HAND SANITIZER- alcohol gel Corporativo Concasa, S.A. de C.V.

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 75% 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.

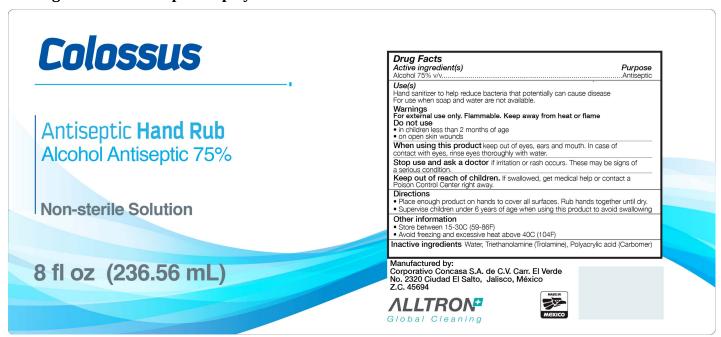
Other information

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

Inactive ingredients

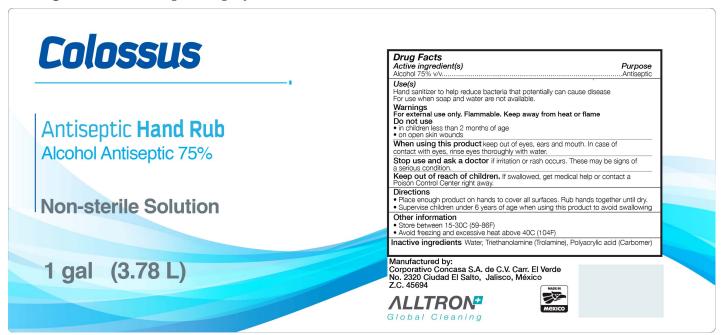
Water, Triethanolamine (Trolamine), polyacrylic acid (carbomer)

Package Label - Principal Display Panel



236.56 mL NDC: 77766-001-01

Package Label - Principal Display Panel



3780 mL NDC code: 77766-001-02

Package Label

Colossus

Antiseptic Hand Rub Alcohol Antiseptic 75%

Non-sterile Solution

5.28 gal (20 L)

Drug Facts Active ingredient(s) Alcohol 75% v/v..... Purpose

Use(s)
Hand sanitizer to help reduce bacteria that potentially can cause disease
For use when soap and water are not available.

Warnings
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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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Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients Water, Triethanolamine (Trolamine), Polyacrylic acid (Carbomer)

Manufactured by: Corporativo Concasa S.A. de C.V. Carr. El Verde No. 2320 Ciudad El Salto, Jalisco, México Z.C. 45694





4 mL in 1000 mL

20000 mL NDC: 77766-001-03

HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77766-001

Route of Administration TOPICAL

POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 760 mL in 1000 mL

Inactive Ingredients Ingredient Name Strength 5 mL in 1000 mL TROLAMINE (UNII: 9O3K93S3TK) WATER (UNII: 059QF0KO0R) 240 mL in 1000 mL

	Packaging					
o de	Package Description	Marketing Start Date	Marketing End Date			
236.56 Produc	6 mL in 1 BOTTLE; Type 0: Not a Combination ct	05/19/2020				
3780 i	mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020				
	, 11	05/19/2020				
-(20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/20 20			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	05/15/2020				

Labeler - Corporativo Concasa, S.A. de C.V. (814988515)

Registrant - Isamar Topete (814988515)

Establishment								
Name	Address	ID/FEI	Business Operations					
Corporativo Concasa, S.A. de C.V.		814988515	manufacture(77766-001)					

Revised: 5/2020 Corporativo Concasa, S.A. de C.V.