NIMBUS- benzalkonium chloride cloth
Nimbus Eco 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.

This is a hand sanitizing wipe manufactured using only the following United States Pharmacopoeia (USP) grade ingredients

a. Benzalkonium Chloride (USP grade) (0.12%, volume/volume (v/v))
b. Water
   c. Propylene Glycol
   d. Ethyl Alcohol
   e. Lauryl Glucoside
   f. Phenoxyethanol
   g. Tetrasodium EDTA
   h. 3-Iodo-2-Propynyl ButylCarbamate
   i. 2-Bromo-2-Nitropropane-1,3-Diol
   j. Citric Acid
   k. Fragrance
   l. Aloe Barbadensis Leaf Extract
   m. Chamomilla Recutita Flower Extract

Active Ingredient(s)

Benzalkonium Chloride 0.1% Purpose: Antibacterial

Purpose

Antibacterial

Use

Decrease bacteria on the skin

Warnings

For external use only.

Do not use

Do not use if irritation and redness develop

When using this product avoid contact with eyes, if contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if condition persists for more than 72 hours.

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

Directions

Open resealable label. Remove one wipe to use. Wipe hands thoroughly with product and allow to dry without wiping.

Close resealable label after use to retain moisture.

Other information

Dispose of wipe in the proper container

Do not flush down the toilet

Kill claims against: Escherichia Coli and Staphylococcus aureus

Inactive ingredients

Water
Propylene Glycol
Ethyl Alcohol
Lauryl Glucoside
Phenoxyethanol
Benzalkonium Chloride
Tetrasodium EDTA
3-Iodo-2-Propynyl ButylCarbamate
2-Bromo-2-Nitropropane-1,3-Diol
Citric Acid
Fragrance N/A
Aloe Barbadensis Leaf Extract
Chamomilla Recutita Flower Extract

Package Label - Principal Display Panel

50 count NDC: 81240-001-50

NIMBUS

benzalkonium chloride cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81240-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.12 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	0.01 mL in 100 mL
ALCOHOL (UNII: 3K9958V90M)	5 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.01 mL in 100 mL

BRONOPOL (UNII: 6PU1E16C9W)	0.1 mL in 100 mL
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	0.5 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	88.36 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	5 mL in 100 mL
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	0.1 mL in 100 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.1 mL in 100 mL
EDETATE SODIUM (UNII: MP1J8420LU)	0.1 mL in 100 mL
CHAMOMILE (UNII: FGL3685T2X)	0.1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81240-001-50	30 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/09/2020	

Labeler - Nimbus Eco Inc. (079445306)

Establishment

Name	Address	ID/FEI	Business Operations
Nimbus Eco Inc.		079445306	label(81240-001)

Establishment

Name	Address	ID/FEI	Business Operations
American Hygienics Corporation		545198454	manufacture(81240-001)

Revised: 1/2022 Nimbus Eco Inc.