HAND SANITIZER- antiseptic foam aerosol, foam
Innovaciones Tecnologicas Concar SA 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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. Glycerol (1.45% v/v).
c. Hydrogen peroxide (0.125% v/v).
d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% 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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

230 mL NDC: 79279-520-08

PROPERTIES

- Alcohol, fragance and dye-free
- Contains emollients

SQ2SKIN

SKIN CARE

ANTISEPTIC HAND SANITIZER FOAM

Benzalkonium Chloride 0.13%

7.8 fl oz (230mL)

7 503024 307269

Drug Facts

Active ingredient **Purpose**
Benzalkonium chloride 0.13% ....Antiseptic

Use
■ for hand washing to decrease bacteria on the skin

Warnings
For external use only.

Do not use in the eyes

Stop use and ask a doctor if
■ irritation and redness develop. If condition persists for more than 72 hours consult a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
wet hands thoroughly with product and allow to dry without wiping

Other information
avoid use in case of hypersensitivity to benzalkonium chloride

Inactive ingredients
Citric Acid, Hydroxyethylcellulose, Lanolin Ethoxylated, Povidone, Propylene Glycol, Water

Questions or Comments?
818-619-2735

DISTRIBUTED BY:
INNOVACIONES TECNOLOGICAS CONCAR, S.A. DE C.V.
Palenque No. 591, Col. Letrán Valle,
Benito Juárez, C.P. 03650,
CDMX, México.
Made in México.

LOT
EXP DATE._____

www.sq2pro.com.mx

It is not medicine
Only for external use

HAND SANITIZER

antiseptic foam aerosol, foam

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79279-520
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.8 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1.45 mL in 100 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:79279-520-08	230 mL in 1 BOTTLE, SPRAY; 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	

Labeler - Innovaciones Tecnologicas Concar SA de CV (951578588)

Establishment

Name	Address	ID/FEI	Business Operations
Innovaciones Tecnologicas Concar SA de CV		951578588	manufacture(79279-520)

Revised: 6/2020 Innovaciones Tecnologicas Concar SA de CV