PRIME HAND SANITIZER- isopropyl 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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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

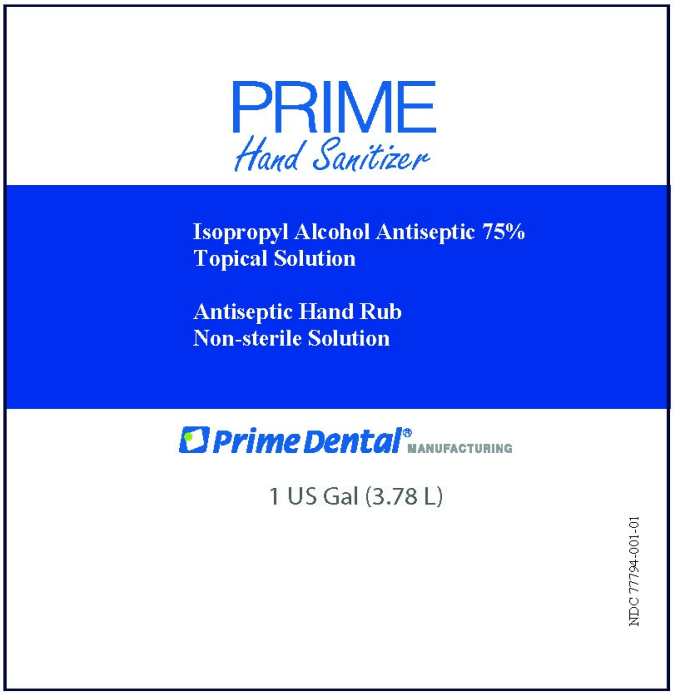
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

3780 mL NDC77794-001-01



Drug Facts

Active ingredient[s] — **Purpose**

Isopropyl alcohol 75% v/v ..... Antiseptic

Use[s]

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings

For external use only. Flammable. Keep away from heat or flame

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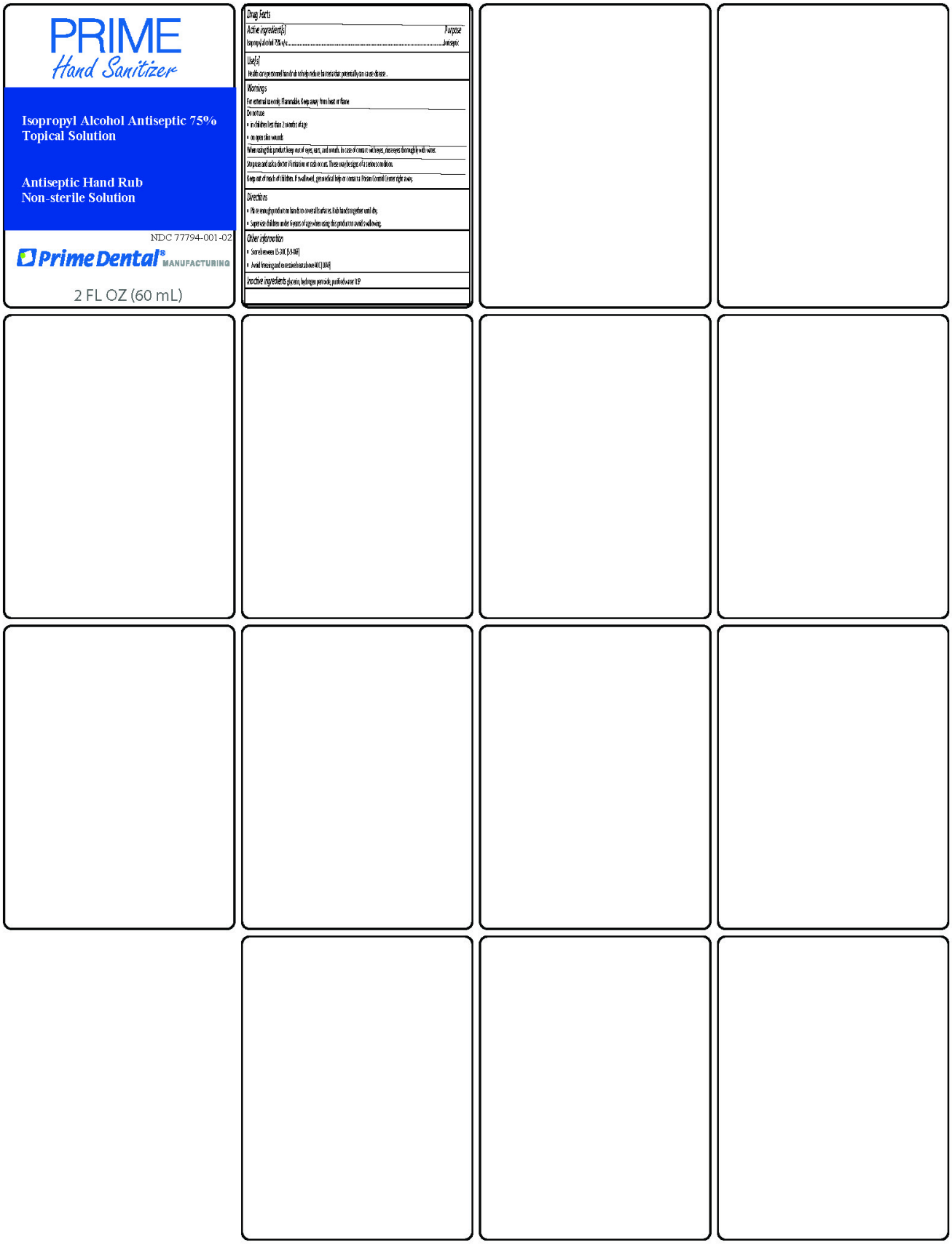
Inactive ingredients glycerin, hydrogen peroxide, purified water USP

