

SANITIZING WIPES- sanitizing wipes patch
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 0.13% w/w. Purpose: Antiseptic

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.

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Directions

Open packet,remove and unfold pre-moistened tissue.

Thoroughly clean hands or affected area and discard in receptacle.Do not flush

Allow to dry without wiping

Be sure to reseal packet completely to retain moisture

Other information

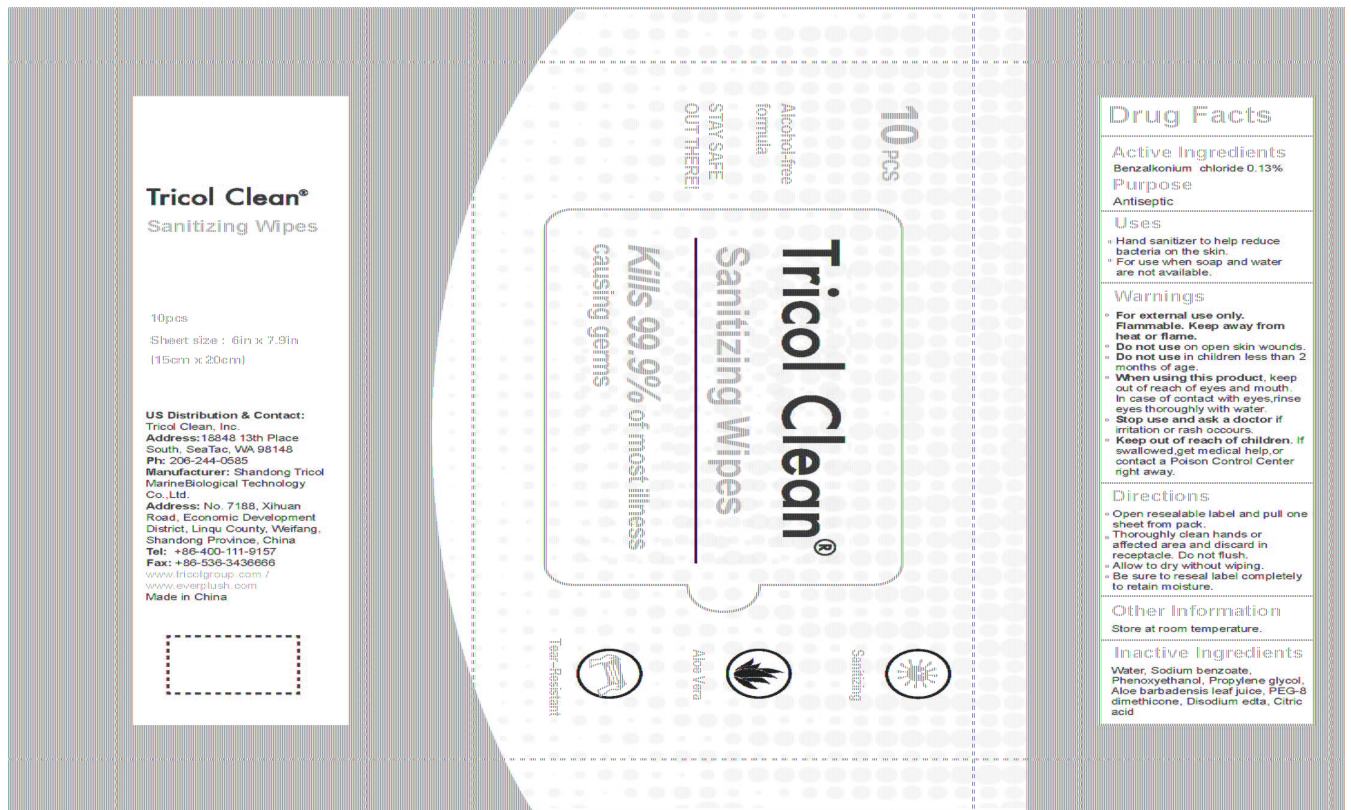
Store at room temperature

Inactive ingredients

Water,Sodium benzoate, Phenoxyethanol, Propylene glycol, Aloe barbadensis leaf juice, PEG-8

dimethicone, Disodium edta, Citric acid

Package Label - Principal Display Panel



SANITIZING WIPES

sanitizing wipes patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54156-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM-UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54156-004-01	1 in 1 PACKET	11/20/2020	
1		4 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:54156-004-02	24 in 1 PACKET	11/20/2020	
2		4 g in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:54156-004-03	10 in 1 PACKET	11/20/2020	
3		4 g in 1 PATCH; Type 0: Not a Combination Product		
4	NDC:54156-004-04	20 in 1 PACKET	11/20/2020	
4		4 g in 1 PATCH; Type 0: Not a Combination Product		
5	NDC:54156-004-05	48 in 1 PACKET	11/20/2020	
5		4 g in 1 PATCH; Type 0: Not a Combination Product		
6	NDC:54156-004-06	96 in 1 PACKET	11/20/2020	
6		4 g in 1 PATCH; Type 0: Not a Combination Product		
7	NDC:54156-004-07	35 in 1 CONTAINER	11/20/2020	
7		4 g in 1 PATCH; Type 0: Not a Combination Product		
8	NDC:54156-004-08	70 in 1 CONTAINER	11/20/2020	
8		4 g in 1 PATCH; Type 0: Not a Combination Product		
9	NDC:54156-004-09	96 in 1 CONTAINER	11/20/2020	
9		4 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 - Shandong Tricol Marine Biological Technology Co.,Ltd (541569370)

Establishment

Name	Address	ID/FEI	Business Operations
Shandong Tricol Marine Biological Technology Co.,Ltd		541569370	manufacture(54156-004)

Revised: 1/2021

Shandong Tricol Marine Biological Technology Co.,Ltd