HAND SANITIZER- is opropyl alcohol spray Hayward Laboratories 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.

4915 Palmers Advand Hand sanitizer with Vitamin E Soothing Aloe

unclassified Section

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. Glycerin (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

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

water (auqa), glycerin, hydrogen peroxide, tocopheryl acetate, aloe barbadensis leaf juice, citric acid, potassium sorbate, sodium benzoate, yellow 5 (CI19140), blue1 (CI 42090)

Package Label - Principal Display Panel

ET Browen Drug Co. Inc.

Englewood Cliffs, NJ 07632 USA

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Made in USA with domestic and imported components

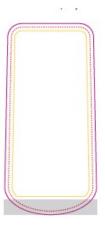
www.palmers.com

Family owned & Operated-seal

Flammble-pictogram









100 ml NDC: 12094-4915-0

HAND SANITIZER

isopropyl alcohol spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12094-4915
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			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.00003 mL in 100 mL			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	0.0001 mL in 100 mL			
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.00005 mL in 100 mL			
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	0.00012 mL in 100 mL			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.0001 mL in 100 mL			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.09973 mL in 100 mL			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)	23.32 mL in 100 mL			
.ALPHATO COPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	0.0001 mL in 100 mL			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12094-4915- 0	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/30/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/30/2020		

Labeler - Hayward Laboratories Inc. (800195513)

Establishment				
Name	Address	ID/FEI	Business Operations	
Hayward Laboraotires Inc.		800195513	manufacture(12094-4915)	

Revised: 9/2020 Hayward Laboratories Inc.