

ALCOHOL DISINFECTANT- alcohol liquid
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.

Alcohol disinfectant

Alcohol disinfectant

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Alcohol disinfectant

Use

Alcohol disinfectant 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.

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.

Directions

- Spray on skin surface 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

purified water USP

Package Label - Principal Display Panel



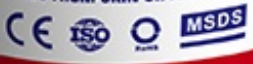


OPULA®



**ALCOHOL
DISINFECTANT
75% ALCOHOL**

**KILL GERMS OR
VIRUS FROM SKIN OR APPLIANCE**



Net Content: 250ml



OPULA®
欧普拉



酒精消毒液

ALCOHOL DISINFECTANT

75% 酒精

+ 抑菌 + 抗菌 + 清洁

适用于皮肤及物品的杀菌消毒用途





OPULA[®]



**ALCOHOL
DISINFECTANT
75% ALCOHOL**

**KILL GERMS OR
VIRUS FROM SKIN OR APPLIANCE**



Net Content: 300ml



OPULA®

SCOPE OF APPLICATION
Designed for skin and object disinfection.

EXPLANATION
Spray directly on the skin or object surface, or spray on the cloth, then wipe and disinfect.

PREDICATION
Infection use with caution in allergic people.
Dry disinfected surfaces and avoid contact with mucous membranes.

STORAGE CONDITIONS
Store in cool, dry and ventilated place without extreme pH environment.
Avoid direct sunlight and keep away from high temperature and fire.



**ALCOHOL
DISINFECTANT**

75% v/v Alcohol

**KILL GERMS OR
VIRUS FROM SKIN OR APPLIANCE**



NW: 100ml



OPULA®



**ALCOHOL
DISINFECTANT**

75% ALCOHOL

**KILL GERMS OR
VIRUS FROM SKIN OR APPLIANCE**



NW: 100ml



ALCOHOL DISINFECTANT

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77980-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77980-201-01	10 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77980-201-02	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77980-201-03	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77980-201-04	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77980-201-05	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:77980-201-06	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:77980-201-07	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:77980-201-08	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:77980-201-09	1000 mL in 1 BOTTLE; 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(77980-201)

Revised: 5/2020

Foshan Clean & Simple Cleaning Products Co., Ltd.