

HAND SANITIZER- alcohol liquid
Agroorganika UAB

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.

Active Ingredient(s)

Alcohol 80% v/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. 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. 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 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.

Inactive ingredients

NDC 78897-001: glycerin, hydrogen peroxide, purified water USP, Fragrance Honey Melon

NDC 78897-002: glycerin, hydrogen peroxide, purified water USP, Fragrance Watermelon

NDC 78897-003: glycerin, hydrogen peroxide, purified water USP, Fragrance Mint

Other information

- Store between 15-30C (59-86F)

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

Package Label - Principal Display Panel

100 mL NDC: 78897-001-01

Active ingredient(s)	Purpose
Alcohol 80% v/v	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 of flame

- **Do not use**
- in children less than 2 months of age
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When using this product keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP, Fragrance Honey Melon

AGRO ORGANIC Specially Manufactured for AGRO Organic Inc
Atlanta, GA, 30327; www.usagrorganic.com,
info@usagrorganic.com, Made in EU

4 779046 260278

500 mL NDC: 78897-001-02

MELON FLAVOR

SterilPro

HAND SANITIZER

KILLS UP TO 99.9% OF MOST GERMS

80% alcohol

For hands

Volume: 16.9 oz (500 ml)

AGRO ORGANIC

Dangerous
Highly flammable liquid and vapor.

CE

Drug Facts

Active ingredient(s) Alcohol 80% v/v	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 of flame	
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4 779046 260285

1000 mL NDC: 78897-001-03

MELON FLAVOR

SterilPro

HAND SANITIZER

KILLS UP TO 99.9% OF MOST GERMS

80% alcohol

For hands

Dangerous
Highly flammable liquid and vapor.

CE AGRO ORGANIC

Volume: 33.8 oz (1000 ml)

Drug Facts

Active ingredient(s) Alcohol 80% v/v	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 of flame	
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4 779046 260292

4000 mL NDC: 78897-001-04

MELON FLAVOR

SterilPro



HAND SANITIZER

KILLS UP TO 99.9% OF MOST GERMS

80% alcohol
For hands

 **Dangerous**
Highly flammable liquid and vapor.

 **AGRO ORGANIC**

Volume: 1.05 gal (4000 ml)

Drug Facts	
Active ingredient(s) Alcohol 80% v/v	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 of flame	
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100 mL NDC: 78897-002-01

STERILPRO

WATERMELON FLAVOR

HAND SANITIZER

KILLS UP TO 99.9% OF MOST GERMS

80% alcohol
For hands

CE **AGRO ORGANIC** Volume: 3.35 oz (100 ml)

Drug Facts

Active ingredient(s)	Purpose
Alcohol 80% v/v	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 of flame	
<ul style="list-style-type: none"> 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	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP, Fragrance Watermelon	

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4 779046 260148

500 mL NDC: 78897-002-02

SterilPro

HAND SANITIZER

KILLS UP TO 99.9% OF MOST GERMS

80% alcohol

For hands

Volume: 16.9 oz (500 ml)

AGRO ORGANIC

Dangerous
Highly flammable liquid and vapor.

CE **AGRO ORGANIC**

WATERMELON FLAVOR

Drug Facts

Active ingredient(s)	Purpose
Alcohol 80% v/v	Antiseptic
Use(s)	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
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4 779046 260179

1000 mL NDC: 78897-002-03

SterilPro

WATERMELON FLAVOR

HAND SANITIZER

KILLS UP TO 99.9% OF MOST GERMS

80% alcohol
For hands

Dangerous
Highly flammable liquid and vapor.

CE **AGRO ORGANIC** Volume: 33.8 oz (1000 ml)

Drug Facts	
Active ingredient(s) Alcohol 80% v/v.....	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 of flame	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP, Fragrance Watermelon	

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4 779046 260193

4000 mL NDC: 78897-002-04

SterilPro

WATERMELON FLAVOR

HAND SANITIZER
KILLS UP TO 99.9% OF MOST GERMS

80% alcohol
For hands

Dangerous
Highly flammable liquid and vapor.

