

ONE DROP CARE HAND SANITIZER- alcohol solution
Guangdong Essence Daily Chemical 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.

Drug Facts

Active ingredient

Alcohol 80% (V/V)

Purpose

Antiseptic

Use

health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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, 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.

Inactive ingredients

Glycerin, hydrogen peroxide, purified water USP

Other information

Store between 15-30 °C (59-86 °F)

avoid freezing and excessive heat above 40 °C (104 °F)

Packaging



One Drop Care

HAND SANITIZER NON-STERILE

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub
Non-sterile Solution
NDC: 73931-012-02

Net: 250ml



Drug Facts

Active ingredient[s] Alcohol 80% V/V	Purpose Antiseptic
Use[s] Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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.	
Directions • Place enough product on hands to cover all surfaces. Rub hands together 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 glycerin, hydrogen peroxide, purified water USP	

NAME OF MANUFACTURER:

Guangdong Essence Daily Chemical Co.,Ltd.

ADDRESS OF MANUFACTURER: No.63,Guoya Road,Shenshan Administrative Area,Jiנגgao Town,Baiyun District, Guangzhou City,Guangdong Province,China
Tel:86-020-28637361

Distributor: ROC AMERICA LLC
B2 Brier Hill Ct 5A, East Brunswick, NJ 08816
MADE IN CHINA



ONE DROP CARE HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73931-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73931-012-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2020	
2	NDC:73931-012-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/18/2020	

Labeler - Guangdong Essence Daily Chemical Co., Ltd (529796211)

Establishment

Name	Address	ID/FEI	Business Operations
Guangdong Essence Daily Chemical Co., Ltd		529796211	manufacture(73931-012)

Revised: 6/2020

Guangdong Essence Daily Chemical Co., Ltd