

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

Colossus

Antiseptic Hand Rub

Alcohol Antiseptic 75%

Non-sterile Solution

8 fl oz (236.56 mL)

Drug Facts	Purpose
Active ingredient(s) Alcohol 75% v/v	Antiseptic
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Manufactured by:
Corporativo Concasa S.A. de C.V. Carr. El Verde
No. 2320 Ciudad El Salto, Jalisco, México
Z.C. 45694

ALLTRON+
Global Cleaning



236.56 mL NDC: 77766-001-01

Package Label - Principal Display Panel

Colossus

Antiseptic Hand Rub

Alcohol Antiseptic 75%


Non-sterile Solution

1 gal (3.78 L)

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

Antiseptic

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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Do not use

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Other information

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

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

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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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	5 mL in 1000 mL
WATER (UNII: 059QF0KO0R)	240 mL in 1000 mL
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	4 mL in 1000 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77766-001-01	236.56 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
2	NDC:77766-001-02	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
3	NDC:77766-001-03	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	

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.