

BLUE BEAR ANTIBACTERIAL HAND WIPES- benzalkonium chloride cloth
Blue Bear Protection 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.

Blue Bear Antibacterial Hand Wipes

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Benzalkonium Chloride (0.23%, weight/weight (w/w))
- b. Aqua,
- c. Benzoic Acid,
- d. Citral,
- e. Dehydroacetic Acid,
- f. Dicaprylyl Carbonate,
- g. Glycerin,
- h. Glyceryl Oleate,
- i. Lauryl Glucoside,
- j. Limonene,
- k. Linalool
- l. Olus Oil,
- m. Parfum,
- n. Phenoxyethanol,
- o. Polyglyceryl-2 Dipolyhydroxystearate,
- p. Polysorbate 20,
- q. Propylene Glycol,
- r. Tetrasodium EDTA

Active Ingredient(s)

Benzalkonium Chloride 0.23% w/w. Purpose: Antibacterial/ Antifungal

Purpose

Antibacterial / Antifungal, Hand Sanitizer

Use

Antibacterial Wet Wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

Keep out of reach of children. For external use only.

Do not use

- in children less than 2 months of age
- on open skin wounds

Do not eat or drink while using the product. Follow all the instructions to avoid risks on human and environmental health. In case of contact with eyes: If you are wearing contact lenses, remove them immediately. Rinse your eyes with plenty of clean 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.

Seek a doctor if redness, swelling, itching, or burning occurs on skin

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

Directions

- Provides practical cleaning without the need of water and soap. It is used for hand cleaning. Open the label and pick up a wipe. Gently wipe your hands with antibacterial wipe. No rinsing required
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store the product dry, cool, clean place and keep away from direct sunlight

Inactive ingredients

Aqua, Benzoic Acid, Citral, Dehydroacetic Acid, Dicaprylyl Carbonate, Glycerin, Glyceryl Oleate, Lauryl Glucoside, Limonene, Linalool Olus Oil, Parfum, Phenoxyethanol, Polyglyceryl-2 Dipolyhydroxystearate, Polysorbate 20, Propylene Glycol, Tetrasodium EDTA

Package Label - Principal Display Panel

160mm

Drug Facts

Active ingredient: Benzalkonium Chloride 0.23% by mass. Purpose: Antibacterial / Antifungal.

USE: Antibacterial Wet Wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings: Keep out of reach of children. For external use only.

Do Not Use: For children less than 6 months of age on open skin wounds.

When Using: Do not eat or drink while using the product. Follow all the instructions to avoid risks to human and environmental health. In case of contact with eyes, if you are wearing contact lenses, remove them immediately. Rinse your eyes with plenty of clean water. If swallowed, get medical help or contact a Poison Control Center right away.

STOP USE: Stop a doctor if redness, swelling, itching, or burning occurs on skin.

DIRECTIONS: Provides practical cleaning without the need of water and soap. It is used for hand cleaning. Open the tab and pull out a wipe. Gently wipe your hands with antibacterial wipe. No rinsing required. Supervise children under 6 years of age when using this product to avoid swallowing.

OTHER INFO: Store the product in a dry cool, clean place and keep away from direct sunlight.

INACTIVE INGREDIENTS: Benzoic Acid, Citric Diphosphoric Acid, Disodium Carbonate, Glycerol, Glyceryl Oleate, Lauryl Glucoside, Limonene, Linalol Dlus Oil, Parfum, Phenylethanol, Polyquatern-15, Polyhydroxyacetone, Polyisobutene 20, Propylene Glycol, Sorbitanole E20A, Water.

NDC Code: 81005-001-02

Provides practical cleaning without the need of water and soap, it is used for hand cleaning. Hygienic cleaning everywhere you need.