CE **AGRO ORGANIC** Volume: 1.05 gal (4000 ml)

Drug Facts	
Active ingredient(s) Alcohol 80% v/v.....	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 of flame	
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Other information	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP, Fragrance Watermelon	

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4 779046 260216

100 mL NDC: 78897-003-01

SterilPro

HAND SANITIZER

KILLS UP TO 99.9% OF MOST GERMS

80% alcohol
For hands

Volume: 3.35 oz (100 ml)

AGRO ORGANIC

Drug Facts

Active ingredient(s) Alcohol 80% v/v	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 of flame.	
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Directions	
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Other Information	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP, Fragrance Mint	

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4 779046 260230

500 mL NDC: 78897-003-02



SterilPro

HAND SANITIZER

KILLS UP TO 99.9% OF MOST GERMS

80% alcohol

For hands

AGRO ORGANIC

Volume: 16.9 oz (500 ml)

Drug Facts

Active ingredient(s) Alcohol 80% v/v	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 of flame.	
<ul style="list-style-type: none"> • 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 a serious condition.	
Keep out reach of children. If swallowed, get medical help or contact a 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	
<ul style="list-style-type: none"> • Store between 59-86F (15-30C) • Avoid freezing and excessive heat above 104F (40C) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP, Fragrance Mint	

Dangerous
Highly flammable liquid and vapor.

AGRO ORGANIC

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4 779046 260247

1000 mL NDC: 78897-003-03

SterilPro

HAND SANITIZER

KILLS UP TO 99.9% OF MOST GERMS

80% alcohol

For hands

Volume: 33.8 oz (1000 ml)

AGRO ORGANIC

Drug Facts

Active ingredient(s) Alcohol 80% v/v	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 of flame.	
<ul style="list-style-type: none"> • Do not use • in children less than 2 months of age • on open skin wounds 	
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Directions	
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Other Information	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP, Fragrance Mint	

CE **AGRO ORGANIC**

Dangerous
Highly flammable liquid and vapor.

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4 779046 260254

4000 mL NDC: 78897-003-04

SterilPro
HAND SANITIZER
 KILLS UP TO 99.9% OF MOST GERMS

MINT FLAVOR

80% alcohol
 For hands

Dangerous
 Highly flammable liquid and vapor.

CE AGRO ORGANIC

Volume: 1.05 gal (4000 ml)

Drug Facts

Active ingredient(s) Alcohol 80% v/v	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 of flame. <ul style="list-style-type: none"> 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 a serious condition. Keep out reach of children. If swallowed, get medical help or contact a 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. 	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP, Fragrance Mint	

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 info@usagrororganic.com, Made in EU

4779046260100

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78897-003
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: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78897-003-01	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/28/2020	
2	NDC:78897-003-02	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/28/2020	
3	NDC:78897-003-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2020	
4	NDC:78897-003-04	4000 mL in 1 BAG; Type 0: Not a Combination Product	07/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/28/2020	

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78897-001
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: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78897-001-01	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/28/2020	
2	NDC:78897-001-02	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/28/2020	
3	NDC:78897-001-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2020	
4	NDC:78897-001-04	4000 mL in 1 BAG; Type 0: Not a Combination Product	07/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/28/2020	

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78897-002
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: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78897-002-01	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/28/2020	
2	NDC:78897-002-02	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/28/2020	
3	NDC:78897-002-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2020	
4	NDC:78897-002-04	4000 mL in 1 BAG; Type 0: Not a Combination Product	07/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/28/2020	

Labeler - Agroorganika UAB (520220822)

Establishment

Name	Address	ID/FEI	Business Operations
Agroorganika UAB		520220822	manufacture(78897-001, 78897-002, 78897-003)

Revised: 7/2020

Agroorganika UAB