

HAND SANITIZER- isopropyl alcohol gel
PMS4PMS, LLC

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.

Isopropyl Alcohol Antiseptic 70% Topical Gel, in three sizes. Not one of the official WHO formulas

Active Ingredient(s)

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

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:

- On 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:

Acrylates/C10-C30 Alkyl Acrylate Crosspolymer, Aloe Leaf Gel, Propylene Glycol, Purified Water, Triethanolamine

Package Label - Principal Display Panel

59 mL NDC: 73603-852-02



Isopropyl Alcohol Antiseptic 70% Topical Gel



Hand Sanitizer
Antiseptic Hand Rub

2 fl.oz/59 ml

Drug Facts	
Active ingredient(s) Isopropyl alcohol 70% v/v	Purpose: 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: • On children in less than 2 months of age. • On open skin wounds	
When using this product keep out of eyes, ears, and mouth. In cases of contact with eyes, rinse eyes thoroughly with water.	
Stop use and 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°-30°C (59°-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients: Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Leaf Gel, Propylene Glycol, Purified Water, Triethanolamine	

Manufactured By:
Alexandria Professional®, LLC
5500 Main Street, Suite 103
Williamsville, NY 14221



236 mL NDC: 73603-852-08



Isopropyl Alcohol Antiseptic 70% Topical Gel



Hand Sanitizer Antiseptic Hand Rub

8 fl. oz / 236 ml

443 mL NDC: 73603-852-15

Drug Facts	
Active ingredient(s) Isopropyl alcohol 70% v/v	Purpose: 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">• On children in less than 2 months of age.• On open skin wounds	
When using this product keep out of eyes, ears, and mouth. In cases of contact with eyes, rinse eyes thoroughly with water.	
Stop use and 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 15°-30°C (59°-86°F)• Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients: Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Leaf Gel, Propylene Glycol, Purified Water, Triethanolamine	

Manufactured By:
Alexandria Professional®, LLC
5500 Main Street, Suite 103, Williamsville, NY 14221





Isopropyl Alcohol Antiseptic 70% Topical Gel



Hand Sanitizer
Antiseptic Hand Rub

15 fl. oz / 443 ml

Drug Facts	
Active ingredient(s) Isopropyl alcohol 70% v/v	Purpose: 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">On children in less than 2 months of age.On open skin wounds	
When using this product keep out of eyes, ears, and mouth. In cases of contact with eyes, rinse eyes thoroughly with water.	
Stop use and 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 15°-30°C (59°-86°F)Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients: Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Leaf Gel, Propylene Glycol, Purified Water, Triethanolamine	

Manufactured By:
Alexandria Professional®, LLC
5500 Main Street, Suite 103, Williamsville, NY 14221



HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73603-852
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)					
WATER (UNII: 059QF0KO0R)					
TROLAMINE (UNII: 9O3K93S3TK)					
Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:73603-852-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2020		
2	NDC:73603-852-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2020		
3	NDC:73603-852-15	443 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2020		
Marketing Information					
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final		part333A	05/06/2020		

Labeler - PMS4PMS, LLC (117393964)

Establishment			
Name	Address	ID/FEI	Business Operations
PMS4PMS, LLC		117393964	manufacture(73603-852)