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

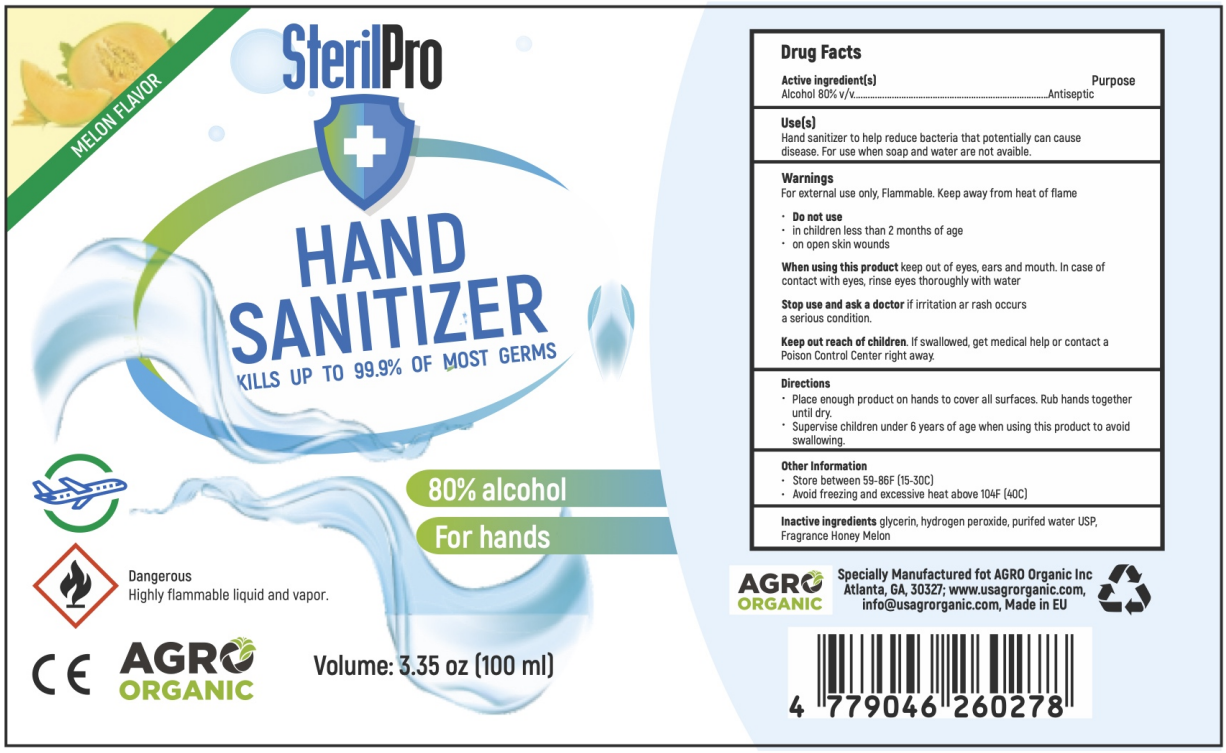
Other information

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

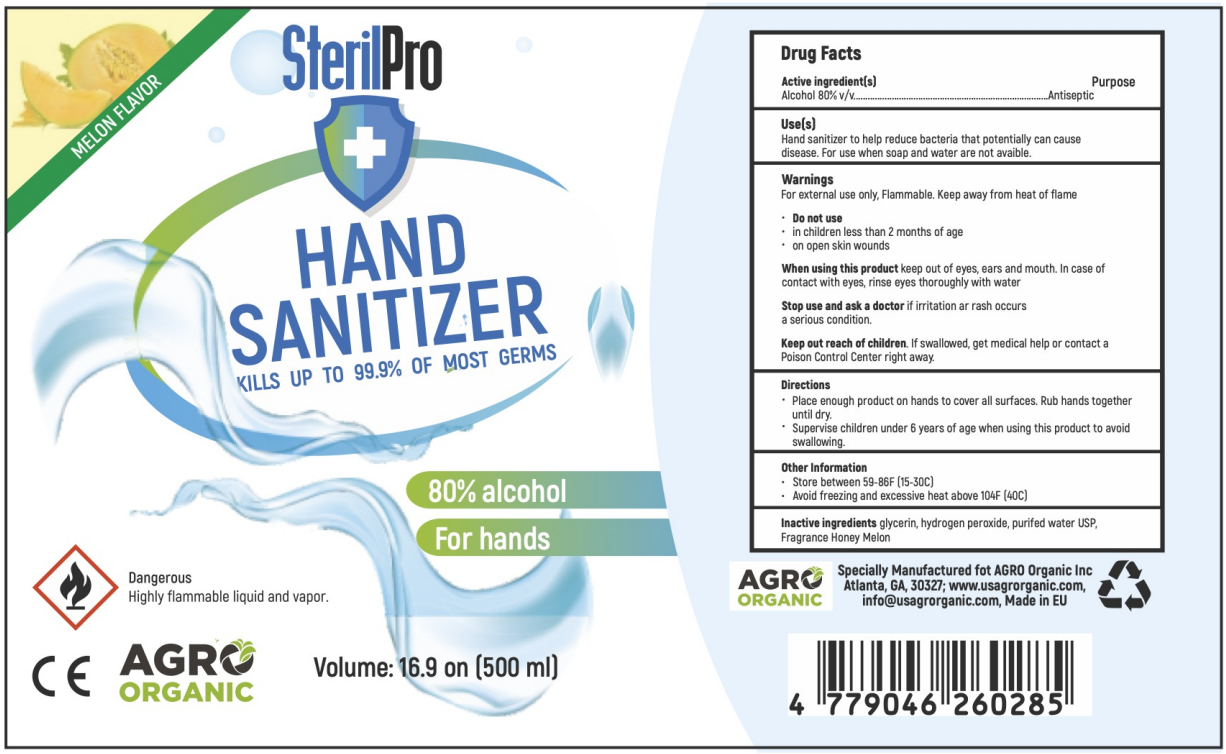
