HAND SANITIZER- ethyl alcohol solution Platinum System 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.

GelShop Hand Sanitizer (Alcohol Antiseptic 70%)

Drug Facts

Medicinal Ingredients

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Use(s)

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available

Warning

For external use only. Flammable. Keep away from heat or flame

Do not use

- On 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 6 years of age when using this product to avoid swallowing

Other information

- Store between 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Non-Medicinal Ingredients

water, glycerin, carbomer, parfume, aloe barbadensis leaf extract, tocopheryl acetate, triethanolamine

Package Label - Principal Display Panel

150 mL NDC: 71316-101-14

ÉLIMINE LES GERMES 99,9% KILLS GERMS

GelShop

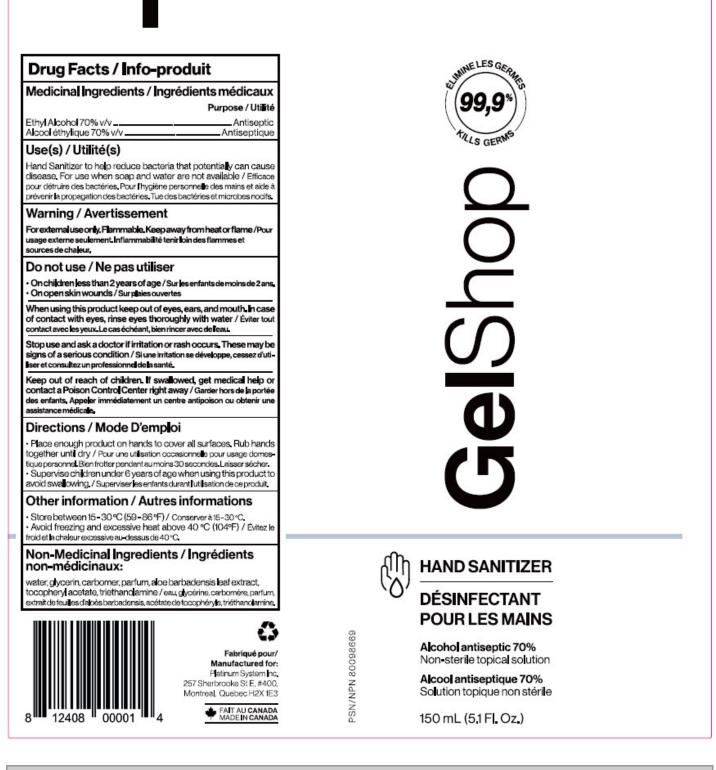
HAND SANITIZER DÉSINFECTANT POUR LES MAINS

Alcohol antiseptic 70% Non-sterile topical solution

Alcool antiseptique 70%

Solution topique non stérile

150 mL (5.1 Fl. Oz.)



HAND SANITIZER			
ethyl alcohol solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78795-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL		
less stive less disets				
Inactive Ingredients				
Ingredient Name		Strength		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM	4307FC)			
WATER (UNII: 059QF0KO0R)				
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
TROLAMINE (UNII: 903K93S3TK)				
GLYCERIN (UNII: PDC6A3C0OX)				

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78795- 101-45	260 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
2	NDC:78795- 101-69	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
3	NDC:78795- 101-76	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
4	NDC:78795- 101-83	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
5	NDC:78795- 101-21	50 in 1 CARTON	06/26/2020	
5		3 mL in 1 PACKET; Type 0: Not a Combination Product		
6	NDC:78795- 101-14	150 mL in 1 TUBE; Type 0: Not a Combination Product	06/26/2020	
7	NDC:78795- 101-50	50 mL in 1 TUBE; Type 0: Not a Combination Product	06/26/2020	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not final	part333A	06/26/2020	

Labeler - Platinum System Inc (204092162)

Establishment				
Name	Address	ID/FEI	Business Operations	
Les Entreprises Stefmar Inc		240496385	manufacture(78795-101)	