60 mL NDC 77794-001-02



118 mL NDC 77794-001-03

PRIME
Hand Sanitizer

Isopropyl Alcohol Antiseptic 75% Topical Solution

Antiseptic Hand Rub Non-sterile Solution

NDC 77794-001-03

Prime Dental® MANUFACTURING

4 FL OZ (118 mL)

Drug Facts

Active ingredient[s] — Purpose

Isopropyl alcohol 75% v/v ..... 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

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- 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.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Pls or enough product on hand 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

236 mL NDC77794-001-04

PRIME
Hand Sanitizer

Isopropyl Alcohol Antiseptic 75% Topical Solution

Antiseptic Hand Rub Non-sterile Solution

NDC 77794-001-04

Prime Dental® MANUFACTURING

8 FL OZ (236 mL)

Drug Facts

Active ingredient(s) — Purpose

Isopropyl alcohol 75% v/v ..... Antiseptic

Use(s)

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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.

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Directions

- Pls or enough product on hand 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)
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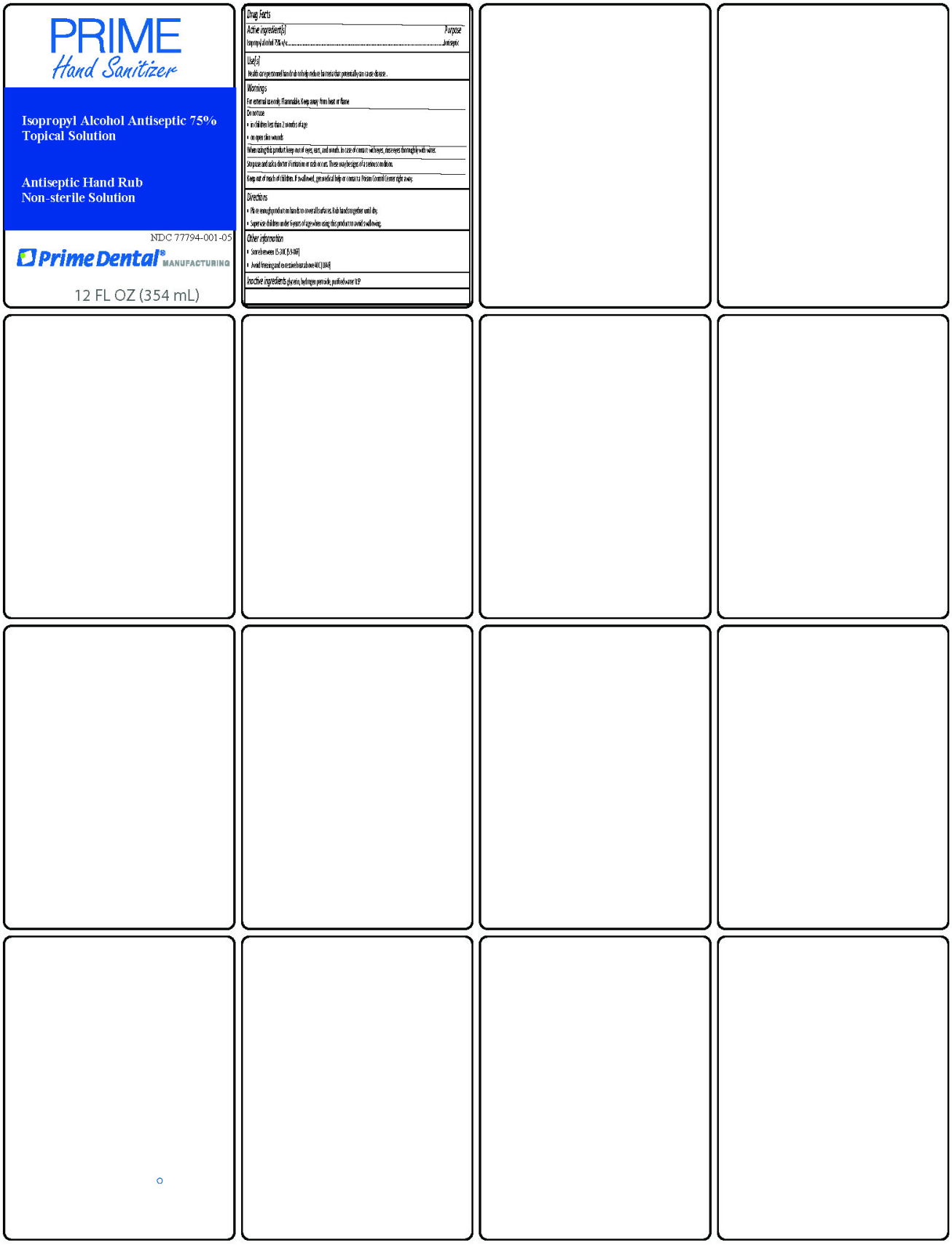
Inactive ingredients glycerin, hydrogen peroxide, purified water USP

354 mL NDC77794-001-05



PRIME HAND SANITIZER

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: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

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 Information

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.