- Avoid freezing and excessive heat above 40C (104F)

Package Label - Principal Display Panel

100 mL NDC: 78897-001-01



500 mL NDC: 78897-001-02



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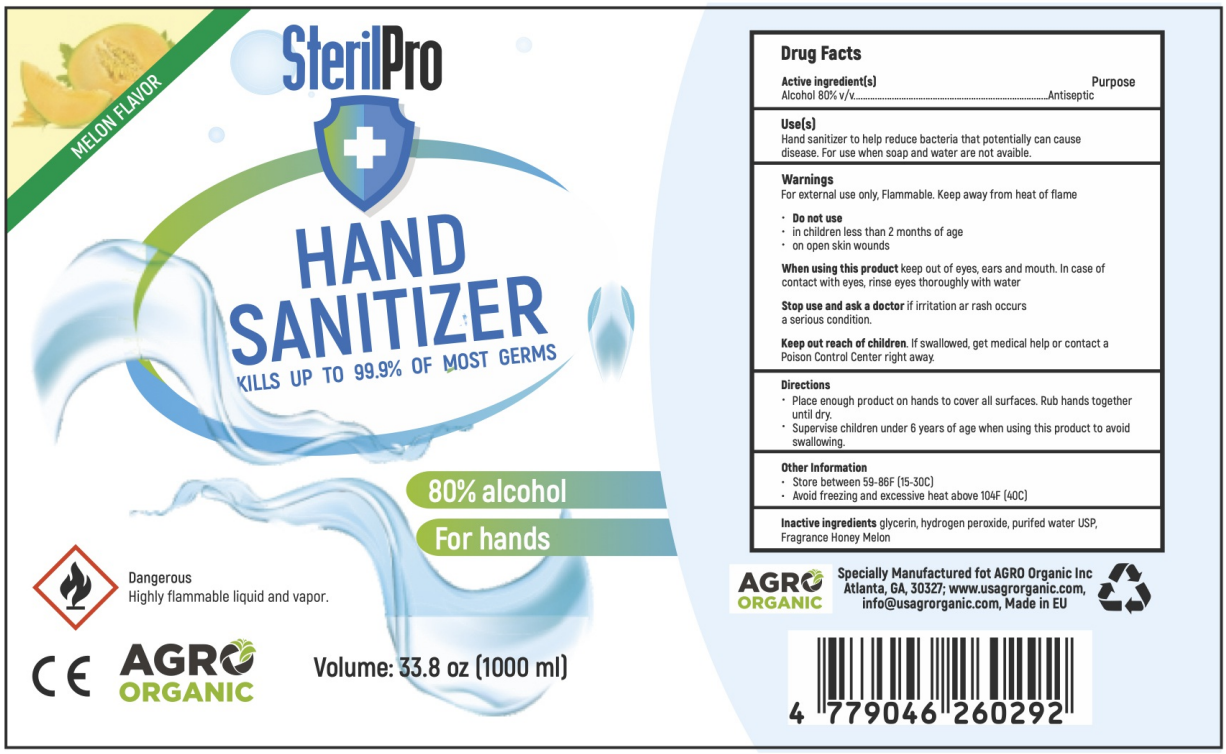

