XANITIZE- 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.

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 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.

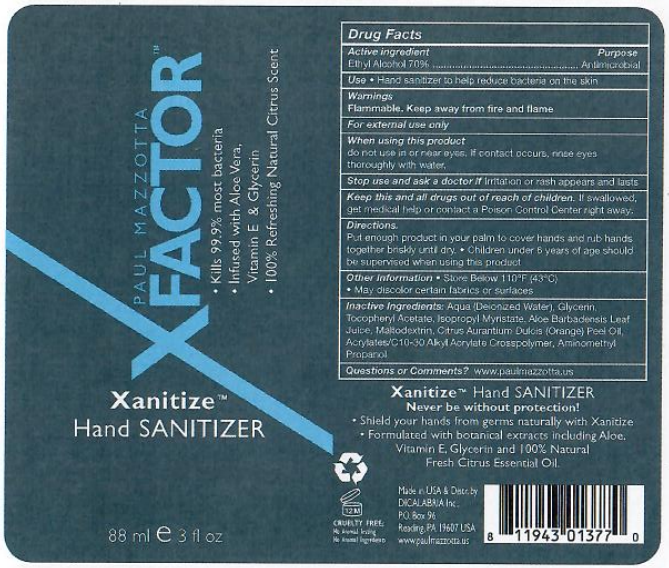
Other information

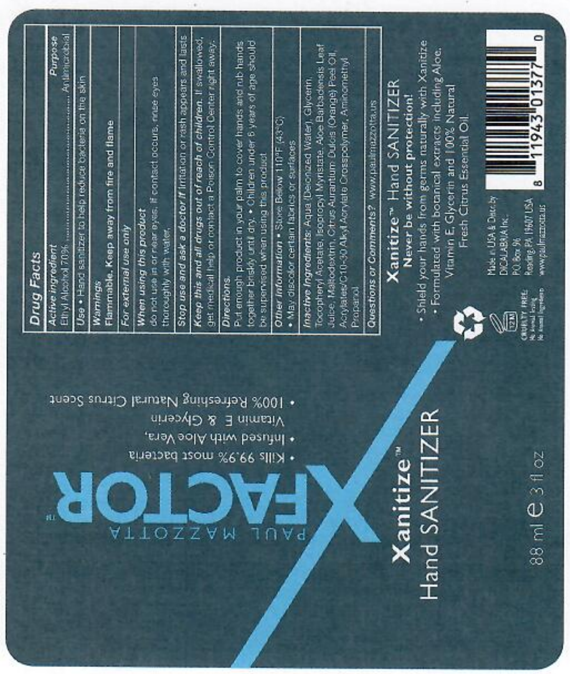
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, tocopheryl acetate, purified water, isopropyl myristate, aloe barbadensis leaf juice, maltodextrin, citrus aurantium dulcis peel oil, acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol

Principle display label


PAUL MAZZOTTA
XFACTOR™
• Kills 99.9% most bacteria
• Infused with Aloe Vera, Vitamin E & Glycerin
• 100% Refreshing Natural Citrus Scent
Xanitize™
Hand SANITIZER
88 ml e 3 fl oz
Drug Facts
Active ingredient
Ethyl Alcohol 70% ..... Purpose
Antimicrobial
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, Tocopheryl Acetate, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Maltodextrin, Citrus Aurantium Dulcis (Orange) Peel Oil, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol
Questions or Comments? www.paulmazzotta.us
Xanitize™ Hand SANITIZER
Never be without protection!
• Shield your hands from germs naturally with Xanitize
• Formulated with botanical extracts including Aloe, Vitamin E, Glycerin and 100% Natural Fresh Citrus Essential Oil.
12 M
CRUELTY FREE
No Animal Testing
No Animal Ingredients
Made in USA & Distr. by
DICALABRIA Inc.
P.O. Box 91
Reading, PA 19607 USA
www.paulmazzotta.us
8 11943 01377 0


PAUL MAZZOTTA
XFACTOR™
• Kills 99.9% most bacteria
• Infused with Aloe Vera,
Vitamin E & Glycerin
• 100% Refreshing Natural Citrus Scent
Xanitize™
Hand SANITIZER
88 ml ℮ 3 fl oz
Drug Facts
Active ingredient Purpose
Ethyl Alcohol 70% .... Antimicrobial
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, Tocopheryl Acetate, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Maltodextrin, Citrus Aurantium Dulcis (Orange) Peel Oil, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol
Questions or Comments? www.paulmazzotta.us
Xanitize™ Hand SANITIZER
Never be without protection!
• Shield your hands from germs naturally with Xanitize
• Formulated with botanical extracts including Aloe. Vitamin E, Glycerin and 100% Natural Fresh Citrus Essential Oil.
12M
CRUELTY FREE:
Made in USA & Distr. by
DICALABRIA Inc.
P.O. Box 96
Reading, PA 19607 USA
www.paulmazzotta.us
8 11943 01377 0

XANITIZE

alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:46607-114
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
ORANGE PEEL (UNII: TI9T76XD44)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALLYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: B9J55EA6QX)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:46607-114-01	242 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	
2	NDC:46607-114-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	
3	NDC:46607-114-03	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	
4	NDC:46607-114-04	88 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/31/2020	

Labeler - Cospro Development Corp (785638821)

Registrant - Cospro Development Corp (785638821)

Establishment

Name	Address	ID/FEI	Business Operations
Cospro Development Corp		785638821	manufacture(46607-114, 46607-114) , label(46607-114)