## CHEMBRITE- hand sanitizer gel Interion Pte Ltd

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.

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### Interion 60% IPA

# **Active Ingredient(s)**

Isopropyl Alcohol 60% v/v. Purpose: Antiseptic

## **Purpose**

Antiseptic, Hand Sanitizer

#### Use

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 Center right away.

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#### **Directions**

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using products.

## Other information

Store below 110°F(43C°) Avoid freezing and excessive heat above 40C (104F)

May discolor certain fabrics or surfaces

## **Inactive ingredients**

Benzyl Alcohol, Carboxymethyl Cellulose, Denatonium Benzoate, Glycerin, Lemon peel oil, Monopropylene Glycol, PEG-6000 Dilaurate, Purified Water, Triethanolamine

## **Package Label - Principal Display Panel**



200 ml NDC: 78036-001-01

## **CHEMBRITE**

hand sanitizer gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78036-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	60 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6 A3C0 OX)				
CARBO XYMETHYLCELLULO SE (UNII: 05JZI7B19 X)				
WATER (UNII: 059QF0KO0R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
TROLAMINE (UNII: 9O3K93S3TK)				
PEG-150 DILAURATE (UNII: CF607I8E19)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)				
LEMON OIL, TERPENELESS (UNII: X69W83NI7V)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78036-001- 01	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2020	
2	NDC:78036-001- 02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2020	
3	NDC:78036-001- 03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2020	
4	NDC:78036-001- 04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2020	
5	NDC:78036-001- 05	5000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/25/2020	
6	NDC:78036-001- 06	10000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/25/2020	
7	NDC:78036-001- 07	20000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/25/2020	
8	NDC:78036-001- 08	25000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/25/2020	
9	NDC:78036-001- 09	30000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/25/2020	
10	NDC:78036-001- 10	200000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/25/2020	
11	NDC:78036-001- 11	209000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/25/2020	
12	NDC:78036-001- 12	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/25/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/25/2020		

# Labeler - Interion Pte Ltd (894599711)

Establishment					
Name	Address	ID/FEI	Business Operations		
Interion Pte Ltd		894599711	manufacture(78036-001)		

Revised: 5/2020 Interion Pte Ltd