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.

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



DRUG FACTS / INFORMATIONS MÉDICAMENT

ACTIVE INGREDIENT......PURPOSE Ethyl Alcohol (Alchohol) 75% v/v... Antiseptic (skin) cleans

INGREDIENT ACTIF.......UTILITÉ

... Antiseptique (peau) nettoyant

Alcool éthylique (Alcool) 75% v/v.............
USE: Antiseptic (skin) cleanser.

USES : Antiseptique (peau) nettoyant

CAUTIONS AND WARNINGS: Flammability Warning, Keep away from open flame & sources of heat. For external use only, Keep out of reach of children. If swallowed, call a poison control center or get medical help right away. Stop use and ask/consult a doctor if irritation develops. When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.

eyes. In contact occurs rinse unaroughly with water.

PRECAUTIONS ET AVERTISSEMENTS: Avertissement din flammabilité. Tenir à fecart des flammes nues et des sources de chaleur. Seulement pour usage externe. Tenir hors de portée des engants. En cas dirigestion, appeler un centre anti-poison ou consultir immédiatement un médicain Arrêtez l'utilisation et demandrez / consultez un médicain / médicain / praticien de soins de santé / fournisseur de soins de santé / professionnel de la santé si une irritation se développe. Lors de l'utilisation de ce produit évitez tout contact avec les yeux. En cas de contact rincer abondamment à feau.

RECOMMENDED DOSAGE: Children, adolescents and adults 2 years and over • for occasional and personal domestic use • supervise children when they use this product.

RECOMMENDED DOSAGE: Enfants, adolescents et adultes de 2 ans et plus Pour usage domestique occasionnel et personnel. Surveil lez les enfants lorsqu'ils utilisent ce produit.

DIRECTIONS: Place enough product on your palm to thoroughly cover your hands • rub thoroughly into hands for at least 30 seconds. Allow to dry.

MODE D'EMPLOI: Mettez suffisamment de produit dans votre paume pour bien couvrir vos mains. Frotter soigneusement dans les mains pendant au moins 30 secondes Laissez sécher.

OTHER INFORMATION: Store below 110°F(43°) • may discolor certain fabrics or surfaces.

AUTRES INFORMATIONS: Á conserver en dessour de 43°C (110°F). Peut décolorer certains tissus ou surfaces.

INACTIVE INGREDIENTS/INGREDIENTS INACTIFS: Water (aqua), Isopropyl Alcohol Propylene Glycol Glycerin Isopropyl Myristate, Toccaherol Acetate (Vitamin E), Alce Barbadensis Leaf Extract. Carbomer, Aminimathyl Propanol, Fragrance (parfum) tissus ou surfaces.

QUESTIONS ? (888) 860-6888



© 2020 Distributed by Hello Bello Los Angeles, CA 90272



HELLO BELLO HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50157-225

Route of Administration 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

ALOE VERA LEAF (UNII: ZY81Z83H0X)

ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	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 Brands International Corporation