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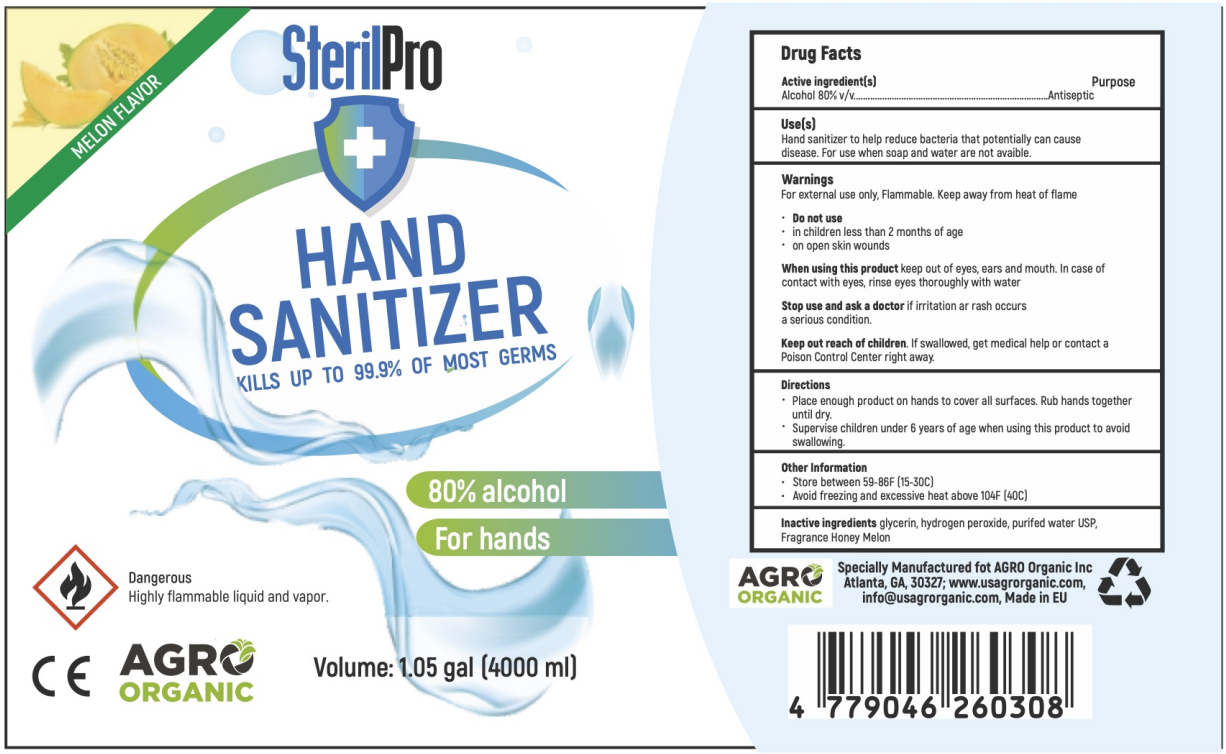

