# DURISAN HAND SANITIZER- benzalkonium chloride liquid Sanit Technologies LLC

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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#### **Duris an Hand Sanitizer - 611**

#### **Active Ingredient**

Benzalkonium Chloride 0.1%

#### Purpose

Antiseptic

#### Keep out of reach of children

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

#### Usage

• To decrease bacteria on the skin

#### Warnings

#### For External use only

When using this product • Keep out of eyes. In case of contact, flush eyes with water.

#### When Using

When using this product • Keep out of eyes. In case of contact, flush eyes with water.

#### Stop Use

**Stop use and consult a doctor if** irritation or redness develops.

#### Dosage

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

#### **Inactive Ingredients**

**Inactive ingredients:** water, laurtrimonium chloride, cetrimonium chloride, glycereth-17 cocoate, dihydroxyethyl cocamine oxide, dihydroxypropyl PEG-5, linoeammonium chloride, citric acid

Item#

#### **Duris an Hand Sanitizer 50 ml**

**Drug Facts** 

**Active Ingredient** 

Purpose

Benzalkonium Chloride 0.1% ...... Antiseptic

Uses

• To decrease bacteria on the skin

**Warnings** 

For External use only

When using this product • Keep out of eyes. In case of contact, flush eyes with water.

**Stop use and consult a doctor if** irritation or redness develops.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

**Directions** 

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

Inactive ingredients: water, laurtrimonium chloride, cetrimonium chloride, glycereth-17 cocoate, dihydroxyethyl cocamine oxide, dihydroxypropyl PEG-5, linoeammonium chloride, citric acid

8 52379 00612 7

Sanit Technologies, LLC 7810 25<sup>th</sup> Court East Unit 106 Sarasota, Florida 34243 844-DURISAN Travel

DHS-0501

Durisan ®

Size

• ANTIMICROBIAL SOLUTIONS

HAND
SANITIZER
ALCOHOL-FREE
LONG-LASTING
NO ODOR
U.S. Patent # 10,058,094
POWERED BY
® SANIT TECHNOLOGIES LLC
50 ml
Net Content 1.69 oz



#### **Duris an Hand Sanitizer 118 ml**

Durisan ®

ANTIMICROBIAL SOLUTIONS

HAND
SANITIZER
ALCOHOL-FREE
LONG-LASTING
NO ODOR
U.S. Patent # 10,058,094
POWERED BY
® SANIT TECHNOLOGIES LLC
118 ml
Net Content 4 oz
Item # DHS-1004

**Drug Facts** 

Active Ingredient Purpose

Benzalkonium Chloride 0.1% ...... Antiseptic

Uses

• To decrease bacteria on the skin

#### Warnings

For External use only

When using this product • Keep out of eyes. In case of contact, flush eyes with water.

**Stop use and consult a doctor if** irritation or redness develops.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

#### **Directions**

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

**Inactive ingredients:** water, laurtrimonium chloride, cetrimonium chloride, glycereth-17 cocoate, dihydroxyethyl cocamine oxide, dihydroxypropyl PEG-5, linoeammonium chloride, citric acid

8 52379 00634 9

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# HAND

ALCOHOL-FREE LONG-LASTING NO ODOR



U.S. Patent# 10,058,094

POWERED BY

118 ml Net Content 4 oz

Item # DHS-1004

Active ingredient Purpose

Benzalkonium Chloride 0.1% ....Antiseptic

# Uses

To decrease bacteria on the skin

# Warnings For External use only

When using this product •Keep out of eyes. In case of contact, flush eyes with water.

Stop use and consult a doctor if irritation or redness develops.

Keep out of reach of children. If swallowed, get medical assistance or contact a Poison Control Center immediately.

Directions •Rub thoroughly over all surfaces of both hands. •Rub hands together briskly until dry.

Inactive ingredients: water, laurtrimonium chloride, cetrimonium chloride, alycereth-17 cocoate



#### Duris an 236

Durisan ®

• ANTIMICROBIAL SOLUTIONS

HAND
SANITIZER
ALCOHOL-FREE
LONG-LASTING
NO ODOR
U.S. Patent # 10,058,094
POWERED BY
® SANIT TECHNOLOGIES LLC
236.58ml
Net Content 8 oz

#### **Drug Facts**

Uses

• To decrease bacteria on the skin

#### **Warnings**

#### For External use only

When using this product • Keep out of eyes. In case of contact, flush eyes with water.

