

PRO CLEAN INSTANT HAND SANITIZER- alcohol liquid

Sistemas de Sanitazion y Fragancias Avanzados S.A.

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.

Pro Clean Instant Hand Sanitizer

Drug Facts

Active ingredient[s]

Ethyl Alcohol 70%

Purpose

Antiseptic

Use[s]

To help reduce bacteria and germs on the skin that potentially can cuase disease. Recommended for repeated use

Warnings

For external use only.

Flammable. Keep away from heat or flame

Do not use

- in eyes, in case of contact rinse eyes thoroughly with water
- 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 20-25C (68-77F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water, carbomer, triethanolamine, glycerin.

Package Labeling:29ml



Drug Facts	
Active ingredient[s]	Purpose
Ethyl Alcohol 70%	Antiseptic
Use[s]	
To help reduce bacteria and germs on the skin that potentially can cause disease. Recommended for repeated use	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
• in eyes, in case of contact rinse eyes thoroughly with water • 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 20-25C (68-77F) • Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients	
Water, carbomer, triethanolamine, glycerin.	

Made in Guatemala by sistemas de sanitización y fragancias avanzados, S.A.
(502) 23042700

Package Labeling:59ml



Drug Facts	
Active ingredient[s]	Purpose
Ethyl Alcohol 70%	Antiseptic
Use[s]	
To help reduce bacteria and germs on the skin that potentially can cause disease. Recommended for repeated use	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> • in eyes, in case of contact rinse eyes thoroughly with water • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 20-25C (68-77F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients	
Water, carbomer, triethanolamine, glycerin.	

Made in Guatemala by sistemas de sanitización y fragancias avanzados, S.A.
(502) 23042700

Package Labeling:236ml



<i>Drug Facts</i>	
<i>Active ingredient[s]</i>	<i>Purpose</i>
Ethyl Alcohol 70%	Antiseptic
<i>Use[s]</i>	
To help reduce bacteria and germs on the skin that potentially can cause disease. Recommended for repeated use	
<i>Warnings</i>	
For external use only. Flammable. Keep away from heat or flame	
<i>Do not use</i>	
<ul style="list-style-type: none"> • in eyes, in case of contact rinse eyes thoroughly with water • 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.	
<i>Directions</i>	
<ul style="list-style-type: none"> • 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. 	
<i>Other information</i>	
<ul style="list-style-type: none"> • Store between 20-25C (68-77F) • Avoid freezing and excessive heat above 40C (104F) 	
<i>Inactive ingredients</i>	
Water, carbomer, triethanolamine, glycerin.	

Made in Guatemala by sistemas de sanitización y fragancias avanzados, S.A.
(502) 23042700

Package Labeling:295ml



Drug Facts	
Active ingredient[s]	Purpose
Ethyl Alcohol 70%	Antiseptic
Use[s]	
To help reduce bacteria and germs on the skin that potentially can cause disease. Recommended for repeated use	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> • in eyes, in case of contact rinse eyes thoroughly with water • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 20-25C (68-77F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients	
Water, carbomer, triethanolamine, glycerin.	

Made in Guatemala by sistemas de sanitización y fragancias avanzados, S.A.
(502) 23042700

Package Labeling:473ml



Drug Facts	
Active ingredient[s]	Purpose
Ethyl Alcohol 70%	Antiseptic
Use[s]	
To help reduce bacteria and germs on the skin that potentially can cause disease. Recommended for repeated use	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> • in eyes, in case of contact rinse eyes thoroughly with water • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 20-25C (68-77F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients	
Water, carbomer, triethanolamine, glycerin.	

Made in Guatemala by sistemas de sanitización y fragancias avanzados. S.A.
(502) 23042700

Package Labeling:3785ml



Drug Facts	
Active ingredient[s]	Purpose
Ethyl Alcohol 70%	Antiseptic
Use[s]	
To help reduce bacteria and germs on the skin that potentially can cause disease. Recommended for repeated use	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> • in eyes, in case of contact rinse eyes thoroughly with water • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 20-25C (68-77F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients	
Water, carbomer, triethanolamine, glycerin.	

Made in Guatemala by sistemas de sanitización y fragancias avanzados. S.A.
(502) 23042700

PRO CLEAN INSTANT HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80570-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80570-001-01	29 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2020	
2	NDC:80570-001-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2020	
3	NDC:80570-001-03	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2020	
4	NDC:80570-001-04	295 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2020	
5	NDC:80570-001-05	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2020	
6	NDC:80570-001-06	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/01/2020	

Labeler - Sistemas de Sanitazion y Fragancias Avanzados S.A. (817612362)

Establishment

Name	Address	ID/FEI	Business Operations
Sistemas de Sanitazion y Fragancias Avanzados S.A.		817612362	manufacture(80570-001)

Revised: 12/2020

Sistemas de Sanitazion y Fragancias Avanzados S.A.