

HAND SANITIZER- isopropyl 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), blue 1 (CI 42090)

Package Label - Principal Display Panel

ET Browne 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

Flammable-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 MONOHYDRATE (UNII: 2968PHW8QP)	0.00012 mL in 100 mL
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.0001 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.09973 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	23.32 mL in 100 mL
.ALPHA.-TOCOPHEROL 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 Laboratires Inc.		800195513	manufacture(12094-4915)