**Stop use and consult a doctor if** irritation or redness develops.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

#### **Directions**

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

Inactive ingredients: water, laurtrimonium chloride, cetrimonium chloride, glycereth-17 cocoate, dihydroxyethyl cocamine oxide, dihydroxypropyl PEG-5, linoeammonium chloride, citric acid

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# Active ingredient

Purpose

Benzalkonium Chloride 0.1% ....

.Antiseptic

## Uses

To decrease bacteria on the skin

# Warnings

For External use only

When using this product •Keep out of eyes. In case of contact, flush eyes with water.

Stop use and consult a doctor if irritation or redness develops.

Keep out of reach of children. If swallowed, get medical assistance or contact a Poison Control Center immediately.

Directions

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

Inactive ingredients: water, laurtrimonium chloride, cetrimonium chloride, glycereth-17 cocoate, dihydroxyethyl cocamine oxide, dihydroxypropyl PEG-5 linoeammonium chloride, citric acid



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844-DURISAN www.DURISAN.com

#### Durisan Hand Sanitizer 250 ml

#### **Drug Facts**

Active Ingredient

**Purpose** 

Benzalkonium Chloride 0.1% ...... Antiseptic

Uses

• To decrease bacteria on the skin

#### Warnings

#### For External use only

When using this product • Keep out of eyes. In case of contact, flush eyes with NO ODOR water.

**Stop use and consult a doctor if** irritation or redness develops.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

#### **Directions**

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

Durisan ®

• ANTIMICROBIAL SOLUTIONS

HAND
SANITIZER
ALCOHOL-FREE
LONG-LASTING
NO ODOR
U.S. Patent #
10,058,094
POWERED BY
® SANIT
TECHNOLOGIES
LLC

250 ml Net Content 8.45 oz

Inactive ingredients: water, laurtrimonium chloride, cetrimonium chloride,

glycereth-17 cocoate, dihydroxyethyl cocamine oxide, dihydroxypropyl PEG-5, linoeammonium chloride, citric acid

ITEM # DHS-2501 8 52379 00611 0 Sanit Technologies, LLC 7810 25<sup>th</sup> Court East Sarasota, Florida 34243 844-DURISAN www.DURISAN.com



#### Duris an Hand Sanitizer 300 ml

Durisan ®

• ANTIMICROBIAL SOLUTIONS

ALCOHOL-FREE HAND SANITIZER Up to 24 hour protection Proudly mad in the USA 300 ml Net Content 10 oz

#### **Drug Facts**

Active Ingredient Purpose
Benzalkonium Chloride 0.1% ........ Antiseptic
Uses

• To decrease bacteria on the skin.

#### **Warnings**

#### For External use only

When using this product • Keep out of eyes. In case of contact, flush eyes with water.

**Stop use and consult a doctor if** irritation or redness develops.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

#### **Directions**

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

Inactive ingredients: water, laurtrimonium chloride, cetrimonium chloride, glycereth-17 cocoate, dihydroxyethyl cocamine oxide, dihydroxypropyl PEG-5, linoeammonium chloride, citric acid

Item # RTHS-3000 52379 00697

Sanit Technologies, LLC 7810 25th Court East Sarasota, Florida 34243 844-DURISAN U.S. Patent # 10,058,094





#### Duris an Hand Sanitizer 550 ml

**Drug Facts** 

**Active Ingredient Purpose** Benzalkonium Chloride 0.1% ...... Antiseptic Uses

• To decrease bacteria on the skin

**Warnings** 

For External use only

SOLUTIONS HAND

ANTIMICROBIAL

Durisan ®

**SANITIZER** ALCOHOL-FREE LONG-LASTING

When using this product • Keep out of eyes. In case of contact, flush eyes with NO ODOR

water.

