BABY SHARK ANTIBACTERIAL HAND SANITIZING WIPES- benzalkonium chloride cloth ZHEJIANG GREENFACE HOUSEWARES 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.

42255-902 BABY SHARK ANTIBACTERIAL HAND SANITIZING WIPES 0.12% benzalkonium chloride

Active ingredient

Benzalkonium chloride 0.12%

Purpose

Antibacterial

Use

decreases bacteria on skin

Warnings

For external use only.

Do not use over large areas of the body

if you are allergic to any of the ingredients.

When using this product do not get into eyes.

If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if irritation or rash

develops and continues for more than 72 hours. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children

if swallowed

get medical help or contact a Poison Control Center right away.

Directions

For adults and children of 2 years and over use on hands and face to clean and refresh, allow skin to air dry.

For children under 2 years ask a doctor before use.

Water, Propylene glycol, Cocamidopropyl betaine, Aloe barbadensis leaf extract, Tocopheryl acetate, Polysorbate 20, Polyaminopropyl biguanide,

Phenoxyethanol, Disodium EDTA, lodopropynyI butylcarbamate, Citric acid.









BABY SHARK ANTIBACTERIAL HAND SANITIZING WIPES

benzalkonium chloride cloth

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42255-902	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM -	BENZALKONIUM	0.12 g		
UNII:7N6JUD5X6Y)	CHLORIDE	in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)			
PHENO XYETHANOL (UNII: HIE492ZZ3T)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11 KX)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			

WATER (UNII: 059QF0KO0R)	
POLYAMINO PRO PYL BIGUANIDE (UNII: DT9 D8 Z79 ET)	
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
POLYSORBATE 20 (UNII: 7T1F30 V5YH)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42255-902- 01	24 in 1 CARTON	09/02/2020	
1		20 in 1 BAG		
1		4.8 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
2	NDC:42255-902- 02	24 in 1 CARTON	09/02/2020	
2		30 in 1 BAG		
2		4.8 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
3	NDC:42255-902- 03	24 in 1 CARTON	09/02/2020	
3		40 in 1 BAG		
3		4.8 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
4	NDC:42255-902- 04	24 in 1 CARTON	09/02/2020	
4		50 in 1 BAG		
4		4.8 g in 1 NOT APPLICABLE; 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	09/02/2020		

Labeler - Zhejiang Greenface Housewares Co., Ltd. (546596567)

Establishment				
Name	Address	ID/FEI	Business Operations	
ZHEJIANG GREENFACE HOUSEWARES CO., LTD.		527999264	manufacture(42255-902)	

Revised: 9/2020 ZHEJIANG GREENFACE HOUSEWARES CO., LTD.