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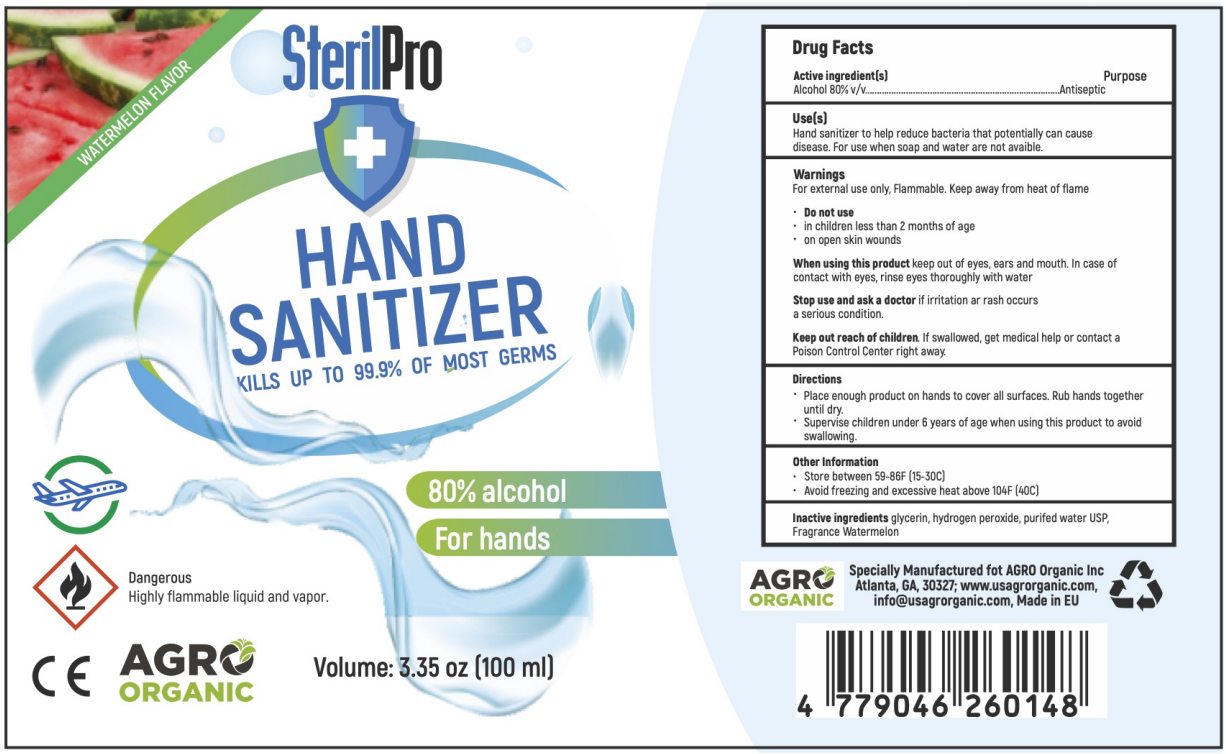

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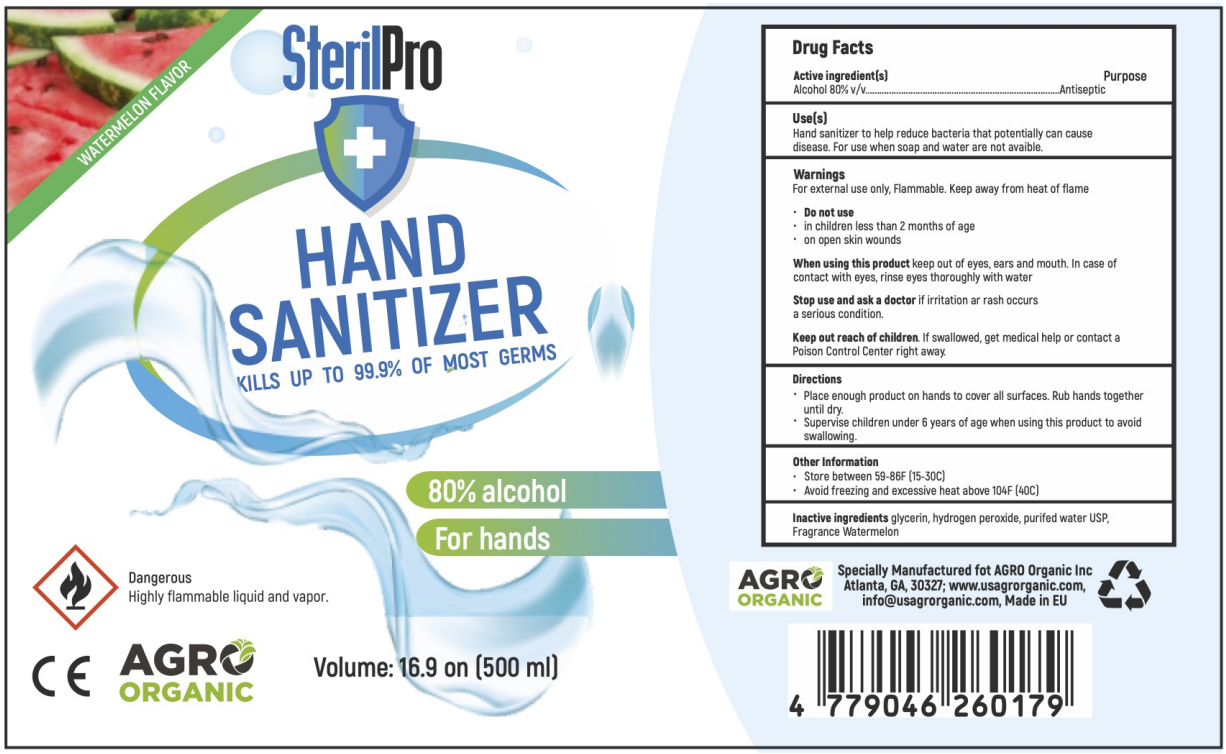

