MANI SPA GUARD ADVANCED HAND SANITIZER- alcohol gel
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 GUARD$_{TM}$ ADVANCED HAND SANITIZER

Drug Facts

Active ingredient

Alcohol 70% 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

water, glycerin, aloe barbadensis leaf juice, tocopheryl acetate, polyacrylate crosspolymer, fragrance

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

• ALCOHOL 70% • GEL FORMULA

• WITH ALOE VERA & VITAMIN E

Manufactured by: PediSource LLC, Cinnaminson, NJ, 08077
www.ManiSpaGuard.co m

Packaging

MANI SPA GUARD ADVANCED HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77591-002
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**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:77591-002-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
2	NDC:77591-002-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
3	NDC:77591-002-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
4	NDC:77591-002-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
5	NDC:77591-002-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
6	NDC:77591-002-07	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/12/2020	

Labeler - Pedisource (023429060)

Establishment

Name	Address	ID/FEI	Business Operations
Pedisource		023429060	manufacture(77591-002)