ECORISO HEALTH CARE HAND SANITIZER- ethyl 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

Ethyl Alcohol 76% v/v

INACTIVE INGREDIENTS

Water, Butylene Glycol, Carbomer, Triethanolamine, Aloe Barbadensis Leaf Extract, Polyoxyethylene Hydrogenated Castor oil, Fragrance

PURPOSE

Antiseptic

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.

Uses:

Hand sanitizer to help reduce bacteria that potentially can cause disease.

For use when soap and water are not available

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)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Antiseptic	Drug Facts	
+ Antiseptic Product HEALTH care	Active Ingredient Purpose Ethyl Alcohol 76% v/v	
Hand sanitizer gel	Uses Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	No4 14/4
Rinse-free Convenient and simple to use hand sanitizer	Warnings For external use only. Flammable. Keep away from heat or flame Do not use in children less than 2 months of ace • on open skin wounds	Net Wt 500mL 16.90 Fl. Oz.
000	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 il initiation 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.	Made in Korea
	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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40C (104F)	604
	Inactive Ingredients Water, Bulylene Glycol, Carbomer, Triethanolamine, Aloe Barbadensis Leaf Extract, Polycoxyethylene Hydrogenated Castor oil, Fragrance	
	Labeler : GM Holdings Co. Ltd. Seocho-gu, Gangnam-daero 331 (Kwangil Plaza 11th Floor), Seoul South Korea Distributor: XPRO 8600 Commodity Cir #121 Orlando, FL 32819 USA Questions or Comments? Call +82 007 S066 4772 (Global), +1 407 431 8893(US)	

Product Inform	ation					
Product T ype		HUMAN OTC DRUG	TC DRUG Item Code (Source)		NDC:69278-120	
Route of Administ	ration	TOPICAL				
Active Ingredie	nt/Active Moi	ety				
Ingredient Name Basis of Strength		asis of Strength	Strength			
ALCOHOL (UNII: 3K	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL				380 mL in 500 mL	
Inactive Ingred	ients					
		Ingredient Name				Strength
Water (UNII: 059QF0	KO0R)					
Butylene Glycol (UN	NII: 3XUS85K0RA)					
CARBO MER HO MO	POLYMER, UNSI	PECIFIED TYPE (UNII: 0A5MM307	7FC)			
TROLAMINE (UNII:	9O3K93S3TK)					
ALOE VERA LEAF (UNII: ZY81Z83H02	X)				
Packaging						
# Item Code		Package Description		Marketing Start Date	Ma	rketing End Date
1 NDC:69278-120- 01	500 mL in 1 BOT Product	TLE, PUMP; Type 0: Not a Combin	ation 06	/0 1/20 20		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	06/01/2020		
OIC monograph not final	part333E	06/01/2020		

Labeler - GM Holdings Co., Ltd (688439958)

Registrant - GM Holdings Co., Ltd (688439958)

Establishment			
Name	Address	ID/FEI	Business Operations
Ester Co., Ltd.		688425766	manufacture(69278-120)

Revised: 6/2020

GM Holdings Co., Ltd