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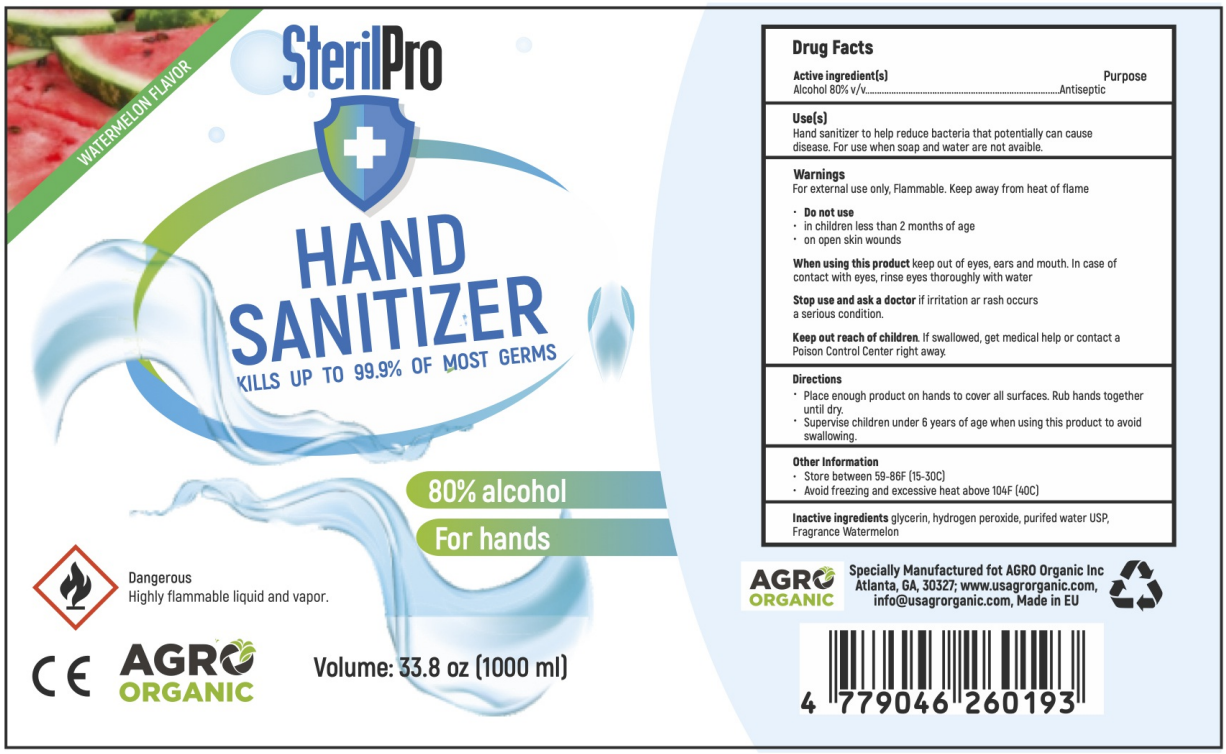

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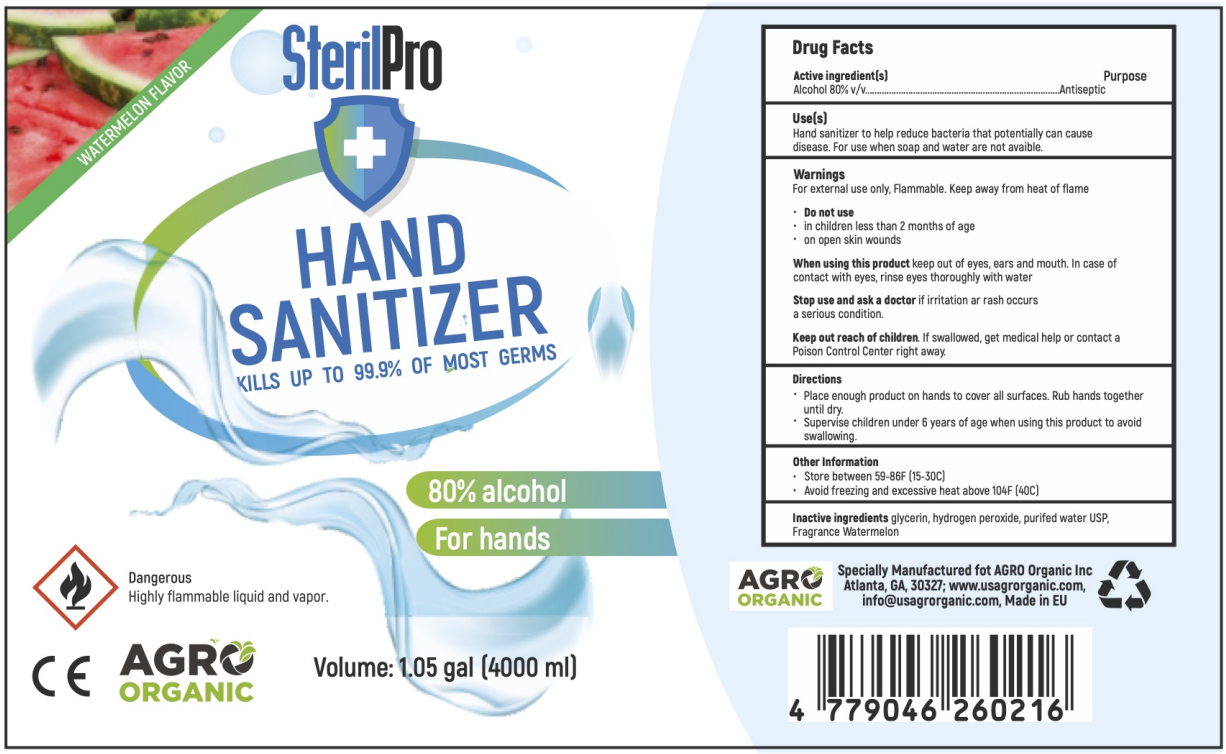

