

LARA MED ANTIBACTERIAL HAND AND SKIN CLEANER- ethyl alcohol, propan-2-ol liquid

LARA KOZMETIK HIJYENIK URUNLERI SANAYI VE DIS 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.

LARA MED ANTIBACTERIAL HAND AND SKIN CLEANER

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (w/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.

Propan-2-ol (10% w/v).

Glycerin

F&D C Blue No.1

Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol (ethanol)(70%, volume/volume (w/v))

Propan-2-ol (10% w/v).

Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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

Warnings

For external use only. Flammable liquid and vapor

Do not use

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

When using this product do not use in or near the eyes. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or 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.

Stop use and ask a doctor if irritation or 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

- Place enough product in your palm to cover hands and rub hands together briskly until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing

Other information

Store between 110F (43 C)

Avoid freezing and excessive heat above 40C (104F)

May discolor certain fabrics or surface.

Ethyl Alcohol % 70

Porpan-2-ol %10

Non sterile topical solution

Inactive ingredients

glycerin, F&D C Blue No.1, purified water USP

Package Label - Principal Display Panel



ANTIBACTERIAL



1000 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease.
For use when soap and water are not available.

Warnings

For external use only.

Flammable liquid and vapor

Do not use

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- on open skin wounds

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Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

Store below 110 °F (43 °C)

Avoid freezing and excessive heat above 104 °F (40 °C)

May discolor certain fabrics or surface

Ethyl Alcohol 70 %

Propan-2-ol 10%

(Non-sterile Topical Solution)

Inactive ingredients

Glycerin, FD&C Blue No:1 , Water

LICENSE HOLDER and MANUFACTURER:

Lara Kozmetik Hijyenik Ürünleri San. ve Dis.Tic.A.S.
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GHS07



GHS02



8 50023 41820 3



ANTIBACTERIAL



5L e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease.

For use when soap and water are not available.

Warnings

For external use only.

Flammable liquid and vapor

Do not use

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

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

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Other Information

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Avoid freezing and excessive heat above 104 °F (40 °C)

May discolor certain fabrics or surface

Ethyl Alcohol 70 %

Propan-2-ol 10%

(Non-sterile Topical Solution)

Inactive ingredients

Glycerin, FD&C Blue No:1 , Water

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GHS07



GHS02



8 50023 41821 0



ANTIBACTERIAL



50L e

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% w/v	Antiseptic
Propan-2-ol 10% w/v	Antiseptic

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease.
For use when soap and water are not available.

Warnings

For external use only.

Flammable liquid and vapor

Do not use

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

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

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Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

Store below 110 °F (43 °C)

Avoid freezing and excessive heat above 104 °F (40 °C)

May discolor certain fabrics or surface

Ethyl Alcohol 70 %

Propan-2-ol 10%

(Non-sterile Topical Solution)

Inactive ingredients

Glycerin, FD&C Blue No:1 , Water

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GHS07



GHS02



8 50023 41823 4



ANTIBACTERIAL



10L e

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% w/v	Antiseptic
Propan-2-ol 10% w/v	Antiseptic

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease.

For use when soap and water are not available.

Warnings

For external use only.

Flammable liquid and vapor

Do not use

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

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

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Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

Store below 110 °F (43 °C)

Avoid freezing and excessive heat above 104 °F (40 °C)

May discolor certain fabrics or surface

Ethyl Alcohol 70 %

Propan-2-ol 10%

(Non-sterile Topical Solution)

Inactive ingredients

Glycerin, FD&C Blue No:1 , Water

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GHS07



GHS02



8 50023 41822 7



ANTIBACTERIAL



150 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease.
For use when soap and water are not available.

Warnings

For external use only.

Flammable liquid and vapor

Do not use

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

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

Store below 110 °F (43 °C)

Avoid freezing and excessive heat above 104 °F (40 °C)

May discolor certain fabrics or surface

Ethyl Alcohol 70 %

Propan-2-ol 10%

(Non-sterile Topical Solution)

Inactive ingredients

Glycerin, FD&C Blue No:1 , Water

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GHS07



GHS02



8 50023 41816 6



ANTIBACTERIAL



500 ml e

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% w/v	Antiseptic
Propan-2-ol 10% w/v	Antiseptic

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease.
For use when soap and water are not available.

