

**DEPENS PREMIUM HAND SANITIZER- ethanol gel
HEALKINBIO CO.**

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(s)

Ethanol 62%

Purpose

Purpose: Antiseptic

Use

☐ Hand sanitizing to help reduce bacteria on the skin

Warnings

- ☐ For external use only.
- ☐ Flammable, keep away from fire or flame.
- ☐ When using this product, avoid contact with the eyes. In case of contact, rinse eyes thoroughly with water.
- ☐ Stop use and ask a doctor if irritation or redness appears and lasts.
- ☐ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

☐ Take suitable amount of sanitizer in the hand. Wet thoroughly and rub hands together until dry

Other information

- ☐ Store in room temperature 0~30☐
- ☐ Period of Use: 36 Months after manufacturing date
- ☐ Manufacturing Date and No. Printed on bottle

Inactive ingredients

Water(Aqua), Carbomer, Triethanolamine, Polyoxyethylene Hydrogenated Caster Oil, Green Tea Extract, Aloe Extract, Tocopheryl Acetate, Fragrance(Parfum)

Package Label - Principal Display Panel

DEPENS Premium Sanitizer



DEPENS PREMIUM HAND SANITIZER

480ml
16.23 fl.oz

ETHANOL 62% v/v

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DEPENS Premium Sanitizer
DEPENS PREMIUM HAND SANITIZER
Removes harmful bacteria on the skin without soap and water



Contains Green Tea & ECOCERT Aloe Extracts



Take suitable amount of sanitizer in the hand



Wet hands thoroughly with product



Rub hands together until dry

[Product Name] DEPENS PREMIUM HAND SANITIZER	
Drug Facts	
Active Ingredients/Purpose	Ethanol 62% Antiseptic
Uses	Hand sanitizing to help reduce bacteria on the skin
Warnings	<ul style="list-style-type: none"> For external use only. Flammable. Keep away from fire or flames. Discontinue use only from fire or flames. Thoroughly wash with soap and water. Stop use and ask a doctor if irritation or redness appears and lasts. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.
Directions	Take suitable amount of sanitizer in the hand. Wet thoroughly and rub hands together until dry.
Inactive Ingredients	<ul style="list-style-type: none"> Water (H₂O); Glycerin; Triethylamine; Polyoxyethylene Hydrogenated Castor Oil; Green Tea Extract; Aloe Extract; Tocopheryl Acetate; Fragrance (Parfum)
Questions or concerns?	<ul style="list-style-type: none"> Manufactured and Distributed by: HANUNTO CO Address: 25-1, Inhyeong-dong, 54 Beom-gil, Namdong-gu, Incheon, 22062, Republic of Korea Tel: +82-22-738-7227
Other Information	<ul style="list-style-type: none"> Store in room temperature 0-30°C Period of Use: 24 Months After Manufacturing Date Manufacturing Date and No. Printed on bottle

This product is eligible for compensation based on consumer dispute settlement.



DEPENS PREMIUM HAND SANITIZER

ethanol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76586-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
alcohol (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	alcohol	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76586-001-01	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/24/2020	

Labeler - HEALKINBIO CO. (694039685)

Establishment

Name	Address	ID/FEI	Business Operations
HEALKINBIO CO.		694039685	manufacture(76586-001)

Revised: 4/2020

HEALKINBIO CO.