The product is effective against harmful organisms:

MICROORGANISMS WHICH THE PRODUCT IS EFFECTIVE	USAGE	DOSE / RANGE OF USE
Staphylococcus aureus ATCC 6538; Pseudomonas aeruginosa ATCC 15442; Enterococcus faecalis ATCC 10541; Escherichia coli ATCC 10536	Antibacterial and Antifungal Wet Wipes. It is used for wiping and cleaning of hands and joints on hands. No rinsing is required.	The number of wet wipes used to wipe the hands, arms and feet is 1.
Candida albicans ATCC 9001; Aspergillus brasiliensis ATCC 16304		

Antibacterial and Antifungal Wet Wipes

Net Quantity: 15 pcs

Weight of 1 dry wipe: 0.830 g/±%10

Amount of solution absorbed into wipe: 2.826 g/±%10

Weight of solution absorbed (Soaked) wipe: 3.752 g/±%10

Amount of active ingredient absorbed in wipe: 0.006653 g/±%10

Provides practical cleaning without the need of water and soap. It is used for hand cleaning. Open the tab and pull out a wipe. Gently wipe your hands with antibacterial wipe. No rinsing required.

Commercial name of the product: Antibacterial Wet Wipes

Formulation Form: Solid (Absorbed solution in fabric)

Fabric structure: Nonwoven fabric.

Active material name and amount: Quaternary ammonium compounds, benzyl (C12-C16) alkyl dimethyl, chlorides (Cas No:68242-85-1) 0,23% (w/w).

Alcohol Free
Ph Balanced

Kills 99.9% of germs and bacteria

Blue Bear 99

Antibacterial Hand Wipes

Alcohol Free
Ph Balanced

Blue Bear 99

Kills 99.9% of germs and bacteria

Lemon scent

15
wipes

Multi purpose hand wipes

Kills
99.9%
of germs and bacteria

Alcohol Free
PH Balanced

Blue Bear 99

Kills 99.9% of germs and bacteria

15
wipes



Produced under hygienic environment and conditions according to ISO 22716:2007 (GMP) and ISO 9001:2015 Quality Management System.

*Kills 99.9% of Staphylococcus aureus ATCC 6538, Pseudomonas Aeruginosa ATCC 15442, Enterococcus hirae ATCC 10541, Escherichia coli ATCC 10536.

Manufactured for:
Blue Bear Protection LLC
841 Lexington Avenue
New York, NY 10022

Manufacturer:
Aksan Kocemir San. Ve Tic. A.Ş.
Deriaskaya Mah. Kısıklı Cad. No:
25/5A
Arnavitköy, İstanbul
Made in Turkey
BlueBearProtection.com



185mm

275mm

Drug Facts
Active Ingredient
Benzalkonium Chloride (0.25% w/w), Antibacterial/Antifungal

Purpose
Antibacterial Wet Wipes to help reduce the number of germs and bacteria on your hands. For use on skin and surfaces.

Warnings
Keep out of reach of children. For external use only. Do not use on open skin wounds.

Directions
Wipe hands for 20 seconds. Do not use on open skin wounds. Do not ingest. Do not use on children less than 2 months of age. Do not use on children less than 2 months of age. Do not use on children less than 2 months of age. Do not use on children less than 2 months of age.

Other information
Do not use on children less than 2 months of age. Do not use on children less than 2 months of age. Do not use on children less than 2 months of age.

INGREDIENTS
Benzalkonium Chloride, Citric Acid, Dihydroxyacetic Acid, Diethylene Glycol, Ethanolamine, Glycerol, Linalool, Linalyl Acetate, Polyethylene Glycol, Polyethylene Glycol, Polysorbate 20, Polyethylene Glycol, Hexadecyltrimethylammonium Chloride, Polysorbate 20, Polyethylene Glycol, Hexadecyltrimethylammonium Chloride.

NDC Code: 81005-001-04

Provides practical cleaning without the need of water and soap. It is used for hand cleaning. Hygienic cleaning everywhere you need.

The product is effective against harmful organisms:

Microorganisms	Usage	Dose / Range of Use
Staphylococcus aureus ATCC 6538	Antibacterial and antifungal wet wipes	The number of wet wipes used to wipe the hands, arms and cleaned area is 6.
Pseudomonas aeruginosa ATCC 27962	Antibacterial and antifungal wet wipes	The number of wet wipes used to wipe the hands, arms and cleaned area is 6.
Enterococcus faecalis ATCC 29212	Antibacterial and antifungal wet wipes	The number of wet wipes used to wipe the hands, arms and cleaned area is 6.
Candida albicans ATCC 10227	Antibacterial and antifungal wet wipes	The number of wet wipes used to wipe the hands, arms and cleaned area is 6.
Aspergillus niger ATCC 1641	Antibacterial and antifungal wet wipes	The number of wet wipes used to wipe the hands, arms and cleaned area is 6.

