SANITIZING WIPES- hand sanitizer cloth Big Time Products, 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.

Active Ingredient(s)

Benzalkonium Chloride 0.45% w/w. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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

Warnings

For external use only. Flammable. Avoid exposure to the sun.

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

- thoroughly wipe skin as desired
- allow to dry without wiping
- discard wipe after use, do not flush

Other information

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

Inactive ingredients

aloe extract, citric acid, glycerin, propylene glycol, purified water USP.

Package Label - Principal Display Panel

100 Wipes in 1 Pail NDC: 80748-529-03





5/	ANITIZING	WIPES							
na	nd sanitizer clo	oth							
D	roduct Infor	motion							
		mation							
P	roduct Type		HUMAN OTC DRUG	ltem (Code (So	ource)	NDC:80748-529		
R	oute of Admini	stration	TOPICAL						
Δ	ctive Ingredi	ent/Active	Moietv						
	Active Ingredient/Active Moiety Ingredient Name Basis of St						enath	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)						BENZ ALKONIUM CHLORIDE		0.45 g in 100 g	
Inactive Ingredients									
Ingredient Name							Strength		
ALOE (UNII: V5VD430YW9)									
			(F417D3PSL)						
	YCERIN (UNII: PD Ropylene Glyco		167//3)						
	ATER (UNII: 059Q		210/03)						
Pa	ackaging								
#	Item Code	Pac	kage Description			ting Start Date		eting End Date	
1	NDC:80748-529- 03	600 g in 1 PAI Product	.; Type 0: Not a Combinatio	on 1	10/08/2020				
M	larketing l	Informat	ion						
	Marketing Category	Applica	tion Number or Monog Citation	graph	Mar	keting Start Date	Mar	keting End Date	

Labeler - Big Time Products, Llc (119031495)

Registrant - Big Time Products, Llc (119031495)

Establishment

Name	Address	ID/FEI	Business Operations
Cangzhou Juyuan Sanitary Prducts Co., Ltd		526891925	manufacture(80748-529)

Revised: 12/2021

Big Time Products, Llc