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.

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 th 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

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: 059QF0KO0R)	13.47 L in 100 L

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:78186-001-04	3.785 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