

CLEAN AND HAND- alcohol gel
Opseve KOREA 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.

ACTIVE INGREDIENT

Active ingredients: ALCOHOL 62%

INACTIVE INGREDIENT

Inactive ingredients:
Water, Butylene Glycol, Carbomer

PURPOSE

Purpose: SANITIZER

WARNINGS

Warnings:

1. Do not use the product on the following areas:

Around the eyes and ears, in the mouth, large body parts and damaged skin (Irritation may occur)

2. If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist.

1) Hypersensitivity symptoms, e.g. rash, erythema, itchiness, and edema

2) Skin irritation symptoms

3. Other precautions

1) For external use only (do not swallow).

2) Avoid contact with eyes. If contact occurs, wash with clean water and consult a doctor or pharmacist.

3) Be careful not to inhale vapors in cases of extended or prolonged use. (Repeating inhaling of large amounts of ethanol vapor may cause irritation of the mucous membranes and headaches).

(Limited to ethanol-containing products)

4) If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal.

5) Do not use sealed bandages, cast bandages, or packs as they may cause irritation.

6) Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns.

7) Use only for the intended purposes.

4. Precautions for storage

1) Keep away from direct sunlight and do not expose the product to heating devices or flame.

2) Keep out of reach of children and go to the hospital immediately if swallowed.

3) After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container.

4) Storing the product in a different container may cause accidents or deterioration of quality. Therefore, keep the product in its original container.

Dust or foreign substances may get on the product while using it.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children and go to the hospital immediately if swallowed.

Uses

Uses:

Disinfection of hands and skin

Directions

Directions:

Take an appropriate amount on your hands and rub thoroughly to dry.

PACKAGE LABEL - Clean & Hand Gel 25mL

Clean&Hand Gel
- Drug Facts -

Active ingredients ALCOHOL 62% **Purpose** SANITIZER
Disinfection of hands and skin


Warnings
1. Do not use the product on the following areas : Around the eyes and ears, in the mouth, large body parts and damaged skin(irritation may occur) 2. If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist. 1) Hypersensitivity symptoms, e.g. rash, erythema, itchiness, and edema 2)Skin irritation symptoms 3.Other precautions 1) For external use only (do not swallow). 2) Avoid contact with eyes. If contact occurs, wash with clean water and consult a doctor or pharmacist. 3)Be careful not to inhale vapors in cases of extended or prolonged use. (Repeating inhaling of large amounts of ethanol vapor may cause irritation of the mucous membranes and headaches). (Limited to ethanol-containing products) 4) If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal. 5) Do not use sealed bandages, cast bandages, or packs as they may cause irritation. 6) Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns. 7) Use only for the intended purposes. 4. Precautions for storage 1) Keep away from direct sunlight and do not expose the product to heating devices or flame. 2) Keep out of reach of children and go to the hospital immediately if swallowed. 3) After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container. 4) Storing the product in a different container may cause accidents or deterioration of quality. Therefore, keep the product in its original container.
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Directions Take an appropriate amount on your hands and rub thoroughly to dry.

Inactive ingredients Water, Butylene Glycol, Carbomer

Opseeve KOREA Co.,Ltd. 364 Seunggicheon-ro,
Namdong-gu, Incheon, S. Korea

Net Wt : 25mL / 0.84 Fl. Oz



Clean&Hand Gel

클린앤핸드겔 (의약외품)

언제 어디서나 물없이 사용하는 손소독제

항균 99.9%

식약청 의약외품
품목허가 제 2호

식약청 품목기준코드 : 200907886

항균 99.9% | 에탄올 62% | 25ml

SKINAZ
A to Z COSMETIC

PACKAGE LABEL - Clean & Hand Gel 100mL

Clean&Hand Gel

클린앤핸드겔 (의약외품)

