

ID ANTI BACTERIAL ALCOHOL BASED HAND DISINFECTANT- alcohol gel

DTH SAGLIK HIZMETLERI TICARET 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.

Hand Sanitizer Gel

Active Ingredient(s)

Ethyl alcohol 70% w/w, 2-Propanol 0.5% w/w

Purpose

Antiseptic

Alcohol-based hand disinfectant ready-to-use gel form

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. Effective against bacteria, fungi, viruses. For use when soap and water are not available.

Warnings

This product is only for external use. Keep away children, food, and animal feed. Do not swallow.

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation and rash occurs. These may be signs of a serious condition.

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

Directions

Put enough product (app.3-5 ml) on hands to cover all surfaces. Rub hands together, until hands feel dry. This should take around 20 seconds. Do not rinse or wipe off the hand sanitizer before it's dry; it may not work as well against germs.

Supervise children under 6 years of age when they use hand sanitizer gel to prevent swallowing alcohol, especially in schools and childcare facilities.

Other information

Do not use other disinfectant and cleaning agents. It should be used in its original packaging. Store between 15-30 C (59-86F).Protect from direct sunlight. Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Glycerin, Carbomer, Triethanolamine, Essence, Purified water USP

Package Label - Principal Display Panel

DTH Saglik Hizmetleri Tic. A.S. Merkez: Incek Mehmetcik Cad. 2654. Sk. No:2 Golbasi-Ankara

T: +90 312 211 05 06 F: +90 312 211 05 00

www.dthsaglik.com - www.idkimya.com

I& D sept GEL

INTERNATIONAL DISINFECTION

ANTI-BACTERIAL ALCOHOL BASED HAND GEL DISINFECTANT

For External Use Only

KILLS 99,9% of germs without water

KILLS 99,9% VIRUSES & BACTERIA



INTERNATIONAL DISINFECTION **sept** GEL



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<p>ACTIVE INGREDIENTS Ethyl alcohol 70% w/w, 2-Propanol 0.5% w/w. Purpose: Antiseptic</p> <p>PURPOSE Alcohol-based hand disinfectant ready-to-use gel form</p> <p>USE Hand Sanitizer to help reduce bacteria that potentially can cause disease. Effective against bacteria, fungi, viruses. For use when soap and water are not available.</p> <hr/> <p>DO NOT USE</p> <ul style="list-style-type: none">❖ in children less than 2 months of age❖ on open skin wounds	<p>STOP USE Stop use and ask a doctor if irritation and rash occurs. These may be signs of a serious condition.</p> <p>KEEP OUT OF REACH OF CHILDREN Keep out of reach of children. If accidentally swallowed, get medical help or contact a Poison Control Center right away.</p> <p>DIRECTIONS Put enough product (app.3-5 ml) on hands to cover all surfaces. Rub hands together, until hands feel dry. This should take around 20 seconds. Do not rinse or wipe off the hand sanitizer before it's dry; it may not work as well against germs. Supervise children under 6 years of age when they use hand sanitizer gel to prevent swallowing alcohol, especially in schools and childcare facilities.</p> <p>OTHER INFORMATIONS</p>
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PRD:

EXP:

LOT



500ml e 16,9 fl. oz.

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1000ml e 33.8 fl. oz.

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ISBN 978-605-60319-0-8



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PRD:

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5 ml e 0,169 fl.oz.   

childcare facilities.

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8681889320582

I D ANTI BACTERIAL ALCOHOL BASED HAND DISINFECTANT

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78992-611
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.5 mL in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Product Characteristics

Color		Score	
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Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78992-611-01	5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78992-611-02	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78992-611-03	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	



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PRD: EXP: LOT



5 ml e 0,169 fl.oz.



8681889320582

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ISBN 978-605-60313-0-8



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500ml e 16.9 fl. oz.



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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - DTH SAGLIK HIZMETLERI TICARET ANONIM SIRKETI (566220129)

Registrant - HARDAL GLOBAL CONSULTING LLC (123584960)

Establishment

Name	Address	ID/FEI	Business Operations
DTH SAGLIK HIZMETLERI TICARET ANONIM SIRKETI		566220129	manufacture(78992-611)

Revised: 6/2020

DTH SAGLIK HIZMETLERI TICARET ANONIM SIRKETI