

DETRODERM SOFT HAND AND SKIN ANTISEPTIC- 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.

DETRODERM SOFT HAND AND SKIN ANTISEPTIC

Drug Facts

Active ingredient

%80 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

Glycerin, citric acid monohydrate, 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

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



DETRODERM SOFT HAND AND SKIN ANTISEPTIC

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1 (L) 33,8 fl oz

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MADE IN TURKEY

Barcode: 8680097101075

PRODUCTION DATE: XXXXXX

LOT: XXXXXXXX

EXPIRY DATE: XXXXXXXX



Producer Name and Address:

Detro Healthcare Kimya Sanayi A.S.

Atatürk mh. Adnan Menderec cd. No:7

Esenyurt/Istanbul-Turkey



DETRODERM SOFT HAND AND SKIN ANTISEPTIC

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79506-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79506-102-01	5000 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/15/2021	
2	NDC:79506-102-02	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2021	
3	NDC:79506-102-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2021	
4	NDC:79506-102-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2021	
5	NDC:79506-102-05	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2021	
6	NDC:79506-102-06	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/15/2021	

Labeler - DETRO HEALTHCARE KIMYA SANAYI ANONIM SIRKETI (533133207)

Establishment

Name	Address	ID/FEI	Business Operations
DETRO HEALTHCARE KIMYA SANAYI ANONIM SIRKETI		533133207	manufacture(79506-102)

Revised: 4/2021

DETRO HEALTHCARE KIMYA SANAYI ANONIM SIRKETI