

ARMOUR HAND AND SKIN SANITIZER- ethyl alcohol liquid
SOZAL KIMYA SANAYI VE 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.

SOZAL ARMOUR HAND AND SKIN SANITIZER

Drug Facts

Active ingredient[s]

Ethyl Alcohol 80% w/w

Purpose

Antiseptic

Uses[s]

▪ 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: Keep away from heat or flame.

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 or rash occurs.

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

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

Store between 15-30°C (59-86F) Avoid freezing and excessive heat above 40°C (104F)

Inactive Ingredients

Deionized water, glycerine, hydrogen peroxide

Alcohol-Based

MANUFACTURED BY

SOZAL

SOZAL KIMYA SAN. ve TIC. A. S.

KOSAB Güvenli Sok.

No. 7 Bursa / TURKEY

Packaging



SÖZAL ARMOUR

HAND AND SKIN SANITIZER

100ml e
(3,38 fl.oz)

%80
Alcohol-Based

Drug Facts	
Active ingredient(s) Ethyl Alcohol 80% w/w	Purpose Antiseptic
Use(s) • 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: Keep away from heat or flame.	
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 or rash occurs. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.	
Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.	
Other information Store between 15-30°C (59-86°F) Avoid freezing and excessive heat above 40°C (104°F)	
Inactive Ingredients Deionized water, glycerine, hydrogen peroxide	

MANUFACTURED BY

SÖZAL
SÖZAL KIMYA SAN. ve TIC. A.Ş.
KOSAB Güvenli Sok.
No.7 Bursa / TURKEY



8 682729 395906



SÖZAL ARMOUR

HAND AND SKIN SANITIZER

250ml e
(8,45 fl.oz)

%80
Alcohol-Based

Drug Facts	
Active ingredient(s) Ethyl Alcohol 80% w/w	Purpose Antiseptic
Use(s) • 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: Keep away from heat or flame.	
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 or rash occurs. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.	
Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.	
Other information Store between 15-30°C (59-86°F) Avoid freezing and excessive heat above 40°C (104°F)	
Inactive Ingredients Deionized water, glycerine, hydrogen peroxide	

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No.7 Bursa / TURKEY



8 682729 395951

SÖZAL ARMOUR



HAND AND SKIN SANITIZER

500ml e
(16,9 fl.oz)

%80
Alcohol-Based

Drug Facts

Active ingredient(s)	Purpose
Ethyl Alcohol 80% w/w	Antiseptic
Use(s) • 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: Keep away from heat or flame.	
Do not use	
<ul style="list-style-type: none"> • 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 or rash occurs. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing. 	
Other information Store between 15-30°C (59-86°F) Avoid freezing and excessive heat above 40°C (104°F)	
Inactive Ingredients Deionized water, glycerine, hydrogen peroxide	

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SÖZAL ARMOUR



HAND AND SKIN SANITIZER

1000ml e
(33,8 fl.oz)

%80
Alcohol-Based

Drug Facts

Active ingredient(s)	Purpose
Ethyl Alcohol 80% w/w	Antiseptic
Use(s) • 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: Keep away from heat or flame.	
Do not use	
<ul style="list-style-type: none"> • 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 or rash occurs. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing. 	
Other information Store between 15-30°C (59-86°F) Avoid freezing and excessive heat above 40°C (104°F)	
Inactive Ingredients Deionized water, glycerine, hydrogen peroxide	

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ARMOUR HAND AND SKIN SANITIZER

ethyl alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:78087-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.8 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78087-001-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2020	
2	NDC:78087-001-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2020	
3	NDC:78087-001-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2020	
4	NDC:78087-001-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/29/2020	

Labeler - SOZAL KIMYA SANAYI VE TICARET ANONIM SIRKETI (355628049)

Establishment

Name	Address	ID/FEI	Business Operations
SOZAL KIMYA SANAYI VE TICARET ANONIM SIRKETI		355628049	manufacture(78087-001)

Revised: 5/2020

SOZAL KIMYA SANAYI VE TICARET ANONIM SIRKETI