

**DETRODERM SOFT GEL HAND AND SKIN ANTISEPTIC- alcohol gel**  
**DETRO HEALTHCARE KIMYA SANAYI ANONIM SIRKETI**

*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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**DETRODERM SOFT GEL HAND AND SKIN ANTISEPTIC**

**Drug Facts**

***Active ingredient***

%80 (V/V) Ethanol

***Purpose***

Antiseptic

***Uses***

Hygienic and surgical antiseptic of hands and skin. It is used at all health institutions like surgery, intensive care, clinics, dental clinics, laboratory, veterinary, patient care at home.

***Warnings***

Flammable. Keep out of ignition sources directly.

**Do not use**

Before reading user manual

After 6 months from cover opening

**When using this product**

No smoking. must not be contacted with powerful oxidants, alkali metals due to fire and explosion possibility. Keep out of reach of children, food and animal foods. Keep out of ignition sources directly. Do not stock with oxidant and spontaneously combustible materials. Obey instructions existed in user manual.

**Stop use and ask a doctor if**

\*In case of poisoning

\*In case of ingestion

\*In case of contact with eyes

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison

Control Center right away.

### ***Directions***

For hygienic hand antiseptic, at least 3 ml solution is applied to hand without dilution and hands are rubbed until drying. For surgical hand antiseptic, 5 ml solution is applied to hand.

### ***Other Information***

Store containers tightly closed and in a well-ventilated area between 0-30°C and away from direct sunlight.

Do not use after expiry date.

### ***Inactive ingredients***

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, glycerin, triethanolamine, essence, deionized water

### ***Questions***

You may also report serious side effects to this phone number (+1-XXX-XXX-XXXX)

Mon-Fri 9:00 AM - 5:00 PM

- Wide Effect Spectrum
- Alcohol Based
- Extensive Skin Compatibility
- Usable at Dispenser

Email: [international@detrox.com.tr](mailto:international@detrox.com.tr)

### ***MADE IN TURKEY***

**detrox®**

### **Integrated Disinfection Solutions**

#### **Producer Name and Address:**

Detro Healthcare Kimya Sanayi A.S.

Ataturk mh. Adnan Menderec cd.

No:7 Esenyurt/Istanbul-Turkey

### **Packaging**



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Email: international@detrox.com.tr

**1 (L) 33,8 fl oz**

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Mon-Fri 9:00 AM - 5:00 PM

### MADE IN TURKEY

Barcode: 8680097103352

PRODUCTION DATE: XXXXXX

LOT: XXXXXXXX

EXPIRY DATE: XXXXXXXX

### Producer Name and Address:

Detro Healthcare Kimya Sanayi A.S.

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No:7 Esenyurt/Istanbul-Turkey



# DETRODERM SOFT GEL HAND AND SKIN ANTISEPTIC

alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79506-103
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:79506-103-01	5000 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/15/2021	
2	NDC:79506-103-02	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2021	
3	NDC:79506-103-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2021	
4	NDC:79506-103-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2021	
5	NDC:79506-103-05	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2021	
6	NDC:79506-103-06	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2021	

## 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	part333A	04/15/2021	

**Labeler** - DETRO HEALTHCARE KIMYA SANAYI ANONIM SIRKETI (533133207)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
DETRO HEALTHCARE KIMYA SANAYI ANONIM SIRKETI		533133207	manufacture(79506-103)

Revised: 4/2021

DETRO HEALTHCARE KIMYA SANAYI ANONIM SIRKETI