

HAND SANITIZER- alcohol liquid
Tecnoglobal Ph7, S.a. De C.v.

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.

Sanitz 75470-110

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.

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

Water, PEG-12 Dimethicone, Glycerin, Carbomer, Propylene Glycol, Aminomethyl Propanol, Phenoxyethanol, Iodoprpylnyl Butylcarbamate, Tetrasodium EDTA, Ext. Violet 2, Aloe Barbadensis Leaf Juice

Package Label - Principal Display Panel

30mL NDC: 75470-110-05

60mL NDC: 75470-110-04

900mL NDC: 75470-110-03



400mL NDC: 75470-110-02



Drug Facts

Active ingredient(s)	Purpose
Ethyl 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

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Other information

• Store between 15-30C (59-86F)

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Inactive ingredients

Water, PEG-12 Dimethicone, Glycerin, Carbomer, Propylene Glycol, Aminomethyl Propanol, Phenoxythano/Modopropyl Butylcarbamate, Tetrasodium EDTA, Ext. Violet 2 (CI 60730), Aloe Barbardensis Leaf Juice.

Meets Food Code Hand Sanitizers criteria (Section 2-301.16) published by the FDA.

NDC 75470-100-03



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Distributed by: Mexilink Incorporated
200 Westlake Park Blvd., Suite 900, Houston, TX 77079
Made in Mexico
www.sanitzproducts.com



251mL NDC: 75470-110-01

Drug Facts	
<i>Active ingredient(s)</i>	<i>Purpose</i>
Ethyl 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 Water, PEG-12 Dimethicone, Glycerin, Carbomer, Propylene Glycol, Aminomethyl Propanol, Phenoxyethanol/Iodopropynyl Butylcarbamate, Tetrasodium EDTA, Ext. Violet 2 (CI 60730), Aloe Barbadosis Leaf Juice.	
Meets Food Code Hand Sanitizers criteria (Section 2-301.16) published by the FDA.	
NDC 75470-100-02	
	
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Distributed by: Mexlink Incorporated 200 Westlake Park Blvd., Suite 900, Houston, TX 77079 Made in Mexico www.sanitzproducts.com	



Drug Facts

Active Ingredient(s)	Purpose
Ethyl 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
Water, PEG-12 Dimethicone, Glycerin, Carbomer, Propylene Glycol, Aminomethyl Propanol, Phenoxyethanol/Iodopropynyl Butylcarbamate, Tetrasodium EDTA, Ext. Violet 2 (CI 60730), Aloe Barbardensis Leaf Juice.

Meets Food Code Hand Sanitizers criteria (Section 2-301.16) published by the FDA.

NDC 75470-100-01



Distributed by: Medlink Incorporated
200 Westlake Park Blvd., Suite 900, Houston, TX 77079
Made in Mexico
www.sanitzproducts.com

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75470-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	

GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE SODIUM (UNII: MP1J8420LU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75470-110-01	251 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75470-110-02	400 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75470-110-03	900 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75470-110-04	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75470-110-05	30 mL in 1 BOTTLE; 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 - Tecnoglobal Ph7, S.a. De C.v. (813006665)

Establishment

Name	Address	ID/FEI	Business Operations
Tecnoglobal Ph7 S.a De C.v.		813006665	manufacture(75470-110)

Revised: 8/2020

Tecnoglobal Ph7, S.a. De C.v.