

GUSTAR HAND SANITIZER (ETHANOL)- alcohol gel
GuStar 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 62%

INACTIVE INGREDIENTS

Water, Glycerin, Carbomer, Triethanolamine, Polysorbate 80

PURPOSE

Antiseptic

WARNINGS

- For external use only.
- Flammable. ■ Keep away from heat and Flame.

When using this product

- Keep out of eyes, ears and mouth.
- If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor

- If irritation and rash occurs.

KEEP OUT OF REACH OF CHILDREN

- If swallowed, get medical help or contact a Poison Control Center right away.

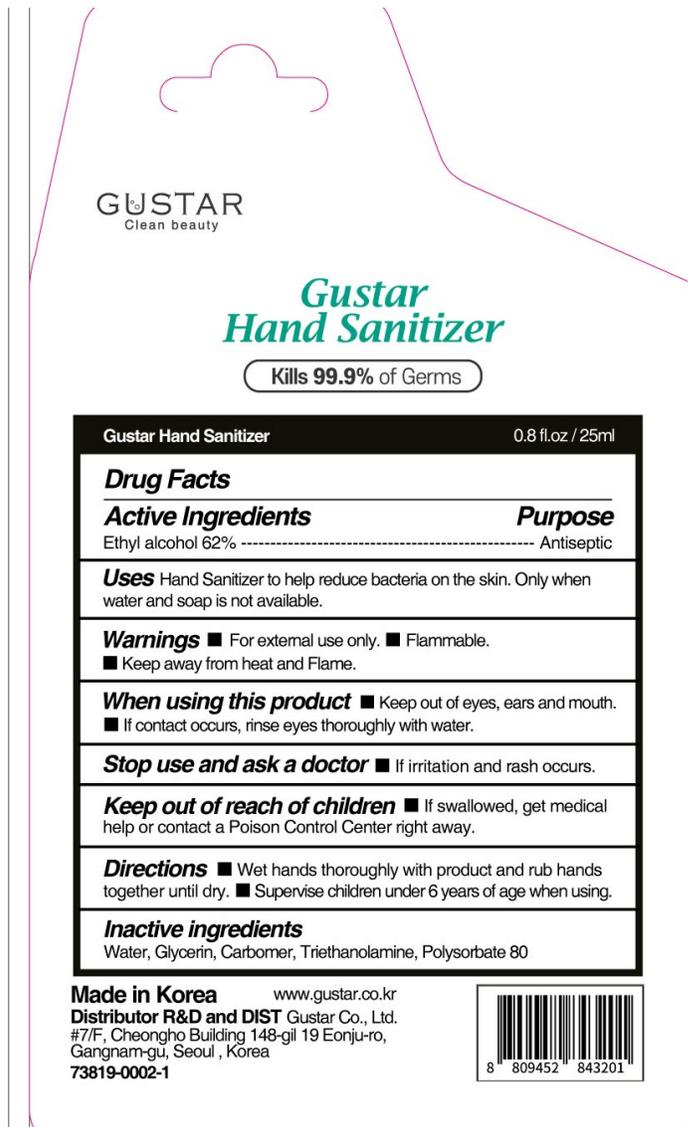
Uses

Hand sanitizer to help reduce bacteria on the skin. Only when water and soap is not available.

Directions

- Wet hands thoroughly with product and rub hands together until dry.
- Supervise children under 6 years of age when using.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



GUSTAR HAND SANITIZER (ETHANOL)

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:738 19-0002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

POLYSORBATE 80 (UNI: 6OZP39ZG8H)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73819-0002-1	25 mL in 1 POUCH; Type 0: Not a Combination Product	03/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/21/2020	

Labeler - GuStar Co Ltd (694234583)

Registrant - GuStar Co Ltd (694234583)

Establishment

Name	Address	ID/FEI	Business Operations
DASOL CO.,LTD.		557839013	manufacture(73819-0002)

Revised: 5/2020

GuStar Co Ltd