**Stop use and consult a doctor if** irritation or redness develops. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

**Directions** 

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

Inactive ingredients: water, laurtrimonium chloride, cetrimonium chloride, glycereth-17 cocoate, dihydroxyethyl cocamine oxide, dihydroxypropyl PEG-5, linoeammonium chloride, citric acid

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844-DURISAN

Sanit Technologies, LLC

U.S. Patent #

10,058,094

® SANIT

LLC

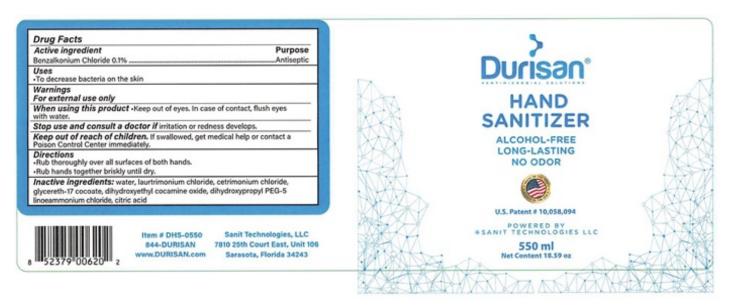
550 ml

**POWERED BY** 

**TECHNOLOGIES** 

Net Content 18.59 oz

ITEM # DHS-0550 7810 25th Court East Sarasota, Florida 34243 www.DURISAN.com



#### **Duris an Hand Sanitizer 1000 ml**

Durisan ®

ANTIMICROBIAL SOLUTIONS

**HAND** SANITIZER ALCOHOL-FREE LONG-LASTING NO ODOR U.S. Patent # 10,058,094 **POWERED BY** ® SANIT TECHNOLOGIES LLC 1000 ml Net Content 33.81 oz

**Drug Facts** 

**Active Ingredient Purpose** Benzalkonium Chloride 0.1% ...... Antiseptic Uses

• To decrease bacteria on the skin

#### Warnings

#### For External use only

When using this product • Keep out of eyes. In case of contact, flush eyes with water.

**Stop use and consult a doctor if** irritation or redness develops.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

#### **Directions**

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

Inactive ingredients: water, laurtrimonium chloride, cetrimonium chloride, glycereth-17 cocoate, dihydroxyethyl cocamine oxide, dihydroxypropyl PEG-5, linoeammonium chloride, citric acid

0.4 Item # DHS-1002 8 50008 48507 7 Sanit Technologies, LLC 7810 25<sup>th</sup> Court East Sarasota, Florida 34243

844-DURISAN www.DURISAN.com

#### **Drug Facts**

#### Uses

• To decrease bacteria on the skin

#### Warnings

#### For External use only

When using this product • Keep out of eyes. In case of contact, flush eyes with water.

**Stop use and consult a doctor if** irritation or redness develops.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

#### **Directions**

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

Inactive ingredients: water, laurtrimonium chloride, cetrimonium chloride, glycereth-17 cocoate, dihydroxyethyl cocamine oxide, dihydroxypropyl PEG-5, linoeammonium chloride, citric acid

0.8 Item # DHS-1008 8 52379 00610 3 Sanit Technologies, LLC 7810 25<sup>th</sup> Court East Sarasota, Florida 34243 844-DURISAN

www.DURISAN.COM



# HAND SANITIZER

ALCOHOL-FREE LONG-LASTING NO ODOR



U.S. Patent # 10,058,094

\*SANIT TECHNOLOGIES LLC

1000 ml Net Content 33.81 oz

## Active ingredient

Purpose

Benzalkonium Chloride 0.1% .....Antiseptic

#### Uses

To decrease bacteria on the skin

## Warnings

For External use only

When using this product • Keep out of eyes. In case of contact, flush eyes with water.

Stop use and consult a doctor if irritation or redness develops.

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

#### **Directions**

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

Inactive ingredients: water, laurtrimonium chloride, cetrimonium chloride, glycereth-17 cocoate, dihydroxyethyl cocamine oxide, dihydroxypropyl PEG-5 linoeammonium chloride, citric acid

0.4 Item # DHS-1002

Sanit Technologies LLC 7810 25th Court East Sarasota, FL 34243 844-DURISAN www.DURISAN.com

## Active ingredient

Purpose

Benzalkonium Chloride 0.1% .....Antiseptic

#### Uses

To decrease bacteria on the skin

## Warnings

For External use only

When using this product . Keep out of eyes. In case of contact, flush eyes with water.

Stop use and consult a doctor if irritation or redness develops.

