XANITIZESPRAY- alcohol solution
Cospro Development Corp

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) (70%, 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.
c. Sterile distilled water or boiled cold water.

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

glycerin, polysorbate 20, purified water, aloe barbadensis leaf juice, citrus aurantium dulcis (orange) peel oil, tocopheryl acetate, maltodextrin, Parfum

Package Label - Principal Display Panel

XANITIZESPRAY

PAUL MAZZOTTA
FACTOR™

- Kills 99.9% most bacteria
- Infused with Aloe Vera, Vitamin E & Glycerin
- Refreshing Scent

Xanitize™ Hand SANITIZER

242 ml e 8.2 fl oz

Drug Facts

Active ingredient — **Purpose**
Ethyl Alcohol 70% ..... Antiseptic

Use • Hand sanitizer to help reduce bacteria on the skin

Warnings
Flammable. Keep away from fire and flame

For external use only

When using this product
do not use in or near eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if Irritation or rash appears and lasts

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

Directions.
Put enough product in your palm to cover hands and rub hands together briskly until dry. • Children under 6 years of age should be supervised when using this product

Other Information • Store Below 110°F (43°C)
• May discolor certain fabrics or surfaces

Inactive Ingredients: Aqua (Deionized Water), Glycerin, Polysorbate 20, Aloe Barbadensis Leaf Juice, Citrus Aurantium Dulcis (Orange) Peel Oil, Tocopheryl Acetate, Maltodextrin, Parfum (Fragrance)

Questions or Comments? www.paulmazzotta.us

Xanitize™ Hand SANITIZER
Never be without protection!
• Shield your hands from germs naturally with Xanitize
• Formulated with Aloe, Vitamin E, and Glycerin.

12M
CRUELTY FREE;
No Animal Testing
No Animal Ingredients

Made in USA & Distr. by
DICALABRIA Inc., P.O. Box 96
Reading, PA 19607 USA
www.paulmazzotta.us

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alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:46607-116
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ORANGE PEEL (UNII: TI9T76XD44)	
ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:46607-116-01	242 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	
2	NDC:46607-116-06	115 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2020	
3	NDC:46607-116-05	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	
4	NDC:46607-116-04	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	
5	NDC:46607-116-03	220 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	
6	NDC:46607-116-02	295 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/13/2020	

Labeler - Cospro Development Corp (785638821)

Registrant - Cospro Development Corp (785638821)

Establishment

Name	Address	ID/FEI	Business Operations
Cospro Development Corp		785638821	manufacture(46607-116) , pack(46607-116) , label(46607-116)