WET WIPES- wet wipes cloth Shandong Tricol Marine Biological Technology Co.,Ltd

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)

Benzethonium chloride 0.03% [w/w]

Purpose

Antiseptic

Use

to help reduce bacteria on the skin.

for use when soap and water are not available.

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.

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

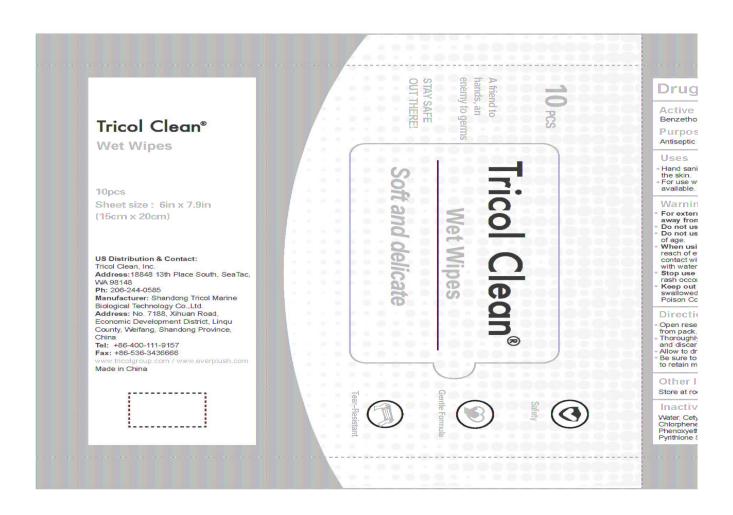
Tear the packaging at the zigzag edge to use

Other information

Store at room temperature

Inactive ingredients

Water, Cetylpyridinium chloride anhydrous, Chlorphenesin, Propylene glycol, Phenoxyethanol, Ethylhexylglycerin, Phrithione Sodium



WET WIPES

wet wipes cloth

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54156-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZETHO NIUM CHLO RIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.03 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
PYRITHIONE SODIUM (UNII: 6L3991491R)		
CHLORPHENESIN (UNII: 1670 DAL4SZ)		
WATER (UNII: 059QF0KO0R)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
CETYLPYRIDINIUM CHLO RIDE ANHYDRO US (UNII: 6BR7T22E2S)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54156-002-01	24 in 1 PACKET	11/20/2020	
1		0.03 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:54156-002-02	20 in 1 PACKET	11/20/2020	
2		0.03 g in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:54156-002-03	10 in 1 PACKET	11/20/2020	
3		0.03 g in 1 PATCH; Type 0: Not a Combination Product		
4	NDC:54156-002-04	48 in 1 PACKET	11/20/2020	
4		0.03 g in 1 PATCH; Type 0: Not a Combination Product		
5	NDC:54156-002-05	96 in 1 PACKET	11/20/2020	
5		0.03 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	part333E	11/20/2020		

Labeler - Shandong Tricol Marine Biological Technology Co.,Ltd (541569370)

Establishment			
Name	Address	ID/FEI	Business Operations
Shandong Tricol Marine Biological Technology Co.,Ltd		541569370	manufacture (54156-002)

Revised: 1/2021