

HAND SANITIZER- alcohol gel
SPEZIERIE PALAZZO VECCHIO DOTT. DI MASSIMO SRL

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.

HAND SANITIZER GEL with LEMON ESSENTIAL OIL

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70,5%, weight/weight (w/w)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1% w/w).
- c. Hydrogen peroxide (0.035% w/w).
- d. Sterile distilled water or boiled cold water.
- e. Aloe barbadensis leaf juice 1 - 5%
- f. Hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer 0.1 - 1%
- g. Squalane 0.1 - 1%
- h. Xanthan gum 0.1 - 1%
- i. Polysorbate 60 0.1 - 1%
- j. CITRUS LIMON PEEL OIL (0,07290%)
- k. Sorbitan isostearate 0 - 0.1%
- l. Chlorhexidine digluconate 0 - 0.1%
- m. LACTIC ACID (0,01500%)

Active Ingredient(s)

Alcohol 70,5% w/w. 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.

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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, Aloe barbadensis leaf juic, Hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, Squalane, Xanthan gum, Polysorbate 60, CITRUS LIMON PEEL OIL , Sorbitan isostearate, Chlorhexidine digluconate, LACTIC ACID

Package Label - Principal Display Panel

100 mL NDC: 81800-657-02

1000 mL NDC: 81800-657-01



SPEZIERIE PALAZZO VECCHIO

GEL MANI
IGIENIZZANTE

LIMONE DI SICILIA

La COSMETICA
FIORENTINA

SPEZIERIE PALAZZO VECCHIO - VIA VACCHERECCIA, 9/R - FIRENZE

INGREDIENTS: ALCOHOL DENAT., AQUA, ALOE BARBADENSIS LEAF JUICE, GLYCERIN
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER,
SQUALANE, XANTHAN GUM, POLYSORBATE 60, LIMONENE, CITRUS LIMON PEEL OIL,
SORBITAN ISOSTEARATE, HYDROGEN PEROXIDE, CHLORHEXIDINE DIGLUCONATE,
LACTIC ACID, CITRAL.

ATTENZIONE: INFIAMMABILE
PRODOTTO COSMETICO - USO ESTERNO

1000 ml e



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SPEZIERIE PALAZZO VECCHIO

GEL MANI
IGIENIZZANTE

LIMONE DI SICILIA

la COSMETICA FIORENTINA

SPEZIERIE PALAZZO VECCHIO - VIA VACCHERECCIA, 9/R - FIRENZE

INGREDIENTS ALCOHOL DENAT., AQUA, ALOE BARBADENSIS LEAF JUICE, GLYCERIN, HYDROXYETHYLCELLULOSE, SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, SQUALANE, XANTHAN GUM, POLYSORBATE 80, LIME OIL, CITRUS LIMON PEE OIL, SORBITAN ISOSTEARATE, HYDROGEN PEROXIDE, CHLORHEXIDINE DIBLUCONATE, LACTIC ACID, CITRAL.

100 ml

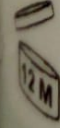
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LOTTO 35620

PRODOTTO COSMETICO
USO ESTERNO

ATTENZIONE: INFIAMMABILE



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81800-657
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70.5 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	0.1 mL in 100 mL
LEMON OIL, COLD PRESSED (UNII: I9GRO824LL)	0.072 mL in 100 mL
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	0.1 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	5 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.035 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	1 mL in 100 mL
SQUALANE (UNII: GW89575KF9)	0.1 mL in 100 mL
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	0.015 mL in 100 mL
XANTHAN GUM (UNII: TTV12P4NEE)	0.1 mL in 100 mL
POLYSORBATE 60 (UNII: CAL22UVI4M)	0.1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81800-657-01	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
2	NDC:81800-657-02	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph not final	part333A	03/30/2020	

Labeler - SPEZIERIE PALAZZO VECCHIO DOTT. DI MASSIMO SRL (431217616)

Registrant - SPEZIERIE PALAZZO VECCHIO DOTT. DI MASSIMO SRL (431217616)

Establishment

Name	Address	ID/FEI	Business Operations
SPEZIERIE PALAZZO VECCHIO DOTT. DI MASSIMO SRL		431217616	manufacture(81800-657)

Revised: 4/2021

SPEZIERIE PALAZZO VECCHIO DOTT. DI MASSIMO SRL