Antibacterial and Antifungal Wet Wipes

Net Quantity: 100 pcs
Weight of 1 dry wipe: 3.28g (gr/piece +/- %10)
Amount of solution absorbed into wipe: 4.53g (gr/piece +/- %10)
Weight of solution absorbed wipe (solution wipe): 5.83g (gr/piece +/- %10)
Amount of active ingredient absorbed in wipes: 0.01005g (gr/piece +/- %10)

100
wipes

Alcohol Free • Ph Balanced
Kills 99.9% of germs and bacteria
Blue Bear 99
Lemon scent

100
wipes

**Antibacterial
Hand Wipes**
Blue Bear 99
Kills 99.9% of germs and bacteria
100wipes



Lemon scent

Multi purpose hand wipes

Kills
99.9%
of germs and bacteria

100
wipes

Blue Bear 99
Kills 99.9% of germs and bacteria
Alcohol Free • Ph Balanced
Lemon scent



Blue Bear PROTECTION

Manufactured for:
Blue Bear Protection LLC
841 Lexington Avenue
New York, NY 10022

Manufacturer:
Aksan Kozmetik San. ve Tic. A.Ş.
Dulkeraya Mah. Kağıt Cad. No:
23-25A
Arnavutköy, İstanbul
Made in Turkey
BlueBearProtection.com

Produced under hygienic environment and conditions according to ISO 22716:2007 (GMP) and ISO 9001:2015 Quality Management System.
*kills 99.9% of Staphylococcus aureus ATCC 6538, Pseudomonas Aeruginosa ATCC 15442, Enterococcus hirae ATCC 10541, Escherichia coli ATCC 10536.



160x140 mm



Antibacterial
HAND WIPES

Kills 99.9% of germs and bacteria

500
wipes

The product is effective against harmful organisms:

MICROORGANISMS WHICH THE PRODUCT IS EFFECTIVE	USAGE	DOSE / RANGE OF USE
Staphylococcus Aureus ATCC 6538, Pseudomonas Aeruginosa ATCC 15442, Enterococcus Hirae ATCC 10541, Escherichia Coli ATCC 10538, Candida Albicans ATCC 10231, Aspergillus Brasiliensis ATCC 16404	Antibacterial and Antifungal Wet Wipes: It is used as wiping in the cleaning of bacteria and fungi in the hands. No rinsing is required.	The number of wet wipes used to wipe the hands, arms and desired area is 1.

Provides practical cleaning without the need of water and soap. It is used for hand cleaning. Open the label and pick up a wipe. Gently wipe your hands with antibacterial wipe. No rinsing required.

Commercial name of the product: Antibacterial Wet Wipes

Formulation Form: Solid/Absorbed solution in fabric

Fabric structure: Nonwoven fabric.

Active material name and amount: Benzalkonium Chloride (Cas No:68242-85-1) was used at 0.23%.

Warnings: Under normal conditions, its shelf life is 2 years. Use the opened product within 3 months. Keep out of reach of children and store in a cool dry place. Avoid direct sunlight and eye contact.

Produced under hygienic environment and conditions according to ISO 22716:2007 (GMP) and ISO 9001:2015 Quality Management System.

ISO 22716:2007 (GMP) ve ISO 9001:2015 Kalite Yönetim Sistemine uygun olarak hijyenik ortam ve koşullarda üretilmiştir.

*kills 99.9% of Staphylococcus Aureus ATCC 6538, Pseudomonas Aeruginosa ATCC 15442, Enterococcus Hirae ATCC 10541, Escherichia Coli ATCC 10538, Candida Albicans ATCC 10231, Aspergillus Brasiliensis ATCC 16404.

*Staphylococcus Aureus ATCC 6538, Pseudomonas Aeruginosa ATCC 15442, Enterococcus Hirae ATCC 10541, Escherichia Coli ATCC 10538, Candida Albicans ATCC 10231, Aspergillus Brasiliensis ATCC 16404 in %99,9unu öldürür.

