

PAWR HAND SANITIZER- alcohol gel
Chemical Solutions de México, 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.

Pawr NDC 78672-002

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

water, phenoxyethanol, triethanolamine, carbomer, aloe vera extract

Package Label - Principal Display Panel

500 mL NDC: 78672-002-01



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	
<ul style="list-style-type: none"> ■ in children less than 2 months of age ■ on open skin wounds 	
When using this product keep away from eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.	
Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.	
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 15-30°C (59-86°F) ■ May discolor certain fabrics or surfaces. 	
Inactive ingredients: water, phenoxyethanol, triethanolamine, carbomer, aloe vera extract.	
<p>MANUFACTURED BY: CHEMICAL SOLUTIONS DE MEXICO, SA DE CV, ALFAREROS 547-B, COL. SANTA CLARA COATITLA, ECATEPEC, EDO. DE MEXICO, 55540. PHONE: (52) 55-5749-5222. MADE IN MEXICO.</p> <p>EXPIRATION DATE AND BATCH NUMBER PRINTED IN THE CONTAINER</p>	

PAWR HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78672-002
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
CARBOMER 934 (UNII: Z135WT9208)	0.2 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.6 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.55 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.1 mL in 100 mL
WATER (UNII: 059QF0K00R)	45.41 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78672-002-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/31/2020	

Labeler - Chemical Solutions de México, S.A. de C.V. (813291820)

Establishment

Name	Address	ID/FEI	Business Operations
Chemical Solutions de México, S.A. de C.V.		813291820	manufacture(78672-002)

Revised: 7/2020

Chemical Solutions de México, S.A. de C.V.