

SAFE CLEANER HAND SANITIZER GEL- alcohol gel
S ONE pharmaceutical inc.

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.

74721-0002

Alcohol

water, glycerine, propylene glycol, carbomer, triethanolamine, sophora extract, grapefruit seed extract, mentha oil

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

keep out of reach of the children

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.

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 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.

for external use only

Safe Cleaner HAND SANITIZER GEL

Drug Facts

100ml / 3.38 fl.oz.

Active Ingredient
Ethyl alcohol 70 %(v/v)

Purpose
Antimicrobial

Uses

- 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 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 Safe Cleaner Hand Sanitizer Gel.

Inactive Ingredients Inactive

Glycerine, Ethanol, Purified water, Propylene glycol, Carbomer, Triethanolamine, Sophora extract, Grapefruit seed extract, Mentha Oil

Product of Korea

Manufacturer, S-Onepharmaceutical Co., Ltd 1073, Jeonnyeong-Ro, Changsu-Myeon, Gyeonggi-do, Korea

70%
ETHYL
ALCOHOL

SAFE CLEANER



HAND SANITIZER

SOPHORA EXTRACT
MINT OIL
GRAPEFRUIT EXTRACT

ETHYL ALCOHOL 70%(v/v)
Powerful Sterilizing Effect
Contains Moisturizer
Kills More Than 99.9% of Germs



S-ONE Pharmaceutical

250ml / 8.4 fl.oz.

| Safe Cleaner Plus Hand Sanitizer | |
|---|--|
| Drug Facts | 250ml / 8.4 fl.oz. |
| Active Ingredient Ethyl alcohol 70 % (v/v) | Purpose Antimicrobial |
| Uses | • Hand sanitizer to help reduce bacteria on the skin. |
| Warnings | • Flammable, Keep away from fire or flame. |
| <i>For external use only</i> | |
| 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 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 Safe Cleaner Hand Sanitizer. |
| Other information | • Store below 110°F (43°C) • May discolor certain fabrics or surfaces. |
| Inactive Ingredients | Glycerine, Purified water, Propylene glycol, Carbomer, Triethanolamine, Sophora extract, Grapefruit seed extract, Mentha Oil |
| Product of Korea | Manufacturer, S-One Pharmaceutical Co., Ltd. 1073, Jeonnyeong-Ro, Changsu-Myeon, Pocheon-Si, Gyeonggi-do, Korea |



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S-ONE Pharmaceutical

300ml / 10.1 fl.oz.

| Safe Cleaner Plus Hand Sanitizer | |
|---|--|
| Drug Facts | 300ml / 10.1 fl.oz. |
| Active Ingredient Ethyl alcohol 70 % (v/v) | Purpose Antimicrobial |
| Uses | • Hand sanitizer to help reduce bacteria on the skin. |
| Warnings | • Flammable, Keep away from fire or flame. |
| <i>For external use only</i> | |
| 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 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 Safe Cleaner Hand Sanitizer. |
| Other information | • Store below 110°F (43°C) • May discolor certain fabrics or surfaces. |
| Inactive Ingredients | Glycerine, Purified water, Propylene glycol, Carbomer, Triethanolamine, Sophora extract, Grapefruit seed extract, Mentha Oil |
| Product of Korea | Manufacturer, S-One Pharmaceutical Co., Ltd. 1073, Jeonnyeong-Ro, Changsu-Myeon, Pocheon-Si, Gyeonggi-do, Korea |



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S-ONE Pharmaceutical

475ml / 16.06 fl.oz.

| Safe Cleaner Plus Hand Sanitizer | |
|---|--|
| Drug Facts | 475ml / 16.06 fl.oz. |
| Active Ingredient Ethyl alcohol 70 % (v/v) | Purpose Antimicrobial |
| Uses | • Hand sanitizer to help reduce bacteria on the skin. |
| Warnings | • Flammable, Keep away from fire or flame. |
| <i>For external use only</i> | |
| 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 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 Safe Cleaner Hand Sanitizer. |
| Other information | • Store below 110°F (43°C) • May discolor certain fabrics or surfaces. |
| Inactive Ingredients | Glycerine, Purified water, Propylene glycol, Carbomer, Triethanolamine, Sophora extract, Grapefruit seed extract, Mentha Oil |
| Product of Korea | Manufacturer, S-One Pharmaceutical Co., Ltd. 1073, Jeonnyeong-Ro, Changsu-Myeon, Pocheon-Si, Gyeonggi-do, Korea |



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S-ONE Pharmaceutical

500ml / 16.9 fl.oz.

Safe Cleaner Plus Hand Sanitizer

| | |
|---|--|
| Drug Facts | 500ml / 16.9 fl.oz. |
| Active Ingredient Ethyl alcohol 70 % (v/v) | Purpose Antimicrobial |
| Uses | • Hand sanitizer to help reduce bacteria on the skin. |
| Warnings | • Flammable, Keep away from fire or flame. |
| <i>For external use only</i> | |
| 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 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 Safe Cleaner Hand Sanitizer. |
| Other information | * Store below 110°F (43°C) * May discolor certain fabrics or surfaces. |
| Inactive Ingredients | Glycerine, Purified water, Propylene glycol, Carbomer, Triethanolamine, Sophora extract, Grapefruit seed extract, Mentha Oil |
| Product of Korea | Manufacturer, S-One Pharmaceutical Co., Ltd. 1073, Jeonnyeong-Ro, Changsu-Myeon, Pocheon-Si, Gyeonggi-do, Korea |



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S-ONE Pharmaceutical

1,000ml / 33.8 fl.oz.