Manufactured for: Blue Bear Protection LLC
641 Lexington Avenue
New York, NY 10022
Manufacturer: Aksan Kozmetik San. Ve Tic. A.Ş.
Made in Turkey
www.bluebear99.com




NDC Code:xxxxxxxx



Antibacterial
HAND WIPES

Kills 99.9% of germs and bacteria

500
wipes

Antibacterial
HAND WIPES

Kills 99.9% of germs and bacteria

Blue Bear 99
Kills 99.9% of germs and bacteria

Alcohol Free • pH Balanced

500
wipes

www.bluebear99.com

Kills 99.9%
of germs and bacteria

316,7x155mm



Antibacterial
HAND WIPES

Kills 99.9% of germs and bacteria

100
wipes

The product is effective against harmful organisms:

MICROORGANISMS WHICH THE PRODUCT IS EFFECTIVE	USAGE	DOSE / RANGE OF USE
Staphylococcus Aureus ATCC 6538, Pseudomonas Aeruginosa ATCC 15442, Enterococcus Hirae ATCC 10541, Escherichia Coli ATCC 10538, Candida Albicans ATCC 10231, Aspergillus Brasiliensis ATCC 16404	Antibacterial and Antifungal Wet Wipes: It is used as wiping in the cleaning of bacteria and fungi in the hands. No rinsing is required.	The number of wet wipes used to wipe the hands, arms and desired area is 1.

Provides practical cleaning without the need of water and soap. It is used for hand cleaning. Open the label and pick up a wipe. Gently wipe your hands with antibacterial wipe. No rinsing required.

Commercial name of the product: Antibacterial Wet Wipes

Formulation Form: Solid/Absorbed solution in fabric

Fabric structure: Nonwoven fabric.

Active material name and amount: Benzalkonium Chloride (Cas No:68242-85-1) was used at 0.23%.

Warnings: Under normal conditions, its shelf life is 2 years. Use the opened product within 3 months. Keep out of reach of children and store in a cool dry place. Avoid direct sunlight and eye contact.

Produced under hygienic environment and conditions according to ISO 22716:2007 (GMP) and ISO 9001:2015 Quality Management System.

*kills 99.9% of Staphylococcus Aureus ATCC 6538, Pseudomonas Aeruginosa ATCC 15442, Enterococcus Hirae ATCC 10541, Escherichia Coli ATCC 10538, Candida Albicans ATCC 10231, Aspergillus Brasiliensis ATCC 16404.

Manufactured for: Blue Bear Protection LLC
641 Lexington Avenue
New York, NY 10022
Manufacturer: Aksan Kozmetik San. Ve Tic. A.Ş.
Made in Turkey
www.bluebear99.com




NDC Code:xxxxxxxx



Antibacterial
HAND WIPES

Kills 99.9% of germs and bacteria

100
wipes

Antibacterial
HAND WIPES

Kills 99.9% of germs and bacteria

Blue Bear 99
Kills 99.9% of germs and bacteria

Alcohol Free • Ph Balanced

100
wipes

www.bluebear99.com

Kills 99.9%
of germs and bacteria

BLUE BEAR ANTIBACTERIAL HAND WIPES

benzalkonium chloride cloth

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:81005-001

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.23 g in 100 g
--	------------------------------	--------------------

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
WATER (UNII: 059QF0K00R)	
CITRAL (UNII: T7EU0O9VPP)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
LINALOOL, (+)- (UNII: F4VNO44C09)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
FATTY-ACID AMIDE HYDROLASE 1 (UNII: E747F394ZQ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81005-001-02	15 in 1 PACKAGE	10/01/2020	
1	NDC:81005-001-01	0.0065835 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:81005-001-04	100 in 1 PACKAGE	10/01/2020	
2	NDC:81005-001-03	0.010206 g in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:81005-001-08	100 in 1 CANISTER	10/01/2020	
3	NDC:81005-001-07	0.0067 g in 1 PATCH; Type 0: Not a Combination Product		
4	NDC:81005-001-06	500 in 1 CANISTER	10/01/2020	
4	NDC:81005-001-05	0.0067 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Blue Bear Protection LLC (131113913)

Registrant - Blue Bear Protection LLC (131113913)

Establishment

Name	Address	ID/FEI	Business Operations
AKSAN KOZMETIK SANAYI VE TICARET ANONIM SIRKETI		365577706	manufacture(81005-001)

Revised: 12/2020

Blue Bear Protection LLC