

**ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION HAND SANITIZER NON-STERILE SOLUTION- alcohol solution**

**Sarkli-Repechage, Ltd.**

*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.*

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**Repechage Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-Sterile Solution**

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.

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.

Warnings

For external use only. Flammable. Keep away from heat or flame.

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

Stop 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.

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

Other information

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Questions or comments?

Call Toll-Free 1-800-SKIN (1-800-248-7546) Monday-Friday 9am-5:30pm ET

**Repechage Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-Sterile Solution**

118 mL, NDC 64521-5678-4

# REPÊCHAGE®

Alcohol Antiseptic 80%  
Topical Solution

## HAND SANITIZER

Non-Sterile Solution

118 ml / 4 fl oz

### 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 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.

### Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
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### Other information

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

### Questions or comments?

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BC45

59 mL, NDC 64521-5678-2

# REPÊCHAGE®

Alcohol Antiseptic 80%  
Topical Solution

## HAND SANITIZER

Non-Sterile Solution

59 ml / 2 fl oz

### 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 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.

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

### Questions or comments?

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BC46

236 mL, NDC 64521-5678-8

**REPÊCHAGE®**

Alcohol Antiseptic 80%  
Topical Solution  
**HAND SANITIZER**  
Non-Sterile Solution

236 ml / 8 fl oz

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 80% v/v.....	Antiseptic
<b>Use[s]</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store between 15–30C (59–86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	
<b>Questions or comments?</b>	
Call Toll-Free 1-800-248-SKIN (1-800-248-7546) Monday-Friday 9am-5:30pm ET	

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6 75765 04 105 8

BC49

473 mL, NDC 64521-5678-1

**REPÊCHAGE®**

REFILL SIZE

Alcohol Antiseptic 80%  
Topical Solution  
**HAND SANITIZER**  
Non-Sterile Solution

473 ml / 16 fl oz

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 80% v/v.....	Antiseptic
<b>Use[s]</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store between 15–30C (59–86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	
<b>Questions or comments?</b>	
Call Toll-Free 1-800-248-SKIN (1-800-248-7546) Monday-Friday 9am-5:30pm ET	

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6 75765 04 108 9

BC52

## ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION HAND SANITIZER NON-STERILE SOLUTION

alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64521-5678	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:64521-5678-4	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/31/2020	
2	NDC:64521-5678-2	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/31/2020	
3	NDC:64521-5678-8	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/14/2020	
4	NDC:64521-5678-1	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part333A	03/31/2020		

**Labeler** - Sarkli-Repechage, Ltd. (012583931)

**Registrant** - Sarkli-Repechage, Ltd. (012583931)

### Establishment

Name	Address	ID/FEI	Business Operations
Sarkli-Repechage, Ltd.		012583931	manufacture(64521-5678)

Revised: 4/2020

Sarkli-Repechage, Ltd.