HAND SANITIZER GEL- benzalonium chloride liquid
HAND SANITIZER FOAM- benzalonium chloride liquid
SANITIZINGSOAP- benzalonium chloride liquid
Landy International

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 0.13% v/v. Purpose: Antiseptic

Benzalkonium Chloride 0.1%

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. 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.

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

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

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

Inactive ingredients

glycerin, Benyzl alcohol, purified water USP, Etc.

Package Label - Principal Display Panel

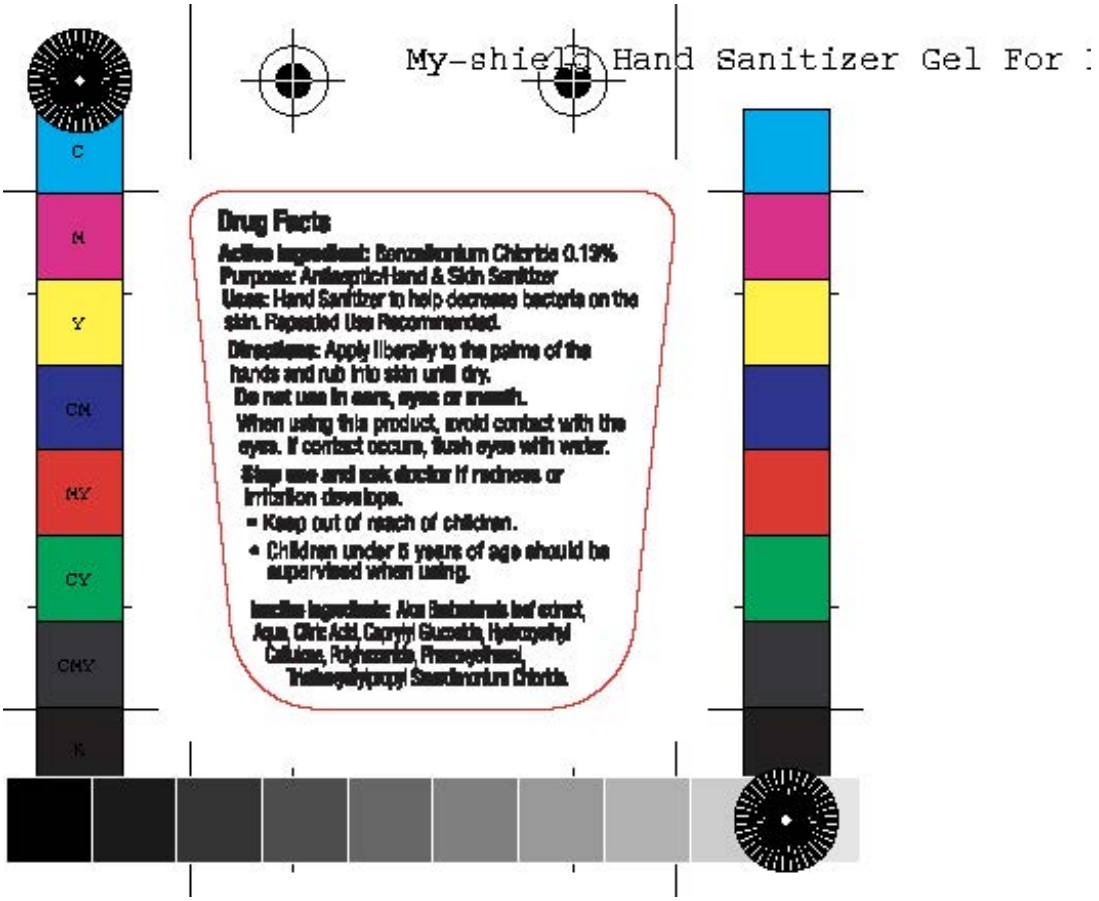
NDC: 51706-803

3.8L sanitizing soap front label / size:151.5*200mm

3.8L sanitizing soap back label / size:151.5*200mm

51706-804

244ml sanitizing soap label / size:216*46mm



51706-805

HAND SANITIZER GEL

benzalonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51706-805
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	13 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
TRIETHOXYSILYLPROPYL STEARDIMONIUM CHLORIDE (UNII: XGN40YQC7B)	0.74952 mL in 100 mL
POLIHEXANIDE (UNII: 322U039GMF)	0.26 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51706-805-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

2	NDC:51706-805-02	244 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/01/2020	

HAND SANITIZER FOAM

benzalonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51706-804
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	13 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TRIETHOXYSILYLPROPYL STEARDIMONIUM CHLORIDE (UNII: XGN40YQC7B)	0.74952 mL in 100 mL
POLIHEXANIDE (UNII: 322U039GMF)	0.26 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51706-804-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:51706-804-02	244 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
3	NDC:51706-804-03	1200 mL in 1 BAG; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/01/2020	

SANITIZINGSOAP

benzalonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51706-803
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	10 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
LAURAMIDOPROPYL BETAINE (UNII: 23D6XVI233)	12 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51706-803-01	1200 mL in 1 BAG; Type 0: Not a Combination Product	06/01/2020	
2	NDC:51706-803-02	244 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
3	NDC:51706-803-03	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/01/2020	

Labeler - Landy International (545291775)

Establishment

Name	Address	ID/FEI	Business Operations
Landy International		545291775	manufacture(51706-803, 51706-804, 51706-805)

Revised: 6/2020 Landy International