

PROTECT BY HAND SANITIZER GEL (ETHANOL)- alcohol gel
Ken Company 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

alcohol

Water

Glycerin

Carbomer

Triethanolamine

Rosmarinus Officinalis (Rosemary) Leaf Extract

Chamomilla Recutita (Matricaria) Flower Extract

Rose Centifolia Flower Water

Citrus Aurantium Dulcis (Orange) Oil

Limonene

Sterilization of hands and skin

KEEP OUT OF REACH OF THE CHILDREN

Apply an appropriate amount on your hands and rub well to dry.

1. Do not use on the following body parts. A wide range of body parts and damaged skin around the eyes and ears, in the oral cavity (may have irritating effects)
2. If the following symptoms appear, stop using them immediately and consult a doctor or pharmacist.
 - 1) Hypersensitivity symptoms such as rash, erythema, itching, and edema
 - 2) Skin irritation symptoms
3. Other precautions
 - 1) For external use only (do not underwear).
 - 2) Be careful not to get into your eyes, and if so, rinse well with clean water and consult a doctor or pharmacist.
 - 3) Be careful not to inhale the vapor when using it extensively or for a long period of time (irritation to the mucous membranes, headaches, etc. may occur if ethanol vapor is consumed in large quantities or repeatedly).
 - 4) If repeated use on the same site, be careful as the skin may become rough due to degreasing.
 - 5) Do not use sealed bandages, cast bandages, packs, etc., as irritation may occur.
 - 6) Do not use this medicine for anal or vaginal compresses as it may cause irritation or chemical burns.
 - 7) Do not use for any other purpose.
4. Precautions for storage
 - 1) Avoid shading and keep in shading.
 - 2) Keep it out of reach of children, and if a child swallows it, go to the hospital right away.
 - 3) After use, close the product completely with a lid to prevent the product from drying out or entering foreign Objects.

for external use only

Protect By Hand Sanitizer Gel(Ethanol)

Drug Facts	
Active Ingredients	Purpose
Ethanol (Synthetic Alcohol) 70% -----	Disinfecting Agent
Uses	
<ul style="list-style-type: none"> ■ instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease ■ instant hand antiseptic to decrease bacteria on the skin 	
Warning	
For external use only	
When using this product	
<ul style="list-style-type: none"> ■ if following abnormal symptoms persist, discontinue use Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes ■ Stop immediately and consult a doctor if you experience <ol style="list-style-type: none"> 1) Hypersensitivity symptoms such as erythema, itching and dermatitis. 2) Skin Irritation 3) Following Instructions when using medication <ol style="list-style-type: none"> (1) For external use only (Do not use internally) (2) Avoid getting into the eyes (if contact occurs, wash well with clean water) ■ Be careful not to inhale or use excessively for a long time (ingesting ethanol repeatedly causes irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly in the same area, skin irritation may occur. ■ Do not use the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin. It is not recommended to use this one areas that have been medically treated with a cast or bandage. ■ Do not use in combination with soap or antibacterial cleansing agents. 	
Directions	
<ul style="list-style-type: none"> ■ Pour a small amount into hands, spread evenly and rub into the skin 	
Other Information	
<ul style="list-style-type: none"> - read the directions and warnings before use - avoid freezing and excessive heat above 40 degree C (104 degree F) 	
Inactive Ingredients	
Purified Water, Glycerin, Carbomers, Trolamine, Rosemary Extract, Matricaria Extract, Rose Water, Orange Oil, Limonene	

PROTECT BY HAND SANITIZER GEL(ETHANOL)

PROTECT BY HAND SANITIZER GEL (ETHANOL)

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80594-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
TROLAMINE (UNII: 9O3K93S3TK)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
ORANGE OIL (UNII: AKN3KSD11B)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80594-0001-1	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/15/2020	

Labeler - Ken Company Co., Ltd. (694883411)

Registrant - Ken Company Co., Ltd. (694883411)

Establishment

Name	Address	ID/FEI	Business Operations
Skin n Skin Co., Ltd.		631090037	manufacture(80594-0001)

Establishment

Name	Address	ID/FEI	Business Operations
Ken Company Co., Ltd.		694883411	label(80594-0001)

