

THE SAEM CLEAN EVERYDAY HAND SANITIZER GEL- alcohol gel
The Saem International 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.

70341-001_the SAEM Clean Everyday Hand Sanitizer Gel

Active ingredient

Ethyl alcohol 70%

Purpose

Antimicrobial

Use

- Hand sanitizer to help reduce bacteria on the skin

Warnings

Flammable. Keep away from fire or flame.

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts

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

Directions

- Put nough produt in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product

Other information

- Store below 110°F (43°C)
- May discolor certain fabrics or surfaces

Inactive ingredients

Water, Dipropylene Glycol, Carbomer, Glycerin, Triethanolamine, PEG-60 Hydrogenated Caster Oil, Panthenol, Camellia Sinensis Leaf Extract, Aloe Barbadensis Leaf Extract, Diethanolamine, Citrus Paradisi (Grapefruit) Peel Oil, Sodium Hyaluronate

**CLEAN
EVERYDAY**
HAND SANITIZER
GEL



e 16.9 fl.oz. / 500 ml

the SAEM

Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 70% v/v	Antimicrobial
Use • hand sanitizer to help reduce bacteria on the skin	
Warnings	
Flammable. Keep away from fire or flame.	
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Stop use and ask a doctor if irritation or rash appears and lasts.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions • Put enough product in your palm to cover hands and rub hands together briskly until dry	
• Children under 6 years of age should be supervised when using this product	
Other information • Store below 104°F(40°C)	
• May discolor certain fabrics or surfaces	
Inactive Ingredients Water, Dipropylene Glycol, Carbomer, Glycerin, Triethanolamine, PEG-60 Hydrogenated Castor Oil, Panthenol, Camellia Sinensis Leaf Extract, Aloe Barbadosensis Leaf Extract, Diethanolamine, Citrus Paradisi (Grapefruit) Peel Oil, Sodium Hyaluronate	

MADE IN KOREA
Manufactured for The SAEM International Co., Ltd.
10F, 35, Cheonggyecheon-ro, Jongno-gu, Seoul, Korea
www.thesaemcosmetic.com



THE SAEM CLEAN EVERYDAY HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70341-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
PEG-60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)	
PANTHENOL (UNII: WV9CM0O67Z)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIETHANOLAMINE (UNII: AZE05TDV2V)	
GRAPEFRUIT OIL (UNII: YR377U58W9)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:70341-001-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	
2	NDC:70341-001-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	
3	NDC:70341-001-03	100 mL in 1 TUBE; Type 0: Not a Combination Product	04/13/2020	
4	NDC:70341-001-04	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/13/2020	
5	NDC:70341-001-05	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	
6	NDC:70341-001-06	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/13/2020	

Labeler - The Saem International Co., Ltd. (689402402)

Registrant - The Saem International Co., Ltd. (689402402)

Establishment

Name	Address	ID/FEI	Business Operations
Rainbow Co Ltd		690423720	manufacture(70341-001)

Revised: 4/2020

The Saem International Co., Ltd.