

## **HELLO BELLO HAND SANITIZER- alcohol gel**

### **Brands International Corporation**

*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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### **Hello Bello Hand Sanitizer**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol
- c. Hydrogen peroxide
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

### **Active Ingredient(s)**

Alcohol 75% v/v

### **Purpose**

Antiseptic Skin Cleanser

### **Use**

Antiseptic (skin) Cleanser

### **Warnings**

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

### **Do not use**

Children adolescents and adults 2 years and over

**Other information**

- Store below 43 degree Celcius/ 100 degree F
- May discolor certain fabrics or surfaces

**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.

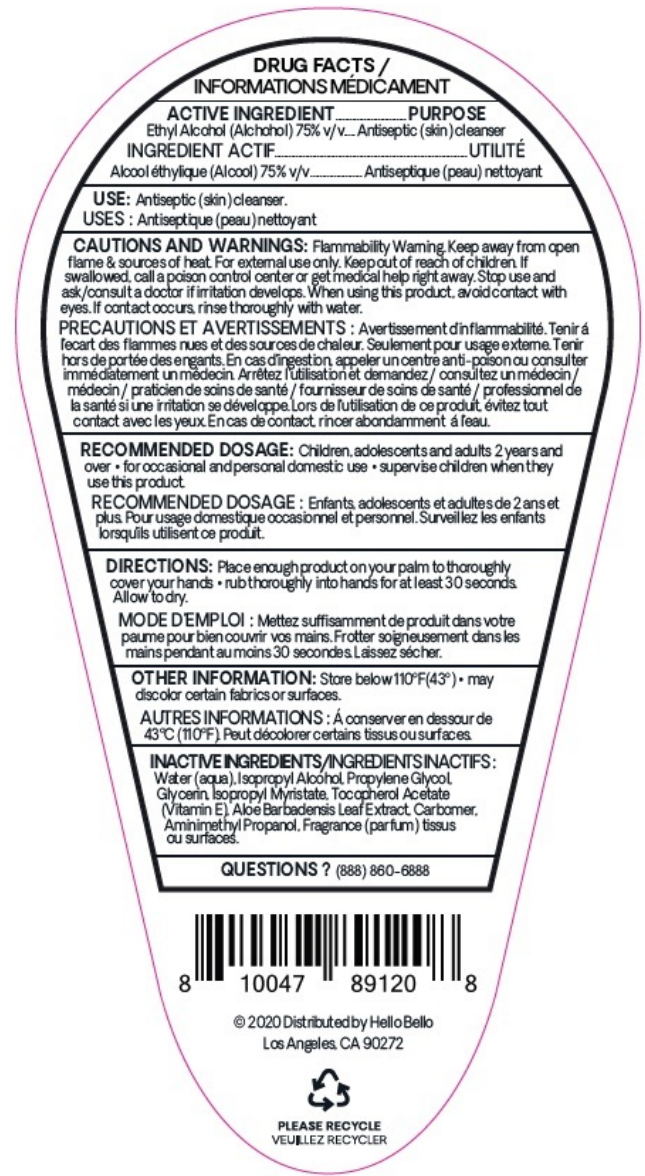
**Directions**

- Place enough product on your palm to thoroughly cover your hands.
- Rub thoroughly into hands for at least 30 seconds. Allow to dry

**Inactive ingredients**

Glycerin, Water, Isopropyl Alcohol, Propylene Glycol, Tocopherol Acetate (Vitamin E), Aloe Barbadensis Leaf Extract, Carbomer, Aminomethyl Propanol, Parfum

**Package Label - Principal Display Panel**



## HELLO BELLO HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50157-225
<b>Route of Administration</b>	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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>AMINOMETHYLPROPANOL</b> (UNII: LU49E6626Q)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-225-10	1000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/23/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/23/2021	

**Labeler** - Brands International Corporation (243748238)

**Registrant** - Brands International Corporation (243748238)

Revised: 12/2021

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