

**HANCHEONSOO HAND ANTISEPTIC- 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.*

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**ACTIVE INGREDIENT**

Active ingredients: ALCOHOL 63%

**INACTIVE INGREDIENT**

Inactive ingredients:

Water, Glycerin, Butylene Glycol, Camellia Sinensis Leaf Extract, Carbomer, Triethanolamine

**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.PRINCIPAL DISPLAY PANEL

<p><b>HANCHEONSOO</b> <b>Hand Antiseptic Gel(Ethanol)</b></p> <table border="1"><tr><td colspan="2"><b>Drug Facts</b></td></tr><tr><td><b>Active Ingredient</b></td><td><b>Purpose</b></td></tr><tr><td>alcohol 53%</td><td>SANITIZER</td></tr><tr><td colspan="2"><b>Uses</b></td></tr><tr><td colspan="2">Disinfection of hands and skin</td></tr><tr><td colspan="2"><b>Warnings</b></td></tr><tr><td colspan="2">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)</td></tr><tr><td colspan="2">2. If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist.</td></tr><tr><td colspan="2">1) Hypersensitivity symptoms, e.g. rash, erythema, itchiness, and edema</td></tr><tr><td colspan="2">2) Skin irritation symptoms</td></tr><tr><td colspan="2">3. 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**HANCHEONSOO HAND ANTISEPTIC**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74195-040
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	63 g in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Butylene Glycol (UNII: 3XUS85K0RA)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:74195-040-02	1 in 1 CARTON	03/01/2020	
1	NDC:74195-040-01	100 mL in 1 CONTAINER; Type 0: Not a Combination Product		

**Marketing Information**

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

**Labeler** - Opseve KOREA Co.,Ltd. (690048629)**Registrant** - Opseve KOREA Co.,Ltd. (690048629)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Opseve KOREA Co.,Ltd.		690048629	manufacture(74195-040)