ISOPROPYL ALCOHOL ANTISEPTIC HAND SANITIZER NON-STERILE- is opropyl alcohol solution SpecGx 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.

4020 Isopropyl Alcohol Antiseptic 75%

Drug Facts Active ingredient(s)

Isopropyl Alcohol 75% 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

- 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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

SpecGx LLC 3600 N. Second St. St. Louis, MO 63147 USA 1-314-654-2000

Rev: 03/2020

Principal Display Panel

Mallinckrodt"

Isopropyl Alcohol Antiseptic 75% Topical Solution

Donated by Mallinckrodt Specialty Generics

Volume: 1 GAL

Hand Sanitizer Non-sterile Solution

CODE: 4020 SKU: 00 EXP 00/0000 LOT: 000000000 CONTAINER: 0

SpecGx LLC 3600 N. Second St St. Louis, MO 63147 USA +1-314-654-2000

03/2020

4020 Isopropyl Alcohol Antiseptic 75%

Drug Facts

Active ingredient[s] Purpose Isopropyl alcohol 75% 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 is 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

glycerin, hydrogen peroxide, purified water USP

SpecGx LLC 3600 N. Second St. St. Louis, MO 63147 USA 1-314-654-2000

Rev: 03/2020

ISOPROPYL ALCOHOL ANTISEPTIC HAND SANITIZER NON-STERILE

isopropyl alcohol solution

Product Information						
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:04	IDC:0406-4020	
Route of Administration	TOPICAL					
Active Ingredient/Active M	niety					
Active ingreatent/Active M	Ulety					
I	ngredient Name		Basis of Str	rength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -ISOPROPYLUNII:ND2M416302)ALCOHOL				75 mL in 100 mL		
Inactive Ingredients						
macuve mgreulents						
	Ingredient Name				Strength	

G	L YCERIN (UNII: PD	C6A3C0O	X)		
Ю	YDRO GEN PERO X	IDE (UNII:	BBX060AN9V)		
W	ATER (UNII: 059QF	F0KO0R)			
P	ackaging				
#	Item Code		Package Description	Marketing Start Date	Marketing End Date
		3785.41 ml Product	L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	¹ 03/30/2020	
2		946.35 mL Product	in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	03/30/2020	
N	Iarketing In	format	ion		
Marketing Category		gory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Dat
	OTC MONOGRAPH NOT FINAL		000.1	03/03/2020	

Labeler - SpecGx LLC (080679498)

Revised: 4/2020

SpecGx LLC