

SANITIZING WIPES- hand sanitizer cloth
Ivy Rose 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 $\geq 0.1\%$, Antimicrobial agent

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.

Do not use

if you are allergic to any of the ingredients.

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 develops and continues for more than 72 hours.

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Directions

- Adults and children 2 years and over.
- Apply to hands allow to dry without wiping.

Other information

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

Inactive ingredients

Water(aqua), Didecyl dimethy ammonium chloride, T5(Glycerin), T3(Aloe), T6(VE), Tributyl phosphate, Citric acid, Alcohol.

Package Label - Principal Display Panel

30 Individually Packed Wipes in 1 BOX NDC: 79247-812-01



Package Label - Principal Display Panel

20 Wipes in 1 BOX NDC: 79247-812-02

KEEP US SAFE

SANITIZING

Wipes



Drug Facts	
Active Ingredient	Purpose
Benzalkonium Chloride >= 0.1%	Antimicrobial agent
Uses •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 Do not use if you are allergic to any of the ingredients When using this product do not get into eyes. If contacts occurs, rinse thoroughly with water.	
Keep away from heat or flames.	
Stop use and ask a doctor if irritation or rash develops and continues for more than 72 hours.	
Keep out of reach of children. If swallowed, seek medical help or contact a Poison Control Center right away.	
Avoid flushing down the toilet	
Directions	
Adults and children 2 years and over	Apply to hands allow to dry without wiping
children under 2 years	ask a doctor before use
Other Information Store between 15 -30° C (59 -86°F) •Avoid freezing and excessive heat above 40° C (104° F)	
Inactive Ingredients Water (aqua), Didecyl dimethyl ammonium chloride, T5 (Glycerin), T3 (Aloe), T6 (VE), Tributyl phosphate, Citric acid, Alcohol	

- Kills 99.9% of Bacteria**
- With Glycerin & Aloe Vera to Replace Moisture**

Item #: 000000
Lot #: 000000



KEEP US SAFE

SANITIZING

Wipes



with Aloe Vera

Kills 99.9% of Bacteria

Antibacterial

Fragrance Free

Made with Moisturizing Formula for Dry Skin

NET WT 4.76 OZ (135g)

PEEL & SEAL

20 Wipes

Wipe Dimensions:
5.9 in x 7.9 in (15cm x 20cm)

Kills Bacteria:

- Staphylococcus aureus
- Escherichia coil
- Pseudomonas aeruginosa
- Candida albicans

How to use:

1. Peel back front label softly.



2. Take out wipe to use.



3. Seal label back down to trap in moisture & store.



How to store:

- Keep in cool dry place.
- Keep flames and heat away.

CAUTION
CHOKING HAZARD
Do not put wipes in mouth or swallow.
Not for children under 2 years.

Distributed by: Ivy Rose Inc.
1928 S. Santa Fe Ave.
Los Angeles, CA 90021
www.ivyroseinc.com

Validity Period: Two years
Production dates:
See outer packaging
Made in China



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With Aloe Vera

Kills 99.9% of Bacteria

Multi-purpose Wipes



Wipe Dimensions:
5.9 in x 7.9 in (15cm x 20cm)

50 Wipes

Sanitizing Wipes

50 Wipes

- Fragrance Free
- Antibacterial
- Made with Moisturizing Formula for Dry Skin



with Aloe Vera



50 Wipes

Sanitizing Wipes



Multi-purpose Wipes

Kills 99.9% of Bacteria

With Aloe Vera

KEEP US SAFE

SANITIZING

Wipes

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Adults and children 2 years and over

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children under 2 years

ask a doctor before use

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Kills 99.9% of Bacteria

With Glycerin & Aloe Vera to Replace Moisture

Item #: 000000

Lot #: 000000



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 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.1 g in 100 g
ALOE (UNII: V5VD430YW9)	0.0025 g in 100 g
WATER (UNII: 059QF0KO0R)	94.915 g in 100 g
ALCOHOL (UNII: 3K9958V90M)	4.7 g in 100 g
TOCOPHEROL (UNII: R0ZB2556P8)	0.0025 g in 100 g
TRI-N-BUTYL PHOSPHATE (UNII: 95UAS8YAF5)	0.01 g in 100 g
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B)	0.16 g in 100 g
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	0.01 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79247-812-01	183 g in 1 BOX; Type 0: Not a Combination Product	08/12/2020	
2	NDC:79247-812-02	122 g in 1 BOX; Type 0: Not a Combination Product	08/12/2020	
3	NDC:79247-812-03	338 g in 1 BOX; Type 0: Not a Combination Product	08/12/2020	
4	NDC:79247-812-04	540 g in 1 BOX; Type 0: Not a Combination Product	08/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/12/2020	

Labeler - Ivy Rose Inc. (037401255)

Registrant - Ivy Rose Inc. (037401255)

Establishment

Name	Address	ID/FEI	Business Operations
Jiangsu Terra Medical Technology Co. Ltd.		421340473	manufacture(79247-812)

Revised: 8/2020

Ivy Rose Inc.