언제 어디서나 물없이 사용하는 손소독제



식약청 품목기준코드 : 200907886

항균 99.9% | 에탄올 62% | 100ml

SKINAZ
A to Z COSMETIC

Clean&Hand Gel

- Drug Facts -

Active ingredients ALCOHOL 62% **Purpose** SANITIZER

Disinfection of hands and skin

Warnings

1. Do not use the product on the following areas : Around the eyes and ears, in the mouth, large body parts and damaged skin(Irritation may occur) 2. If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist. 1) Hypersensitivity symptoms, e.g, rash, erythema, itches, and edema 2)Skin irritation symptoms 3.Other precautions 1) For external use only (do not swallow). 2) Avoid contact with eyes. If contact occurs, wash with clean water and consult a doctor or pharmacist. 3)Be careful not to inhale vapors in cases of extended or prolonged use. (Repeating inhaling of large amounts of ethanol vapor may cause irritation of the mucous membranes and headaches). (Limited to ethanol-containing products) 4) If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal. 5) Do not use sealed bandages, cast bandages, or packs as they may cause irritation. 6) Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns. 7) Use only for the intended purposes. 4. Precautions for storage 1) Keep away from direct sunlight and do not expose the product to heating devices or flame. 2) Keep out of reach of children and go to the hospital immediately if swallowed. 3) After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container. 4) Storing the product in a different container may cause accidents or deterioration of quality. Therefore, keep the product in its original container.

Dust or foreign substances may get on the product while using it.

Directions Take an appropriate amount on your hands and rub thoroughly to dry.

Inactive ingredients Water, Butylene Glycol, Carbomer

Opseve KOREA Co.,Ltd. 364 Seunggicheon-ro,
Namdong-gu, Incheon, S. Korea

Net Wt : 100mL / 3.38 Fl. Oz



PACKAGE LABEL - Clean & Hand Gel 500mL

Clean&Hand Gel
- Drug Facts -

Active ingredients ALCOHOL 62% **Purpose** SANITIZER

Uses Disinfection of hands and skin

Warnings

1. Do not use the product on the following areas : Around the eyes and ears, in the mouth, large body parts and damaged skin(Irritation may occur) 2. If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist. 1) Hypersensitivity symptoms, e.g. rash, erythema, itchiness, and edema 2) Skin irritation symptoms 3. Other precautions 1) For external use only (do not swallow). 2) Avoid contact with eyes. If contact occurs, wash with clean water and consult a doctor or pharmacist. 3) Be careful not to inhale vapors in cases of extended or prolonged use. (Repeating inhaling of large amounts of ethanol vapor may cause irritation of the mucous membranes and headaches). (Limited to ethanol-containing products) 4) If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal. 5) Do not use sealed bandages, cast bandages, or packs as they may cause irritation. 6) Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns. 7) Use only for the intended purposes. 4. Precautions for storage 1) Keep away from direct sunlight and do not expose the product to heating devices or flame. 2) Keep out of reach of children and go to the hospital immediately if swallowed. 3) After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container. 4) Storing the product in a different container may cause accidents or deterioration of quality. Therefore, keep the product in its original container.

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Directions Take an appropriate amount on your hands and rub thoroughly to dry.

Inactive ingredients Water, Butylene Glycol, Carbomer

Opseve KOREA Co.,Ltd. 364 Seunggicheon-ro, Namdong-gu, Incheon, S. Korea

Net Wt : 500mL / 16.90 Fl. Oz.



Clean&Hand Gel

클린앤핸드겔 (의약외품)

언제 어디서나 물없이 사용하는 손소독제



살균소독

식약청 의약외품
품목허가 제 2호

식약청 품목기준코드 : 200907886

살균·소독 | 에탄올 62% | 500ml

SKINAZ
A to Z COSMETIC

CLEAN AND HAND

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74195-010
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
Water (UNII: 059QF0KO0R)	
Butylene Glycol (UNII: 3XUS85K0RA)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74195-010-01	25 mL in 1 POUCH; Type 0: Not a Combination Product	03/01/2020	
2	NDC:74195-010-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2020	
3	NDC:74195-010-03	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/01/2020	

Labeler - Opseve KOREA Co.,Ltd. (690048629)

Registrant - Opseve KOREA Co.,Ltd. (690048629)

Establishment

Name	Address	ID/FEI	Business Operations
Opseve KOREA Co.,Ltd.		690048629	manufacture(74195-010)

Revised: 4/2020

Opseve KOREA Co.,Ltd.