#### SANITIZER REFRESHING GEL- alcohol gel AEGIS SYSTEM 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.

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Ethyl alcohol

Water Carbomer Glycerin Tea tree leaf Oil Lavender Oil Lemonglass Oil

- instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease
- 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
- 1) Hypersensitivity symptoms such as erythema, itching and dermatitis.
- 2) Skin Irritation
- 3) Following Instructions when using medication
- (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.
- Keep Out of Reach of Children.
- Pour a small amount into hands, spread evenly and rub into the skin

for topical use only



SANITIZER REFRESHIN	NG GEL					
alcohol gel						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC	NDC:78423-0004	
Route of Administration	TOPICAL					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Strengt	th	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL		70 mL in 100 mL	

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TEA TREE OIL (UNII: VIF565UC2G)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 934 (UNII: Z135WT9208)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78423-0004- 1	4000 mL in 1 CONTAINER; Type 0: Not a Combination Product	06/01/2020	
2	NDC:78423-0004- 2	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
Marketing Information				
	Markating Catag	Application Number or Monograph Citation	Markating Start Data	Marketing End Date

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

# Labeler - AEGIS SYSTEM CO.,LTD (694802962)

### **Registrant -** AEGIS SYSTEM CO.,LTD (694802962)

## Establishment

Name	Address	ID/FEI	Business Operations
AEGIS SYSTEM CO.,LTD		694802962	manufacture(78423-0004)

Revised: 6/2020

AEGIS SYSTEM CO.,LTD