

OPTOCAL SANITIZING WIPES- alcohol cloth
Foshan Clean & Simple Cleaning Products Co., 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.

OPTOCAL Sanitizing Wipes

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Active Ingredient(s)

Alcohol 3mL/pcs. Purpose: Antiseptic

Purpose

Antiseptic, OPTOCAL Sanitizing Wipes

Use

OPTOCAL Sanitizing Wipes 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

- Wipe the surface of the skin and let it dry naturally
- 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
Chlorhexidine acetate
Preservatives
Ammonium lauryl sulfate

Package Label - Principal Display Panel



OPTICAL SANITIZING WIPES

alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77980-701
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	3 mL

Inactive Ingredients

Ingredient Name	Strength
CHLORHEXIDINE ACETATE (UNII: 5908ZUF22Y)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77980-701-01	412 in 1 CYLINDER; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Foshan Clean & Simple Cleaning Products Co., Ltd. (407577237)**Establishment**

Name	Address	ID/FEI	Business Operations
Foshan Clean & Simple Cleaning Products Co., Ltd.		407577237	manufacture(77980-701)

Revised: 8/2020

Foshan Clean & Simple Cleaning Products Co., Ltd.