HANDS OUT HAND SANITIZER GEL- alcohol gel
Spa Dent 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.

Hands Out Hand Sanitizer Gel

PRODUCT FACTS

ACTIVE INGREDIENT

Alcohol 70% v/v

PURPOSE

Antiseptic

USE(S)

• Antiseptic (skin) cleanser • Medicated (skin) cleanser • Antibacterial (skin) cleanser • Effective in destroying (harmful) bacteria to provide antiseptic cleansing • For personal hand hygiene to help prevent the spread of bacteria

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 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) out of direct sunlight • Avoid freezing and excessive heat above 40° C (104° F).

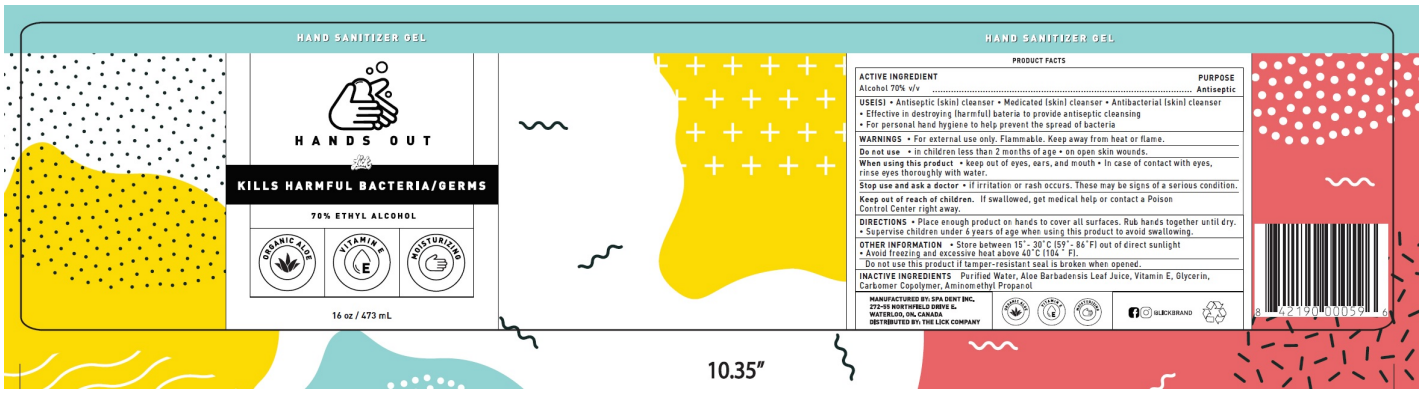
Do not use this product if tamper-resistant seal is broken when opened.

INACTIVE INGREDIENTS

Purified Water, Aloe Barbadensis Leaf Juice, Vitamin E, Glycerin, Carbomer Copolymer, Aminomethyl Propanol

Package Labeling:79147-004-01

Package Labeling:79147-004-02



HANDS OUT HAND SANITIZER GEL

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79147-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:79147-004-01	6 in 1 CASE	09/15/2020	
1		946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:79147-004-02	12 in 1 CASE	09/15/2020	
2		473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/15/2020	

Labeler - Spa Dent Inc. (203478896)

Revised: 10/2020 Spa Dent Inc.