:76851-102-30	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/06/2020	
4	NDC:76851-102-50	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/06/2020	
5	NDC:76851-102-11	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/06/2020	
6	NDC:76851-102-55	5000 mL in 1 CAN; Type 0: Not a Combination Product	05/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/06/2020	

Labeler - Grace & Stella Inc (204270191)

Revised: 5/2020

Grace & Stella Inc