

## **PUROX HAND SANITIZER- alcohol gel**

### **Purox**

*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.*

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### ***Active Ingredient***

Alcohol 85% v/v

### ***Purpose***

Antimicrobial

### ***Use***

Hand Sanitizer to help reduce bacteria on the skin.

### ***Warnings***

**Flammable. Keep away from heat or flame**

**For external use only**

#### **When using this product**

- do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

#### **Stop use and ask a doctor if**

- irritation or rash appears and lasts.

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

#### **Do not use**

- in children less than 2 months of age
- on open skin wounds

#### **Directions**

- Place enough product in your palm to thoroughly spread on both hands and rub into the skin until dry.
- Children under 6 years old should be supervised when using this product.

#### ***Other information:***

- store between 106F (41C)
- may discolor certain fabrics or surfaces

#### ***Inactive ingredients:***

Deionized Water, Aloe, Triethanolamine, Carbomer



MADE IN U.S.A.



Manufactured & Distributed by:

**Purox Brands**

Miami, FL 33178

Questions & Comments:

1-888-920-0131



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**Rinse Free & Non Sticky**

16 fl.oz. (0.473 L)

**PUROX HAND SANITIZER**

alcohol gel

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78186-001
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	85 L in 100 L

## Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	0.05 L in 100 L
TROLAMINE (UNII: 9O3K93S3TK)	0.03 L in 100 L
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	1.45 L in 100 L
WATER (UNII: 059QF0K00R)	13.47 L in 100 L

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78186-001-03	0.473 L in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/08/2020	

**Labeler** - Purox (121224718)

## Establishment

Name	Address	ID/FEI	Business Operations
Purox		121224718	manufacture(78186-001)

Revised: 7/2020

Purox