

**DETROX - DETRODERM HAND AND SKIN ANTISEPTIC- isopropyl alcohol liquid**  
**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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**DETROX DETRODERM HAND AND SKIN ANTISEPTIC**

**Drug Facts**

***Active ingredient***

%70 Isopropyl Alcohol

***Purpose***

Antiseptic

***Uses***

Hygienic and surgical antiseptics 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 antiseptics, at least 3 ml solution is applied to hand without dilution and hands are rubbed until drying. For surgical hand antiseptics, 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**

1,3-butanediol, glycerin, 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 Compatability
- Usable at Dispenser

Email: international@detrox.com.tr

### **MADE IN TURKEY**

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

Detro Healthcare Kimya Sanayi A.S.  
Atatürk mh. Adnan Menderes cd. No:7  
Esenyurt/Istanbul-Turkey

### **Packaging**



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# 1 (L) 33,8 fl oz

|  |
|--|
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| <b>Stop use and ask a doctor if</b><br>*In case of poisoning<br>*In case of ingestion<br>*In case of contact with eyes   |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.  |
| <b>Directions</b><br>For hygienic hand antisepsis, at least 3 ml solution is applied to hand without dilution and hands are rubbed until drying. For surgical hand antisepsis, 5 ml solution is applied to hand. |
| <b>Other Information</b><br>Store containers tightly closed and in a well-ventilated area between 0 – 30 °C and away from direct sunlight.<br>Do not use after expiry date.                                      |
| <b>Inactive ingredients</b><br>1,3-butanediol, glycerin, essence, deionized water  |
| <b>Questions</b><br>You may also report serious side effects to this phone number (+1-XXX-XXX-XXXX)<br>Mon-Fri 9:00 AM - 5:00 PM   |

**MADE IN TURKEY**

**Barcode:** 8680097100955

**PRODUCTION DATE:** XXXXXX

**LOT:** XXXXXXXX

**EXPIRY DATE:** XXXXXXXX



**Producer Name and Address:**

Detro Healthcare Kimya Sanayi A.S.  
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## DETROX - DETRODERM HAND AND SKIN ANTISEPTIC

isopropyl alcohol liquid

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:79506-100 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength           |
|--|-------------------|--------------------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 70 mL<br>in 100 mL |

### Inactive Ingredients

| Ingredient Name                    | Strength |
|------------------------------------|----------|
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) |          |
| GLYCERIN (UNII: PDC6A3C0OX)        |          |
| WATER (UNII: 059QF0K00R)           |          |

### Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:79506-100-01 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 06/30/2020           |                    |
| 2 | NDC:79506-100-02 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 06/30/2020           |                    |
| 3 | NDC:79506-100-03 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 06/30/2020           |                    |
| 4 | NDC:79506-100-04 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/30/2020           |                    |
| 5 | NDC:79506-100-05 | 5000 mL in 1 CAN; Type 0: Not a Combination Product    | 06/30/2020           |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 06/30/2020           |                    |

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

### Establishment

| Name   | Address | ID/FEI    | Business Operations    |
|--|---------|-----------|------------------------|
| DETRO HEALTHCARE KIMYA SANAYI ANONIM SIRKETI |         | 533133207 | manufacture(79506-100) |

Revised: 7/2020

DETRO HEALTHCARE KIMYA SANAYI ANONIM SIRKETI