Warnings

For external use only.

Flammable liquid and vapor

Do not use

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

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

Store below 110 °F (43 °C)

Avoid freezing and excessive heat above 104 °F (40 °C)

May discolor certain fabrics or surface

Ethyl Alcohol 70 %

Propan-2-ol 10%

(Non-sterile Topical Solution)

Inactive ingredients

Glycerin, FD&C Blue No:1 , Water

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GHS07



GHS02



8 50023 41819 7



ANTIBACTERIAL



250 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease.
For use when soap and water are not available.

Warnings

For external use only.

Flammable liquid and vapor

Do not use

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

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

Store below 110 °F (43 °C)

Avoid freezing and excessive heat above 104 °F (40 °C)

May discolor certain fabrics or surface

Ethyl Alcohol 70 %

Propan-2-ol 10%

(Non-sterile Topical Solution)

Inactive ingredients

Glycerin, FD&C Blue No:1 , Water

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GHS07



GHS02



8 50023 41818 0



ANTIBACTERIAL



50 ml e

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% w/v	Antiseptic
Propan-2-ol 10% w/v	Antiseptic

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease.
For use when soap and water are not available.

Warnings

For external use only.

Flammable liquid and vapor

Do not use

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

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

Store below 110 °F (43 °C)

Avoid freezing and excessive heat above 104 °F (40 °C)

May discolor certain fabrics or surface

Ethyl Alcohol 70 %

Propan-2-ol 10%

(Non-sterile Topical Solution)

Inactive ingredients

Glycerin, FD&C Blue No:1 , Water

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GHS07



GHS02



8 50023 41814 2



ANTIBACTERIAL



100 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease.
For use when soap and water are not available.

Warnings

For external use only.

Flammable liquid and vapor

Do not use

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

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

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Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

Store below 110 °F (43 °C)

Avoid freezing and excessive heat above 104 °F (40 °C)

May discolor certain fabrics or surface

Ethyl Alcohol 70 %

Propan-2-ol 10%

(Non-sterile Topical Solution)

Inactive ingredients

Glycerin, FD&C Blue No:1 , Water

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GHS07



GHS02



8 50023 41815 9



ANTIBACTERIAL



200 ml e

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% w/v	Antiseptic
Propan-2-ol 10% w/v	Antiseptic

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease.
For use when soap and water are not available.

Warnings

For external use only.

Flammable liquid and vapor

Do not use

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

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

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Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

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Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

Store below 110 °F (43 °C)

Avoid freezing and excessive heat above 104 °F (40 °C)

May discolor certain fabrics or surface

Ethyl Alcohol 70 %

Propan-2-ol 10%

(Non-sterile Topical Solution)

Inactive ingredients

Glycerin, FD&C Blue No:1, Water

LICENSE HOLDER and MANUFACTURER:

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GHS07



GHS02



8 50023 41817 3

LARA MED ANTIBACTERIAL HAND AND SKIN CLEANER

ethyl alcohol, propan-2-ol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86994-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 g in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86994-009-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	
2	NDC:86994-009-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	
3	NDC:86994-009-03	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	
4	NDC:86994-009-04	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	
5	NDC:86994-009-05	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	
6	NDC:86994-009-06	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	
7	NDC:86994-009-07	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	
8	NDC:86994-009-08	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	
9	NDC:86994-009-09	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	
10	NDC:86994-009-10	50000 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/01/2020	

Labeler - LARA KOZMETIK HIJYENIK URUNLERI SANAYI VE DIS TICARET ANONIM SIRKETI (502977856)

Registrant - LARA KOZMETIK HIJYENIK URUNLERI SANAYI VE DIS TICARET ANONIM SIRKETI (502977856)

Establishment

Name	Address	ID/FEI	Business Operations
LARA KOZMETIK HIJYENIK URUNLERI SANAYI VE DIS TICARET ANONIM SIRKETI		502977856	manufacture(86994-009)

Revised: 10/2020

LARA KOZMETİK HIJYENİK URUNLERI SANAYI VE DIS TICARET ANONIM SIRKETI