HARD ROCK HOTEL UNIVERSAL ORLANDO HAND SANITIZER GEL- ethyl alcohol gel
Carretta USA, 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.

Hard Rock Hotel Universal Orlando Hand Sanitizer Gel

Drug Facts

Active Ingredient

Ethyl Alcohol 75% v/v

Purpose

Antiseptic

Uses[s]

Hand sanitizer to help reduce bacteria that potentially can cause disease.

For use when soap and water are not available.

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 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 15-30C (59-83F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients:

Water,Glycerin,Propylene glycol,Carbomer,Aloe Vera Extract,Triethanolamine,Disodium Edta

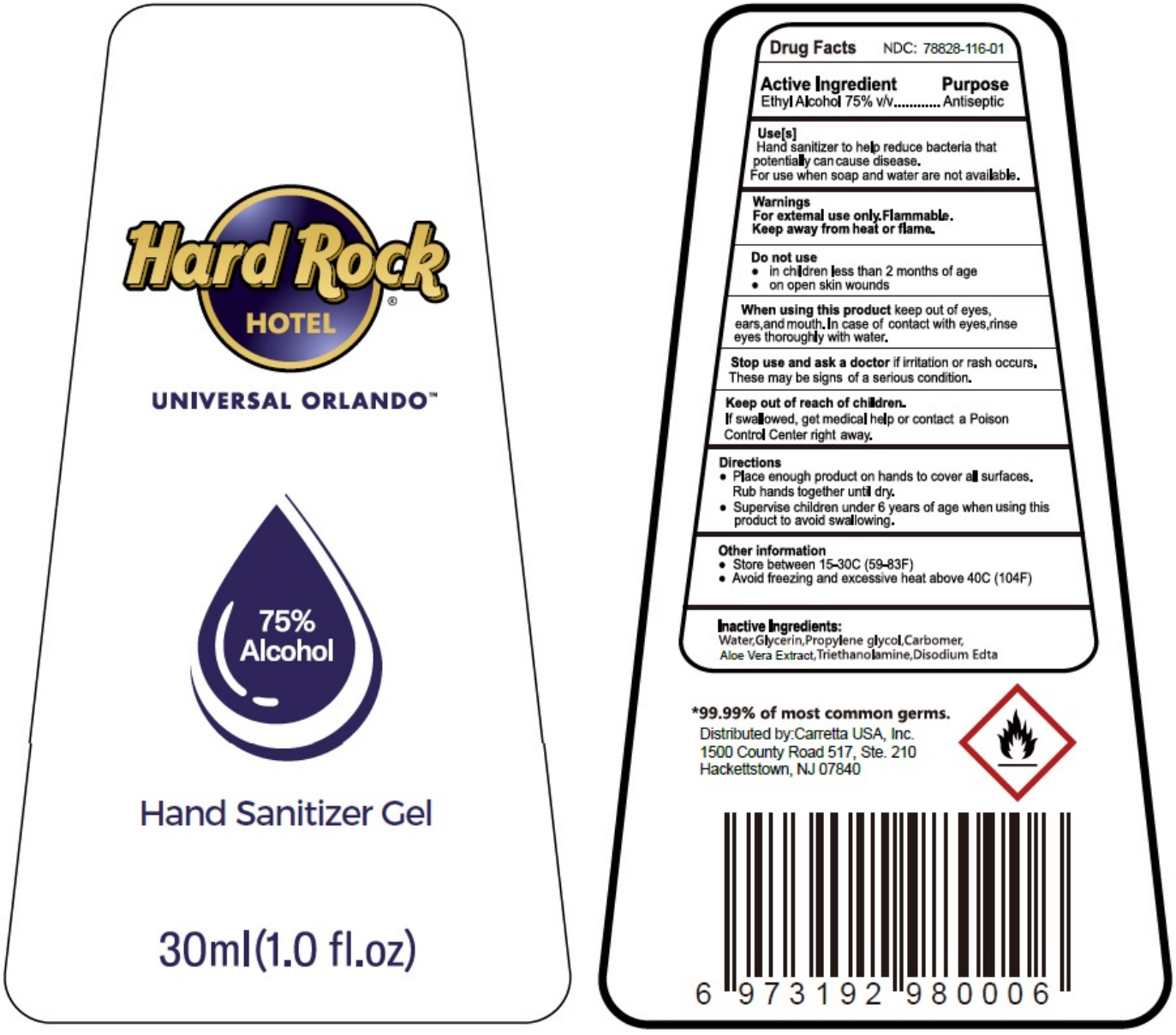
***99.99% of most common germs.**

Distributed by:Carretta USA, Inc.

1500 County Road 517, Ste. 210

Hackettstown, NJ 07840

Packaging



HARD ROCK HOTEL UNIVERSAL ORLANDO HAND SANITIZER GEL

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78828-116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:78828-116-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/12/2020	

Labeler - Carretta USA, Inc (010851173)

Revised: 6/2020 Carretta USA, Inc