

MANI SPA GUARD ANTISEPTIC HAND SANITIZER- alcohol solution

Pedisource

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.

MANI SPA GUARDTM ANTISEPTIC HAND SANITIZER

Drug Facts

Active ingredient

Alcohol 80% v/v

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame

For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists 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

- wet hands thoroughly with product and allow to dry without wiping
- 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, water

Questions?

+1-856-320-6927

You may also report serious side effects to this phone number. Mon-Fri 9:00 AM - 5:00 PM

MADE IN * THE USA**

TOPICAL SOLUTION

NON-STERILE SOLUTION

Manufactured by: PediSource LLC, Cinnaminson, NJ, 08077

www.ManiSpaGuard.com

Packaging



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alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77591-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77591-001-05	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/28/2020	
2	NDC:77591-001-06	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/28/2020	
3	NDC:77591-001-07	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/28/2020	

Labeler - Pedisource (023429060)**Establishment**

Name	Address	ID/FEI	Business Operations
Pedisource		023429060	manufacture(77591-001)

Revised: 5/2020

Pedisource