

XANITIZE- alcohol solution
ICM Distributing Company, INC

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.

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin.

Warnings

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

Do not use

- in children less than 2 months of age
- on open skin wounds

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 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.

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

Directions

- Place enough product in your palm to cover hands and rub hands together briskly until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store below 110°F (43°C)

Inactive ingredients

deionized water, glycerin, polysorbate 20, aloe leaf juice, orange peel oil, tocopheryl acetate, maltodextrin, parfum

Package Label - Principal Display Panel

Never be without protection!
Shield your hands from germs naturally with our plant-based hand sanitizers. Infused with Aloe Vera, Vitamin E and Glycerin to keep your hands feeling silky smooth. Now you can cleanse and protect your hands with our vegan formula that leaves your hands hydrated & healthy.

Hand SANITIZER

Kills 99.9% of Most Bacteria

Infused with
Aloe Vera,
Vitamin E & Glycerin

Xanitize[™]

Citrus
Scent

242 ml e 8.2 fl oz

Drug Facts

Active ingredient

Ethyl Alcohol 70% Antiseptic

Purpose

Hand sanitizer to help reduce bacteria on the skin

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 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 Barbacensis Leaf Juice, Citrus Aurantium Dulcis (Orange) Peel Oil, Tocopheryl Acetate, Maltodextrin, Parfum (Fragrance)

Questions or Comments? 1-800-848-9692

CRUELTY FREE;
No Animal Testing
No Animal Ingredients



Made in USA
Distr. by ICM
Distributing Company
1755 Enterprise Pkwy
Twinsburg, OH 44087



XANITIZE

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77516-111
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
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE (UNII: V5VD430YW9)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ORANGE PEEL (UNII: T9T76XD44)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77516-111-01	242 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/13/2020	
2	NDC:77516-111-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/13/2020	

Labeler - ICM Distributing Company, INC (780594458)

Registrant - Cospro Development Corp (785638821)

Establishment

Name	Address	ID/FEI	Business Operations
Cospro Development Corp		785638821	manufacture(77516-111) , label(77516-111) , pack(77516-111)