

CLEENSCENT HAND SANITIZER GEL- isopropyl alcohol gel
XMA Servicios de Manufactura S de RL de CV

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.

CleenScent Hand Sanitizer Gel

This is a hand sanitizer manufactured according to the **Topical Antimicrobial Drug Products for Over-the-Counter Human Use Final Rule (84 FR 14847) (effective April 12, 2020).**

The hand sanitizer is manufactured using United States Pharmacopoeia (USP) grade ingredients in the preparation of the product, with percentages of the active ingredient consistent with the above mentioned final rule, Isopropyl Alcohol (70%, v/v).

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

Hand Sanitizer

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

For external use only. Flammable. Keep away from heat or flame

- 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.

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.

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

glycerin, purified water USP, carbomer, trolamine



CleanScent



70%
IPA Alcohol

Hand Sanitizer Gel



fragrance-free
Soft hands feeling

2 fl oz (60 ml)

60 ml NDC: 78108-1704-2



Drug Facts

Active Ingredient[s]	Purpose
Isopropyl Alcohol 70% v/v	Antiseptic

Use[s]:

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.

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: Glycerin, Purified Water, Carbomer, Triethylamine

NDC CODE 78108-1704-2



7 500464 382689

Manufactured by XMA Servicios de Manufactura S de RL de CV,
Juarez, CH, 32590. Questions? contact@puregel.mx
+52 656 887 3756, Made In Mexico.

CLENSCENT HAND SANITIZER GEL

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78 108-1704
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	
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)			1 mL in 100 mL	
CARBOMER 940 (UNII: 4Q93RCW27E)			0.3 g in 100 mL	
TROLAMINE (UNII: 9O3K93S3TK)			0.1 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78108-1704-2	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/04/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	08/04/2020	

Labeler - XMA Servicios de Manufactura S de RL de CV (951577310)

Establishment			
Name	Address	ID/FEI	Business Operations
XMA Servicios de Manufactura S de RL de CV		951577310	manufacture(78108-1704)

Revised: 8/2020 XMA Servicios de Manufactura S de RL de CV