HAND SANITIZER- alcohol gel
OXYGEL ALOE VERA- alcohol gel
Matilde Gómez López

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)

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.

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 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

NDC 78084-001: purified water USP, glycerin, carbomer, triethanolamine.

NDC 78084-002: purified water USP, glycerin, carbomer, triethanolamine, aloe vera.

Package Label - Principal Display Panel

500 mL NDC:78084-001-01

1000 mL NDC: 78084-001-02

200000 mL NDC: 78084-001-03

500 mL NDC:78084-002-01

1000 mL NDC:78084-002-02

250 mL NDC:78084-002-03

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78084-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER 940 (UNII: 4Q93RCW27E)	1.8 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	6.7 mL in 100 mL
TRIETHANOLAMINE HYDRIODIDE (UNII: DT98IT03JK)	1.8 g in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78084-001-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78084-001-02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78084-001-03	200000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

OXYGEL ALOE VERA

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78084-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	3 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	5 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF POLYSACCHARIDES (UNII: W21O437517)	5 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78084-002-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/2020	
2	NDC:78084-002-02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/2020	
3	NDC:78084-002-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/22/2020	

Labeler - Matilde Gómez López (951577135)

Registrant - Matilde Gómez López (951577135)

Establishment

Name	Address	ID/FEI	Business Operations
Matilde Gómez López		951577135	manufacture(78084-001, 78084-002) , pack(78084-001, 78084-002) , label(78084-001, 78084-002)

Revised: 7/2020 Matilde Gómez López