PRIME HAND SANITIZER- is opropyl alcohol gel Prime Dental Manufacturing, Inc.

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.

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. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Isopropyl Alcohol 75% v/v. 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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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

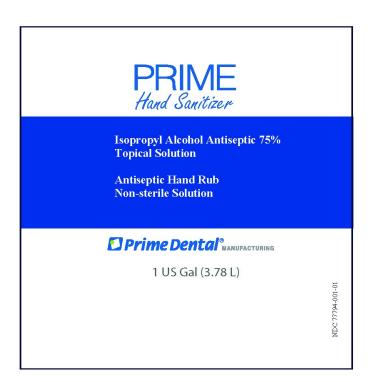
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

3780 mL NDC77794-001-01



Drug Facts	
Active ingredient[s]	Purpose
sopropyl alcohol 75% v/vA	Antiseptic
Use[s]	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings	
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Do not use	
• in children less than 2 months of age	
on open skin wounds	
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Topic opp A. Accided Antitiegatic 75% Topic of Solution Antierptic Hand Rob Non-steride Solution **SEC 7779-1.00 tg 75 **Prime Dential** Assumations **SEC 7779-1.00 tg 75 **SEC 7	14 10 %	5.67.70		
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isopropyl alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77794-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6 A3C0 OX)	1.45 mL in 100 mL			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:77794-001-01	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2020		
2	NDC:77794-001-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2020		
3	NDC:77794-001-03	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2020		
4	NDC:77794-001-04	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2020		
5	NDC:77794-001-05	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2020		

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

Labeler - Prime Dental Manufacturing, Inc. (083614037)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Dental Manufacturing, Inc.		083614037	manufacture(77794-001)

Revised: 5/2020 Prime Dental Manufacturing, Inc.