Safe Cleaner Plus Hand Sanitizer

| | |
|---|--|
| Drug Facts | 1,000ml / 33.8 fl.oz. |
| Active Ingredient Ethyl alcohol 70 % (v/v) | Purpose Antimicrobial |
| Uses | • Hand sanitizer to help reduce bacteria on the skin. |
| Warnings | • Flammable, Keep away from fire or flame. |
| <i>For external use only</i> | |
| 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 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 Safe Cleaner Hand Sanitizer. |
| Other information | * Store below 110°F (43°C) * May discolor certain fabrics or surfaces. |
| Inactive Ingredients | Glycerine, Purified water, Propylene glycol, Carbomer, Triethanolamine, Sophora extract, Grapefruit seed extract, Mentha Oil |
| Product of Korea | Manufacturer, S-One Pharmaceutical Co., Ltd. 1073, Jeonnyeong-Ro, Changsu-Myeon, Pocheon-Si, Gyeonggi-do, Korea |



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S-ONE Pharmaceutical

1,000ml / 33.8 fl.oz.

Safe Cleaner Plus Hand Sanitizer

| | |
|---|--|
| Drug Facts | 1,000ml / 33.8 fl.oz. |
| Active Ingredient Ethyl alcohol 70 % (v/v) | Purpose Antimicrobial |
| Uses | • Hand sanitizer to help reduce bacteria on the skin. |
| Warnings | • Flammable, Keep away from fire or flame. |
| <i>For external use only</i> | |
| 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 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 Safe Cleaner Hand Sanitizer. |
| Other information | * Store below 110°F (43°C) * May discolor certain fabrics or surfaces. |
| Inactive Ingredients | Glycerine, Purified water, Propylene glycol, Carbomer, Triethanolamine, Sophora extract, Grapefruit seed extract, Mentha Oil |
| Product of Korea | Manufacturer, S-One Pharmaceutical Co., Ltd. 1073, Jeonnyeong-Ro, Changsu-Myeon, Pocheon-Si, Gyeonggi-do, Korea |





SAFE CLEANER PLUS



HAND SANITIZER

SOPHORA EXTRACT
MINT OIL
GRAPEFRUIT EXTRACT

ETHYL ALCOHOL 70%(v/v)

- Powerful Sterilizing Effect
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| Safe Cleaner Plus Hand Sanitizer | |
|---|---|
| Drug Facts | 2,000ml / 67.6 fl.oz. |
| Active Ingredient Ethyl alcohol 70 % (v/v) | Purpose Antimicrobial |
| Uses | • Hand sanitizer to help reduce bacteria on the skin. |
| Warnings | • Flammable. Keep away from fire or flame. |
| <i>For external use only</i> | |
| 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 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 Safe Cleaner Hand Sanitizer. | |
| Other information * Store below 110°F (43°C) * May discolor certain fabrics or surfaces. | |
| Inactive Ingredients Glycerine, Purified water, Propylene glycol, Carbomer, Triethanolamine, Sophora extract, Grapefruit seed extract, Mentha Oil | |
| Product of Korea Manufacturer, S-One Pharmaceutical Co., Ltd. 1073, Jeonnyeong-Ro, Changsu-Myeon, Pocheon-Si, Gyeonggi-do, Korea | |





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| Safe Cleaner Plus Hand Sanitizer | |
|---|---|
| Drug Facts | 4,000ml / 135.2 fl.oz. |
| Active Ingredient Ethyl alcohol 70 % (v/v) | Purpose Antimicrobial |
| Uses | • Hand sanitizer to help reduce bacteria on the skin. |
| Warnings | • Flammable, Keep away from fire or flame. |
| <i>For external use only</i> | |
| 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 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 Safe Cleaner Hand Sanitizer. | |
| Other information | |
| * Store below 110°F (43°C) | |
| * May discolor certain fabrics or surfaces. | |
| Inactive Ingredients Glycerine, Purified water, Propylene glycol, Carbomer, Triethanolamine, Sophora extract, Grapefruit seed extract, Mentha Oil | |
| Product of Korea Manufacturer, S-One Pharmaceutical Co., Ltd. 1073, Jeonnyeong-Ro, Changsu-Myeon, Pocheon-Si, Gyeonggi-do, Korea | |



SAFE CLEANER HAND SANITIZER GEL

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74721-0002 |
| 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 |
|--|-----------------|
| MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N) | |
| WATER (UNII: 059QF0KO0R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K) | |
| CITRUS PARADISI SEED (UNII: 12F08874Y7) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:74721-0002-1 | 100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 04/06/2020 | |
| 2 | NDC:74721-0002-2 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/05/2020 | |
| 3 | NDC:74721-0002-3 | 300 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/05/2020 | |
| 4 | NDC:74721-0002-4 | 475 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/05/2020 | |
| 5 | NDC:74721-0002-5 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/05/2020 | |
| 6 | NDC:74721-0002-6 | 1000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 06/05/2020 | |
| 7 | NDC:74721-0002-8 | 2000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/05/2020 | |
| 8 | NDC:74721-0002-7 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/05/2020 | |
| 9 | NDC:74721-0002-9 | 4000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/05/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

| | | | |
|-------------------------|----------|------------|--|
| OTC monograph not final | part333A | 04/06/2020 | |
|-------------------------|----------|------------|--|

Labeler - S ONE pharmaceutical inc. (694626932)

Registrant - S ONE pharmaceutical inc. (694626932)

| Establishment | | | |
|---------------------------|----------------|---------------|--|
| Name | Address | ID/FEI | Business Operations |
| S ONE pharmaceutical inc. | | 694626932 | manufacture(74721-0002) , label(74721-0002) , pack(74721-0002) |

Revised: 6/2020

S ONE pharmaceutical inc.