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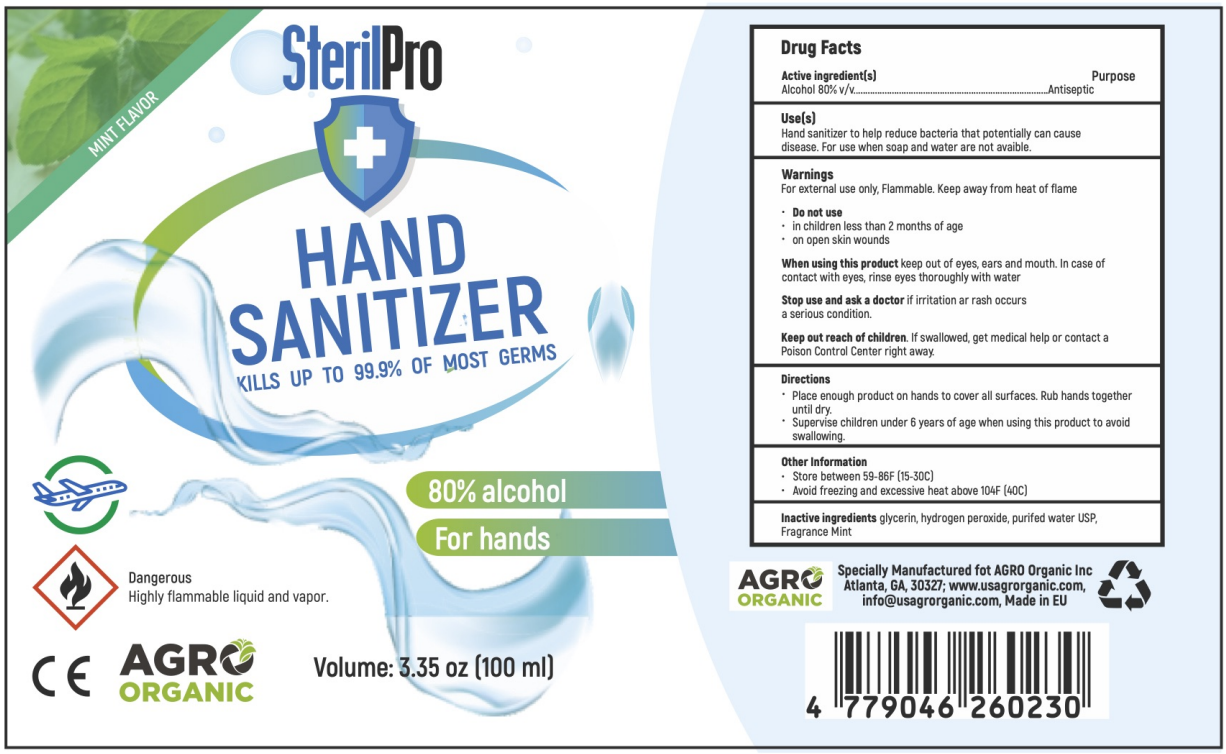

