DEFENDER REPELLANT HAND SANITIZER GEL- 80% alcohol gel Prime Leather Finishes Company

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.

Defender Repellant Gel Hand Sanitizer

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

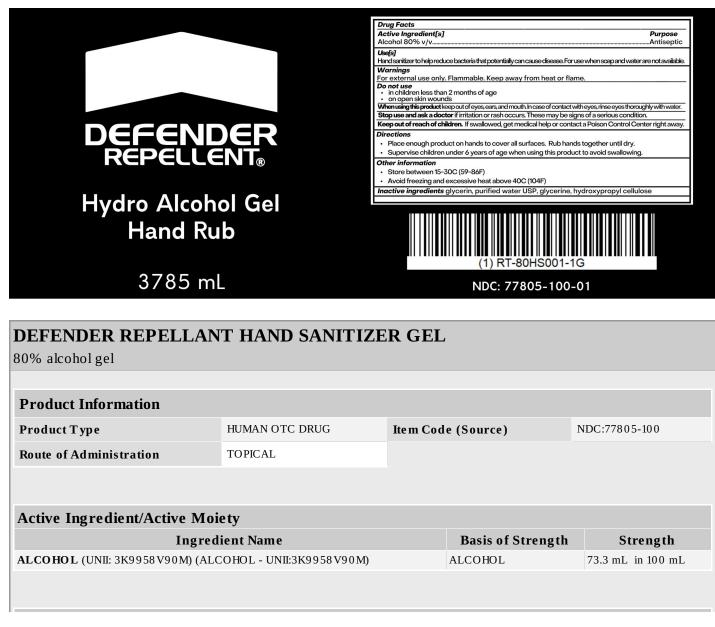
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

3785 mL, 1 Gallon

3785 mL, NDC: 77805-100-01



Inactive Ingre	dients			
Ingredient Name				
WATER (UNII: 059	QF0KO	0 R)		
GLYCERIN (UNII:)	PDC6A3	COOX)		
HYDRO XYPRO PY	L CELI	LULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)		
Packaging				
			Marketing Start	Marketing End
# Item Code		Package Description	Date	Date
 # Item Code 1 NDC:77805-100- 01 	- 3785 Prod	mL in 1 BOTTLE, PUMP; Type 0: Not a Combination	Date 08/24/2020	-
1 NDC:77805-100-		mL in 1 BOTTLE, PUMP; Type 0: Not a Combination		-
1 NDC:77805-100- 01	Pro d	mL in 1 BOTTLE, PUMP; Type 0: Not a Combination uct		-
1 NDC:77805-100- 01	Pro d	mL in 1 BOTTLE, PUMP; Type 0: Not a Combination uct		-
1 NDC:77805-100-	Prod nfor	mL in 1 BOTTLE, PUMP; Type 0: Not a Combination uct		-

Labeler - Prime Leather Finishes Company (006430284)

Registrant - Prime Leather Finishes Company (006430284)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Leather Finishes Company		006430284	manufacture(77805-100)

Revised: 6/2020

Prime Leather Finishes Company