

ANTIBACTERIAL FOAMING HAND- benzalkonium chloride solution
Jets, Sets, & Elephants Beauty Corp.

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.

The Wiggles® Antibacterial Foaming Hand Soap - Banana, Blueberry, Cherry, Grape

Active ingredient

Benzalkonium Chloride 0.11%

Purpose

Antiseptic

Use

- hand washing to decrease bacteria on skin.

Warnings

For external use only.

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

Discontinue use if irritation and redness develop.

Keep Out of Reach of Children.

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

Directions

- wet hands
- work into rich lather
- rinse well

Inactive ingredients

Banana

Benzophenone-4, Citric Acid, Cocamidopropyl Betaine, Parfum, Methylisothiazolinone, Phenoxyethanol, Polysorbate 20, Retinyl Palmitate, Sodium Lauroyl Glutamate, Sodium Lauroyl Sarcosinate, Tocopheryl Acetate, Aqua, Yellow 5

Blueberry

Benzophenone-4, Citric Acid, Cocamidopropyl Betaine, Parfum, Methylisothiazolinone, Phenoxyethanol, Polysorbate 20, Retinyl Palmitate, Sodium Lauroyl Glutamate, Sodium Lauroyl Sarcosinate, Tocopheryl Acetate, Aqua, Blue 1, Red 33

Cherry

Benzophenone-4, Citric Acid, Cocamidopropyl Betaine, Parfum, Methylisothiazolinone, Phenoxyethanol, Polysorbate 20, Retinyl Palmitate, Sodium Lauroyl Glutamate, Sodium Lauroyl

Sarcosinate, Tocopheryl Acetate, Aqua, Red 33, Red 40

Grape

Benzophenone-4, Citric Acid, Cocamidopropyl Betaine, Parfum, Methylisothiazolinone, Phenoxyethanol, Polysorbate 20, Retinyl Palmitate, Sodium Lauroyl Glutamate, Sodium Lauroyl Sarcosinate, Tocopheryl Acetate, Aqua, Blue 1, Red 33

Questions?

1-800-FDA-1088

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IMPORTED BY:

JETS, SETS, & ELEPHANTS BEAUTY CORP.

LAVAL (QC) CANADA H7T 2R2

DEVELOPED IN NORTH AMERICA

MADE IN CHINA

Principal Display Panel - Bottle Label

The Wiggles®

Antibacterial

Foaming

Hand Soap

BRIGHT COLORED FOAM

PARABEN FREE

BANANA

10 fl. oz.

As The Wiggles say,

Wash Your Hands! This foaming hand soap not only smells delicious but will make your child's hand washing routine fun with its colored foam! The natural formula is enriched with vitamins A & E that will moisturize and protect your child's sensitive skin.

Free of: Synthetic Fragrances, Phthalates, Parabens, Sulfates



Banana Bottle Label

Principal Display Panel - Bottle Label

The Wiggles®

Antibacterial

Foaming

Hand Soap

BRIGHT COLORED FOAM

PARABEN FREE

BLUEBERRY

10 fl. oz.

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Phthalates, Parabens, Sulfates



Blueberry Bottle Label

Principal Display Panel - Bottle Label

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Antibacterial

Foaming

Hand Soap

BRIGHT COLORED FOAM

PARABEN FREE

CHERRY

10 fl. oz.

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Principal Display Panel - Bottle Label

The Wiggles®

Antibacterial

Foaming

Hand Soap

BRIGHT COLORED FOAM

PARABEN FREE

GRAPE

10 fl. oz.

As The Wiggles say,
Wash Your Hands! This foaming hand soap not only

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Wash Your Hands! This foaming hand soap not only smells delicious but will make your child's hand washing routine fun with its colored foam! The natural formula is enriched with vitamins A & E that will moisturize and protect your child's sensitive skin.

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Drug Facts	
Active ingredient	Purpose
Benzalkonium Chloride 0.11%	Antiseptic
Use • hand washing to decrease bacteria on skin.	
Warnings For external use only. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Discontinue use if irritation and redness develop. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions • wet hands • work into rich lather • rinse well	
Inactive ingredients Benzophenone-4, Citric Acid, Cocamidopropyl Betaine, Fragrance (Parfum), Methylisothiazolinone, Phenoxyethanol, Polysorbate 20, Red 33, Red 40, Retinyl Palmitate, Sodium Lauryl Glutamate, Sodium Lauryl Sarcosinate, Tocopheryl Acetate, Water (Aqua).	
Questions? 1-800-FDA-1088	

© 2012 The Wiggles Pty Ltd.
 IMPORTED BY / IMPORTÉ PAR:
 JETS, SETS & ELEPHANTS BEAUTY CORP.
 1 AV. 100 CANADA, H7T 2H9
 DEVELOPED IN NORTH AMERICA
 DÉVELOPPÉ EN AMÉRIQUE DU NORD
 MADE IN CHINA / FABRIQUÉ EN CHINE



smells delicious but will make your child's hand washing routine fun with its colored foam! The natural formula is enriched with vitamins A & E that will moisturize and protect your child's sensitive skin.

Free of: Synthetic Fragrances, Phthalates, Parabens, Sulfates



Grape Bottle Label

ANTIBACTERIAL FOAMING HAND

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50988-290
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.325 mL in 295.74 mL
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Inactive Ingredients

Ingredient Name	Strength
SULISOBENZONE (UNII: 1W6L629B4K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM LAUROYL GLUTAMATE (UNII: NCX1UU2D33)	
SODIUM LAUROYL SARCO SINATE (UNII: 632GS99618)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50988-290-00	295.74 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/25/2012	

ANTIBACTERIAL FOAMING HAND

benzalkonium chloride solution

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SODIUM LAUROYL SARCO SINATE (UNII: 632GS99618)
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)
WATER (UNII: 059QF0KO0R)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)

Packaging

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PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

SODIUM LAUROYL GLUTAMATE (UNII: NCX1UU2D33)
 SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)
 .ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)
 WATER (UNII: 059QF0KO0R)
 D&C RED NO. 33 (UNII: 9DBA0SBB0L)
 FD&C RED NO. 40 (UNII: WZB9127XOA)

Packaging

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OTC monograph not final	part333A	01/25/2012	

Labeler - Jets, Sets, & Elephants Beauty Corp. (243254039)**Establishment**

Name	Address	ID/FEI	Business Operations
Gold Orient International Limited		679905914	MANUFACTURE(50988-290, 50988-291, 50988-292, 50988-293)

Revised: 1/2012

Jets, Sets, & Elephants Beauty Corp.