SOPURE- denatured ethanol cloth EnviroServe Chemicals & Cleaners Ltd

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.

SOPURE Sanitizing Wipes

Active Ingredient

Ethanol USP 80%v/v

Purpose

Medicated Skin Cleanser Kills harmful bacteria/germs

Warnings

- Avoid contact with eyes. In case of contact, rinse eyes thoroughly with water.
- If irritation develops, consult a doctor. Keep out of reach of children.
- Do not use on children / infants less than 2 years of age (unless directed by a doctor or physician).
- Ifswallowed, call a poison control center or get medical help right away.
- Keep away from open flame and sources of heat.

Uses

Hand Sanitizing wipes Kills harmful bacteria/germs.

Directions

Use as need on basis. Wipe your hands to help prevent spread of bacteria.

Keep out of reach of Children

Do not use on children / infants less than 2 years of age (unless directed by a doctor or physician.)

Inactive Ingredients

Water, glycerin, hydrogen peroxide, alpha tocopherol acetate

Product Label



SOPURE

denatured ethanol cloth

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:80773-002 Route of Administration TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.8			

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:80773-002- 01	100 in 1 POUCH; Type 0: Not a Combination Product	11/23/2021			
2	NDC:80773-002- 02	80 in 1 POUCH; Type 0: Not a Combination Product	11/23/2021			
3	NDC:80773-002- 03	120 in 1 POUCH; Type 0: Not a Combination Product	11/23/2021			
4	NDC:80773-002- 04	160 in 1 POUCH; Type 0: Not a Combination Product	11/23/2021			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	11/23/2021			

Labeler - EnviroServe Chemicals & Cleaners Ltd (243690711)

Revised: 11/2021 EnviroServe Chemicals & Cleaners Ltd