

CELLAPY CLEANTECH DERMA SANITIZER- alcohol gel
GM Holdings 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

ACTIVE INGREDIENT: Ethyl Alcohol 65.3% v/v

INACTIVE INGREDIENT

INACTIVE INGREDIENT:

Water, Glycerin, Carbomer, Trolamine, Fragrance

PURPOSE

PURPOSE: Antiseptic

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Uses:

Uses :

Hand sanitizer to help reduce bacteria that potentially can cause disease.
For use when soap and water are not available

WARNINGS

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

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

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



CELLAPY CLEANTECH DERMA SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69278-116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	16.32 mL in 25 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
Trolamine (UNII: 9O3K93S3TK)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69278-116-01	25 mL in 1 POUCH; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/01/2020	

Labeler - GM Holdings Co., Ltd (688439958)**Registrant** - GM Holdings Co., Ltd (688439958)**Establishment**

Name	Address	ID/FEI	Business Operations
Kukbo Science Co., Ltd.		687792812	manufacture(69278-116)

Revised: 4/2020

GM Holdings Co., Ltd