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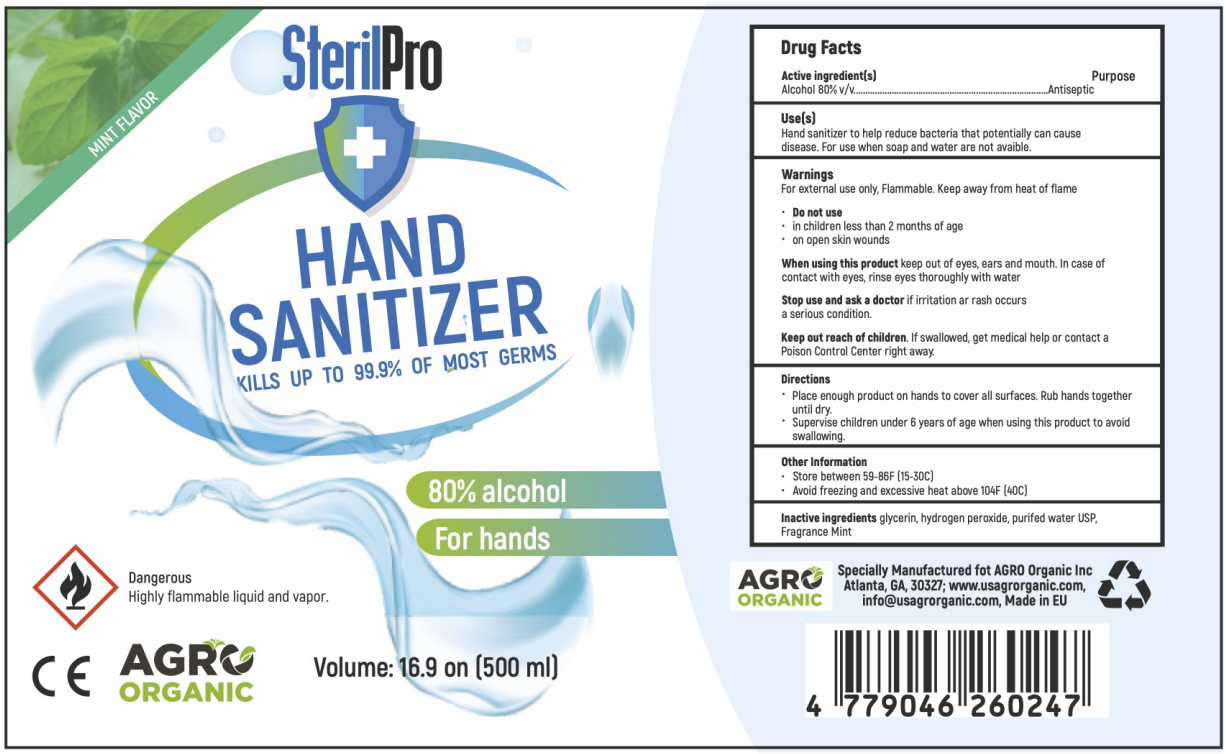

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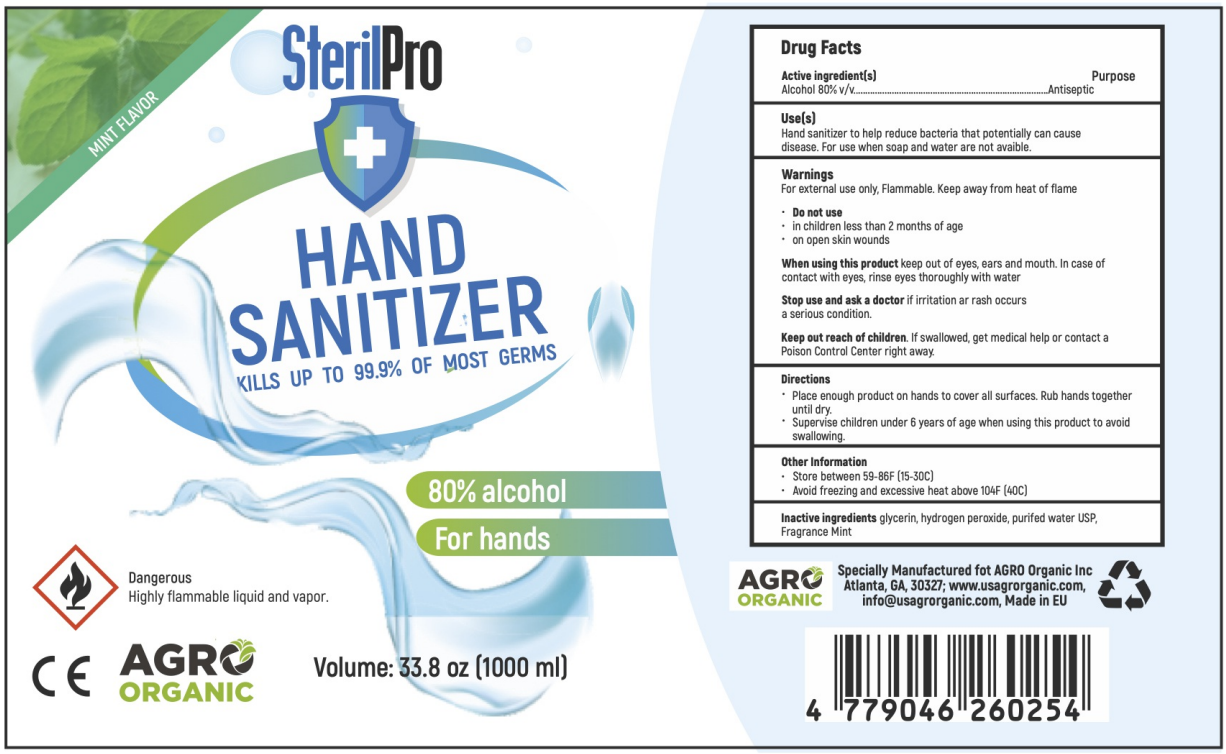

