

SAFE - X- benzalkonium chloride 0.1% liquid
Green Smart Plastics 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.

PROUDLY MADE IN THE USA

Medical Grade

Alcohol Free

Fragrance Free

Safe - X

ANTIBACTERIAL

INSTANT FOAM Hand Sanitizer

KILLS 99.9% OF GERMS*

KILLS GERMS IN 15 SECONDS

Non-Flammable, Non-Toxic

A Safe & Effective Antiseptic

128 FL OZ (1 GAL)

MADE IN USA

Questions / Comments - Info@Safex-USA.com

Drug Facts

Active Ingredients	Purpose
Benzalkonium Chloride, 0.13%	Antimicrobial
Uses	
<ul style="list-style-type: none">■ For hand sanitizing to decrease bacteria on the skin that cause disease■ Recommended for repeated use	
Warnings	
<ul style="list-style-type: none">■ For external use only: hands	
When using this product	
<ul style="list-style-type: none">■ Avoid contact with eyes. In case of contact with eyes, flush thoroughly with water■ Do not inhale or ingest	
Stop use and ask a doctor if	
<ul style="list-style-type: none">■ Irritation or redness develops■ Conditions persists for more then 72 hours	
Keep out of reach of children.	
<ul style="list-style-type: none">■ If swallowed, get medical help or contact a Poison Control Center right away	
Directions	
<ul style="list-style-type: none">■ Pump a small amount of foam into palm of hand■ Rub thoroughly over all surfaces of both hands■ Rub hands together briskly until dry	
Inactive Ingredients	
<ul style="list-style-type: none">■ water, centrimonium chloride, laurtrimonium chloride, dihydroxyethyl cocamine oxide, glycereth-17 cocoate, citric acid	

*Effective at eliminating 99.99% of many common harmful germs and bacteria in as little as 15 seconds.

Active Ingredient



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Safe-X - alcohol free, instant foaming, hand sanitizer produces a non-sticky foam that contains unique fast drying, conditioning and moisturizing ingredients, leaving the skin with a soft, refreshing and silky afterfeel and does NOT contain polymer thickeners or silicones like other brands which can cause skin damage and dry skin.

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Warnings

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Ask Doctor section



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Keep out children



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16 FL OZ (473ml)



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6 38632 93680 2

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Inactive Ingredient



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4 FL OZ (118 ml)


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Indication Usage



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Dosage



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Dosage & Admin



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Purpose section

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128 FL OZ (1 GAL)

MADE IN USA

6 38632 93681 9

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Drug Facts

Active Ingredients	Purpose
Benzalkonium Chloride, 0.13%	Antimicrobial

Uses

- For hand sanitizing to decrease bacteria on the skin that cause disease
- Recommended for repeated use

Warnings

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When using this product

- Avoid contact with eyes. In case of contact with eyes, flush thoroughly with water
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Inactive Ingredients

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Package label

SAFE - X			
benzalkonium chloride 0.1% liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77164-6 18
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 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIHYDROXYETHYL COCAMINE OXIDE (UNII: 8AR51R3BL5)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
WATER (UNII: 059QF0K00R)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
GLYCERETH-17 COCOATE (UNII: 3057VPT0KC)	
LAURTRIMONIUM CHLORIDE (UNII: A81MS10FIC)	

Product Characteristics

Color	white (clear, liquid)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77164-618-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	06/01/2020	
2	NDC:77164-618-04	29 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2020	
3	NDC:77164-618-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2020	



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Benzalkonium Chloride .01%	Antimicrobial

Uses

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Warnings

- For external use only; hands

When using this product

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128 FL OZ (1 GAL)

Manufactured by: SafeX-USA
Bensalem, PA 19020

Questions / Comments - info@safex-usa.com

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

Labeler - Green Smart Plastics LLC (117045702)

Registrant - Green Smart Plastics LLC (117045702)

Establishment

Name	Address	ID/FEI	Business Operations
Green Smart Plastics LLC		117045702	manufacture(77164-618)

Revised: 6/2020

Green Smart Plastics LLC