

SANITIZER WIPES- benzalkonium chloride solution
AMSAT International, Inc.

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)

BENZALKONIUM CHLORIDE 0.1%

Purpose

Purpose: Antimicrobial

Use

Hand Sanitizer to help reduce bacteria on the skin

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

- Wet hands thoroughly with product and allow to dry.
- Discard wipes in trash receptacle after use. Do not flush
- Children under 6 years of age should be supervised when using this product.

Inactive ingredients

Ethylhexylglycerin, Glycerin, Phenoxyethanol, Polyaminopropyl biguanide, Propylene Glycol, Purified water

Package Label - Principal Display Panel

10 mL NDC: 79438-002-10

Drug Facts	
Active Ingredient	Purpose
Benzalkonium Chloride 0.1%.....	Antimicrobial
Use	
Hand sanitizer to help reduce bacteria on the skin	
Warnings	
For external use only	
When using this product do not use in or near eyes.	
In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash appears and lasts	
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Directions	
<ul style="list-style-type: none"> Wet hands thoroughly with product and allow to dry Discard wipes in trash receptacle after use. Do not flush Children under 6 years of age should be supervised when using this product 	
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Disinfectant Wipe

10 Wipes



- ✓ Unscented
- ✓ Anti-bacteria kills 99.9% of germs
- ✓ Soft, cloth-like texture for thorough cleansing
- ✓ The quick and easy way to keep your family hygienically clean and protected at home and on the way

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 Winter Park, FL 32789
 FDA MedWatch Number :
 1-888-463-6332

USE RANGE:

Hand Bag Trunk Phone Computer Car

75 mL NDC: 79438-002-75

AMSAT Int'l

Disinfectant Wipe

Kills 99.9% of Viruses & Bacteria

Unscented

75 Wipes



AMSAT Int'l

- ✓ Unscented
- ✓ Anti-bacteria kills 99.9% of germs
- ✓ Soft, cloth-like texture for thorough cleansing
- ✓ The quick and easy way to keep your family hygienically clean and protected at home and on the way

DIRECTION OF USE



WARNING

- For external use only
- Do not use in eyes
- Discontinue use if irritation and redness develop.
- If condition persists if more than 72 hours, consult a doctor.
- Keep out of reach of children
- If swallowed, get medical help or contact a Poison Control Centre right away.
- Flammable, keep away from fire or flame.
- Do not flush used wipes into toilet



Drug Facts	
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Use Hand sanitizer to help reduce bacteria on the skin	
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Directions • Wet hands thoroughly with product and allow to dry • Discard wipes in trash receptacle after use. Do not flush • Children under 6 years of age should be supervised when using this product	
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50 mL NDC: 79438-002-50

AMSAT Int'l

Disinfectant Wipe

Kills 99.9% of Viruses & Bacteria

Unscented

50 Wipes

AMSAT Int'l

- ✓ Unscented
- ✓ Anti-bacteria kills 99.9% of germs
- ✓ Soft, cloth-like texture for thorough cleansing
- ✓ The quick and easy way to keep your family hygienically clean and protected at home and on the way

DIRECTION OF USE



WARNING

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SANITIZER WIPES

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79438-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYAMINOPROPYL BIGUANIDE (UNII: DT9D8Z79ET)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79438-002-10	10 mg in 1 PACKET; Type 0: Not a Combination Product	07/23/2020	
2	NDC:79438-002-75	75 mg in 1 PACKET; Type 0: Not a Combination Product	07/23/2020	
3	NDC:79438-002-50	50 mg in 1 PACKET; Type 0: Not a Combination Product	07/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/23/2020	

Labeler - AMSAT International, Inc. (806393943)**Establishment**

Name	Address	ID/FEI	Business Operations
Hangzhou Caring Cleaning Commodity Co., Ltd		413905445	manufacture(79438-002)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Furuisen Spunlaced Nonwovens Co., Ltd.		723796509	manufacture(79438-002)

Establishment

Name	Address	ID/FEI	Business Operations
AMSAT International, Inc.		806393943	manufacture(79438-002)

Revised: 8/2020

AMSAT International, Inc.