NATURAL- antibacterial gel
INTERNATIONAL GENERAL TRADING CORP

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.

NATURAL CARE ANTIBACTERIAL

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 (1.45% v/v).
c. Hydrogen peroxide (0.125% v/v).
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)

BENZALKONIUM CHLORIDE

Purpose

Antibacterial

Use

FOR HANDWASHING TO DECREASE BATERIA ON THE SKIN

Warnings

For external use only.

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product do not get into yes. If contact occurs rinse eye throughly with water

stop use and ask a docor if irritation or redness develops

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Wash hands, apply palful to hhand rub thoughly and rinse

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

WATER, SODIUM LAURYLETHER SULFATHEM COCOAMIDO PROPYL, BETAINE, GLYCERIN, ESSENTIAL OILS, SODIUM CHORIDE, COLLAGEN. SODIUMFEINT, SALT, ALOE VERA, YELLOW#5 d&c, RED#4 D&C

Package Label - Principal Display Panel


64 FL OZ (1,8 L)


REFILL BOTTLE

NATURAL

antibacterial gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78440-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78440-001-01	1892 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
2	NDC:78440-001-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
3	NDC:78440-001-02	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
4	NDC:78440-001-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
5	NDC:78440-001-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	


REFILL BOTTLE
Natural Care®
Antibacterial
Hand Soap
with Moisturizers
64 FL OZ (1,8 L)

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/13/2020	

Labeler - INTERNATIONAL GENERAL TRADING CORP (825499598)

Registrant - INTERNATIONAL GENERAL TRADING CORP (825499598)

Establishment

Name	Address	ID/FEI	Business Operations
House and Beauty Care México, S.A. de C.V.		812821623	api manufacture(78440-001)

Establishment

Name	Address	ID/FEI	Business Operations
INTERNATIONAL GENERAL TRADING CORP		825499598	relabel(78440-001)

Revised: 7/2020 INTERNATIONAL GENERAL TRADING CORP