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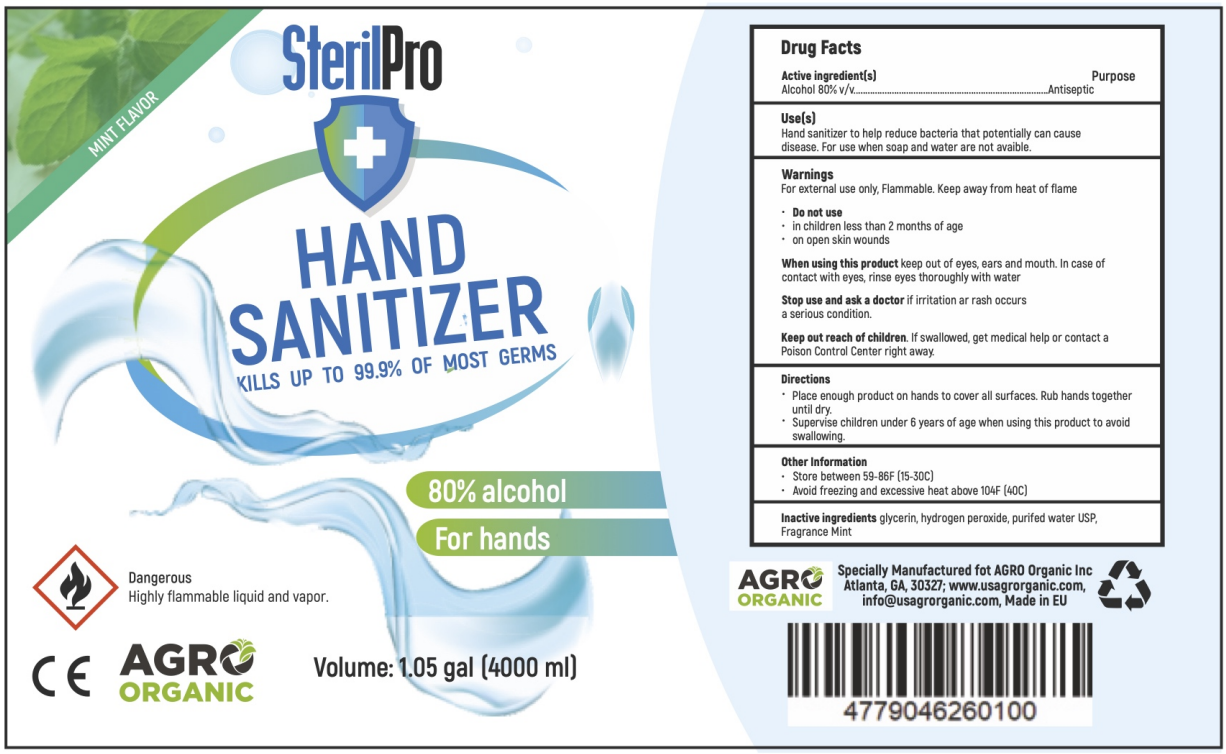

HAND SANITIZER

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: 059QF0KO0R)	

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: 059QF0KO0R)	

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: 059QF0KO0R)	

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)