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

#### Directions

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

Inactive ingredients: water, laurtrimonium chloride, cetrimonium chloride, glycereth-17 cocoate, dihydroxyethyl cocamine oxide, dihydroxypropyl PEG-5 linoeammonium chloride, citric acid

0.8 Item # DHS-1008

Sanit Technologies LLC 7810 25th Court East Sarasota, FL 34243 844-DURISAN WWW.DURISAN.COM

#### **Duris an Hand Sanitizer 1 Gallon**

Sanit Technologies, **Drug Facts** 

**Active Ingredient** LLC **Purpose** 7810 25<sup>th</sup> Court East Benzalkonium Chloride 0.1% ...... Antiseptic

Sarasota, Florida

Uses 34243 • To decrease bacteria on the skin

844-DURISAN

www.DURISAN.comWarnings

For External use only ITEM # DHS-3785

52379 00621 9 When using this product • Keep out of eyes. In case of

contact, flush eyes with water.

**Stop use and consult a doctor if** irritation or redness

develops.

**Keep out of reach of children.** If swallowed, get medical ® SANIT help or contact a Poison Control Center immediately.

**Directions** 

• Rub thoroughly over all surfaces of both hands.

• Rub hands together briskly until dry.

Inactive ingredients: water, laurtrimonium chloride, cetrimonium chloride, glycereth-17 cocoate,

dihydroxyethyl cocamine oxide, dihydroxypropyl PEG-5,

linoeammonium chloride, citric acid

Durisan ®

 ANTIMICROBIAL **SOLUTIONS** 

HAND

**SANITIZER** 

ALCOHOL-FREE

LONG-LASTING

NO ODOR

U.S. Patent #

10,058,094

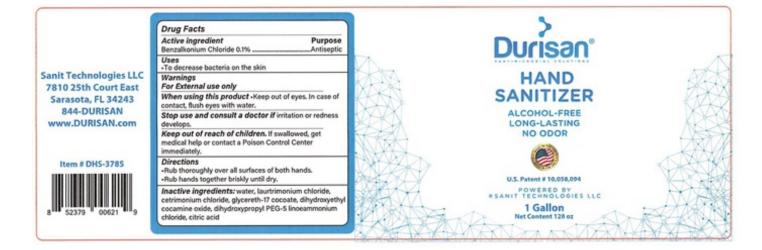
POWERED BY

**TECHNOLOGIES** 

LLC

1 Gallon

Net Content 128 oz



#### DURISAN HAND SANITIZER benzalkonium chloride liquid **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:71120-611 **Route of Administration** TOPICAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength

BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM -
UNII:7N6JUD5X6Y)

BENZALKONIUM CHLORIDE 2.5 mg in 250 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
DIHYDRO XYPRO PYL PEG-5 LINO LEAMMO NIUM CHLO RIDE (UNII: 0 Y0 NQR2GH1)			
GLYCERETH-2 CO CO ATE (UNII: JWM0 0 VS7HC)			
BEHENTRIMO NIUM CHLO RIDE (UNII: X7GNG3S47T)			
DIHYDRO XYETHYL CO CAMINE O XIDE (UNII: 8 AR51R3BL5)			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:71120-611- 01	20 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	0 1/0 1/20 16	02/28/2020	
2	NDC:71120-611- 02	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	0 1/0 1/20 16		
3	NDC:71120-611- 03	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	0 1/0 1/20 16		
4	NDC:71120-611- 04	550 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	0 1/0 1/20 16		
5	NDC:71120-611- 05	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	0 1/0 1/20 16		
6	NDC:71120-611- 06	1000 mL in 1 CONTAINER; Type 0: Not a Combination Product	0 1/0 1/20 16		
7	NDC:71120-611- 07	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	0 1/0 1/20 16		
8	NDC:71120-611- 08	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	0 1/0 1/20 16		
9	NDC:71120-611- 09	4 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	0 1/0 1/20 16	02/28/2020	
10	NDC:71120-611- 10	8 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	0 1/0 1/20 16	02/28/2020	
11	NDC:71120-611- 11	300 mL in 1 CONTAINER; Type 0: Not a Combination Product	0 1/0 1/20 16		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	0 1/0 1/20 16		

## Labeler - Sanit Technologies LLC (075711022)

Establishment				
Name	Address	ID/FEI	Business Operations	
Lab Express International		800875106	relabel(71120-611), api manufacture(71120-611), repack(71120-611)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Organics Corporation of America DBA Ambix Laboratories		061061164	manufacture(71120-611)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Durisan		085479946	manufacture(71120-611)	

Revised: 3/2020 Sanit Technologies LLC