HELIOS HAND SANITIZER- alcohol gel
Pretty Woman LLC

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.

Helios Hand Sanitizer Gel 80 mL

Active Ingredient(s)

Ethyl alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

- to decrease bacteria on the skin that could cause disease
- recommended for repeated use

Warnings

For external use only: hands. Flammable. Keep away from fire or flame.

When using this product

- keep out of eyes. In case of contact with eyes, flush thoroughly with water.
- avoid contact with broken skin
- do not inhale or ingest

Stop use and ask a doctor if

- irritation or redness develops
- conditions persists more that 72h

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

Directions

Directions

- wet hands thoroughly with product and allow to dry without wiping
- for children under 6 years of age, use only under adult supervision
- not recommended for infants

Other information

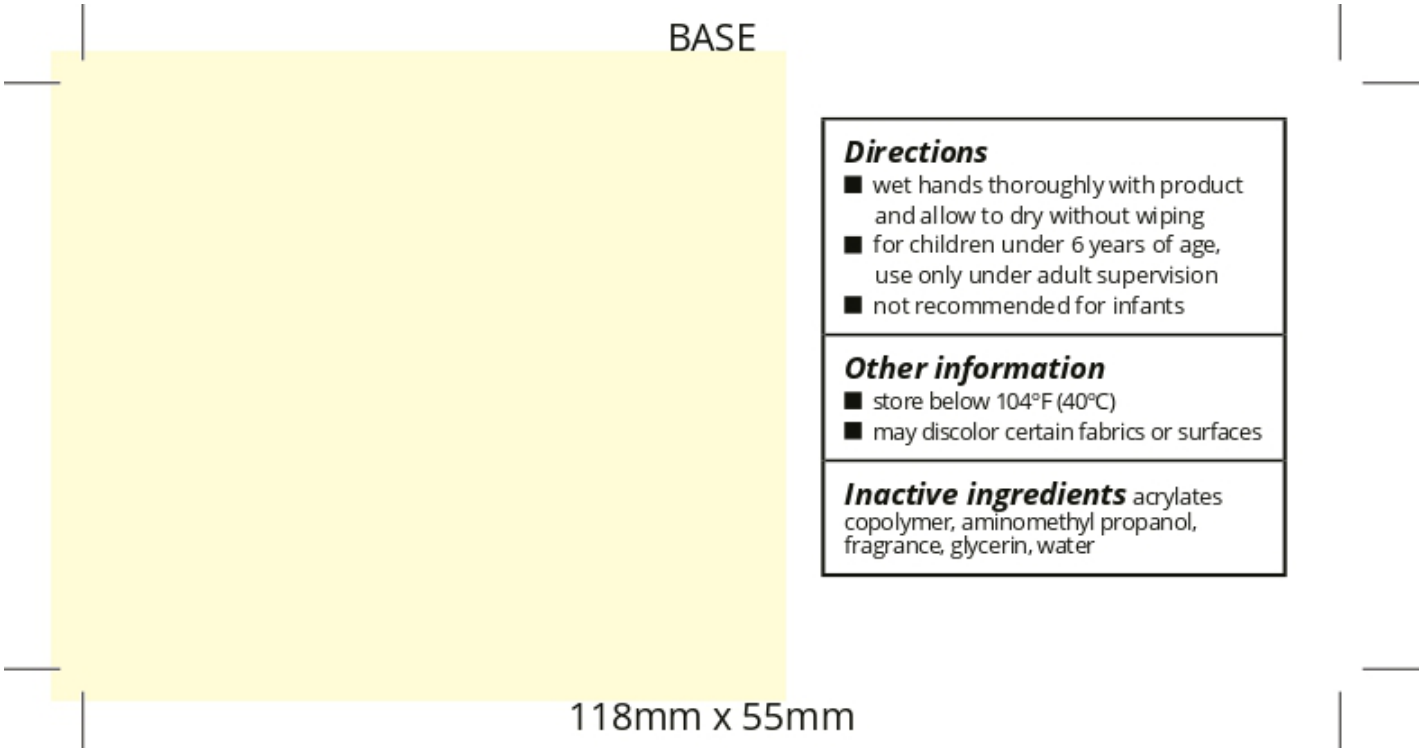
Other information

- store below 104°F (40°C)
- may discolor certain fabrics or surfaces

Inactive ingredients

acrylates copolymer, aminomethyl propanol, fragrance, glycerin, water

Package Label - Principal Display Panel



80 mL NDC: 74140-200-01

HELIOS HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74140-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:74140-200-01	80 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/21/2020	

Labeler - Pretty Woman LLC (008134996)

Establishment

Name	Address	ID/FEI	Business Operations
Pretty Woman LLC		008134996	manufacture(74140-200) , pack(74140-200) , label(74140-200)

Revised: 5/2020 Pretty Woman LLC