HAND SANITIZER- isopropyl alcohol gel
Neptune Health & Wellness Innovation, 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.

Active Ingredient(s)

Isopropyl Alcohol 70% 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

- 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

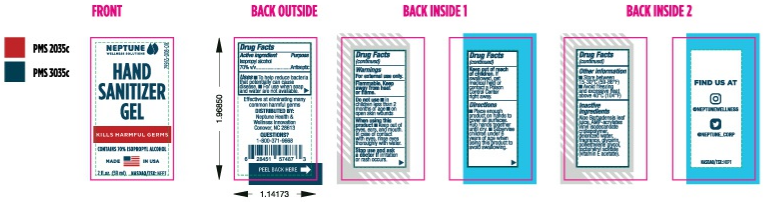
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

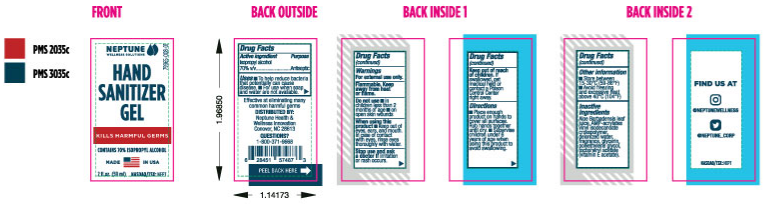
Aloe Barbadensis leaf juice, AMP-acrylates vinyl isodecanoate crosspolymer, deionized water, fragrance, glycerin, polyethylene glycol, tocopheryl acetate (vitamin E acetate).

Package Label - Principal Display Panel

2 fl. oz. (60 ml) NDC: 79965-008-00



2 fl. oz. (60 ml) NDC: 79965-008-01



33.8 fl. oz. (1.1 qt.) / 1 L NDC: 79965-008-11

PMS 3035C

PMS 2191C

4.75”

6”

HAND SANITIZER

isopropyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79965-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	0.1 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.3 mL in 100 mL
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	0.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	1.7 mL in 100 mL
WATER (UNII: 059QF0KO0R)	26.8 mL in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:79965-008-00	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2020	
2	NDC:79965-008-11	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/19/2020	

Labeler - Neptune Health & Wellness Innovation, Inc. (117560399)

Establishment

Name	Address	ID/FEI	Business Operations
Shotwell Hydrogenics, LLC		108985732	manufacture(79965-008) , pack(79965-008) , label(79965-008)

Revised: 9/2020 Neptune Health & Wellness Innovation, Inc.