

BOREL ANTISEPTIC HAND SANITIZER- ethyl alcohol liquid
Eti Maden Isletmeleri Genel Mudurlugu

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.

ETİMADEN BOREL ANTISEPTIC HAND SANITIZER LIQUID

Drug Facts

Active ingredient

Ethyl alcohol 80% w/w

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame
For external use only

Do not use

- in children under three (3) years old
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-25°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

aloe vera (*Aloe barbadensis*) extract, boric acid, disodium tetraborate decahydrate, glycerin, lavender (*Lavandula angustifolia*) oil, tea tree (*Melaleuca alternifolia*) oil, water

Questions?

+1-833-267-3500

You may also report serious side effects to this phone number.

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

ANTI BACTERIAL

ALCOHOL **80%**

With Aloe Vera Extract

Manufactured for: ETI MADEN ISLETMELERI GENEL MUDURLUGU,
Kizilirmak Mahallesi 1443. Cadde No:5 06530 Cukurambar-Cankaya/ANKARA
TURKEY 06530

Country of origin : TURKEY

Ministry of Health License Date and Number: 06/10/2020 – 2020/7

The shelf life of the product whose package cover is not opened is 2 years at room temperature. Use the product with opened packaging within 6 months.

BEFORE USING READ THE LABEL AND THE PROSPECTUS

KEEP AWAY FROM CHILDREN, FOOD AND FEEDS

DO NOT EAT ANYTHING DURING USE. DO NOT DRINK, DO NOT SMOKE.

Developed by BOREN Laboratories.

FOLLOW USAGE INSTRUCTION TO AVOID RISKS ON HUMAN AND ENVIRONMENTAL HEALTH

Empty packaging disposal method: Destroyed with the scope of National Legislation

Packaging

PACKAGE - 100 mL

<i>Drug Facts</i> (continued)
Other information
<ul style="list-style-type: none">• store between 15-25°C (59-86°F)• avoid freezing and excessive heat above 40°C (104°F)



Drug Facts	
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Ethyl alcohol 80% w/w.....	Antiseptic
Uses	

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ANTISEPTIC HAND SANITIZER LIQUID

ANTI BACTERIAL

ALCOHOL 80%



With Aloe Vera Extract

Net contents 3.38 fl oz (100 mL)

- hand sanitizer to decrease bacteria on the skin
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PACKAGE - 1 Liter

ETI MADEN

BOREL

ANTISEPTIC HAND SANITIZER LIQUID

ANTI BACTERIAL

ALCOHOL 80%

With Aloe Vera Extract

Net contents 33.8 fl oz (1 Liter)

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Drug Facts (continued)

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Empty packaging disposal method: Destroyed with the scope of National Legislation

PACKAGE - 5 Liter

ETIMADEN

BOREL

ANTI
BACTERIAL

ALCOHOL
80%

ANTISEPTIC HAND SANITIZER LIQUID

Net contents 169 fl oz (5 Liter)

With Aloe Vera
Extract

BOREL

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BOREL ANTISEPTIC HAND SANITIZER

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81126-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
TEA TREE OIL (UNII: VIF565UC2G)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81126-020-01	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/20/2020	
2	NDC:81126-020-02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2020	
3	NDC:81126-020-03	5000 mL in 1 JUG; Type 0: Not a Combination Product	12/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/20/2020	

Labeler - Eti Maden Isletmeleri Genel Mudurlugu (552251787)