

HAND SANITISER FOAM- benzalonium chloride liquid
SANITIZING SOAP- benzalonium chloride liquid
HAND SANITIZER GEL- benzalonium chloride liquid
Landy International

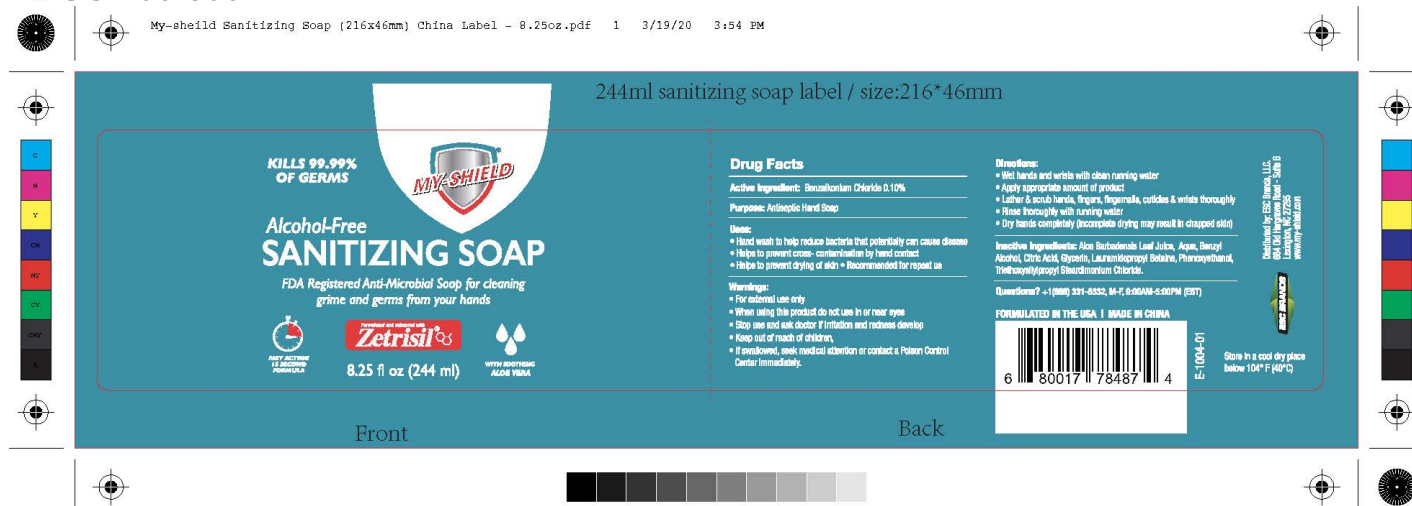
Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Purified water □ Benzalkonium Chloride □ TRIETHOXYSILYL PROPYL STEARDIMONIUM CHLORIDE □ Polyaminopropyl biguanide hcl

Benzalkonium Chloride 0.13%

Benzalkonium Chloride 0.1%

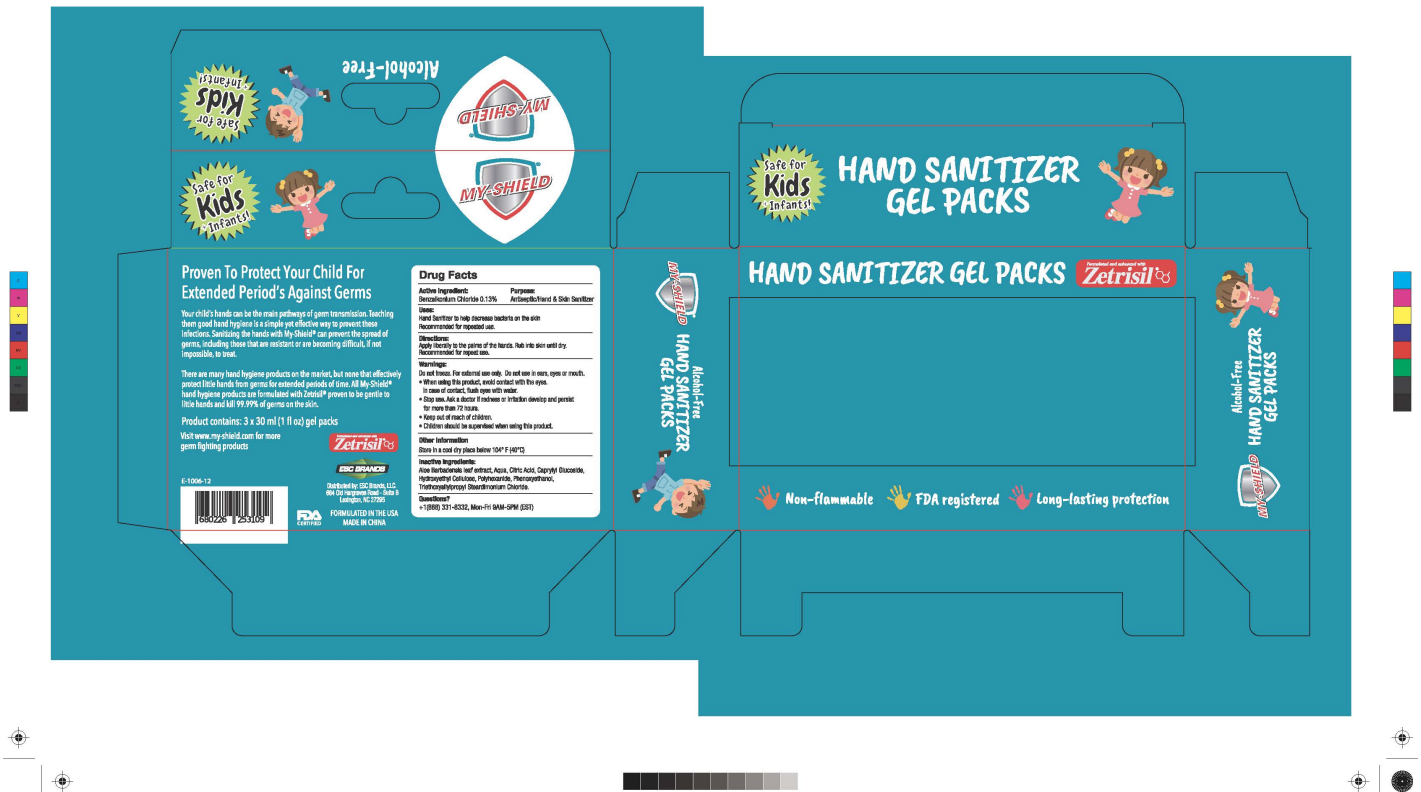
NDC 51706-806



51706-807 NDC



51706-808 NDC



HAND SANITISER FOAM
benzalonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51706-807
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
WATER (UNII: 059QF0K00R)	96.59 mL in 100 mL
POLYHEXANIDE (UNII: 322U039GMF)	0.26 mL in 100 mL
TRIETHOXYSYLILPROPYL STEARDIMONIUM CHLORIDE (UNII: XGN40YQC7B)	0.74952 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51706-807-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:51706-807-02	244 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
3	NDC:51706-807-03	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	

SANITIZING SOAP

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51706-806
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
WATER (UNII: 059QF0K00R)	80.6 mL in 100 mL
LAURAMIDOPROPYL BETAINE (UNII: 23D6XVI233)	12 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51706-806-01	1200 mL in 1 BAG; Type 0: Not a Combination Product	06/01/2020	
2	NDC:51706-806-02	244 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
3	NDC:51706-806-03	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	

HAND SANITIZER GEL

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51706-808
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
WATER (UNII: 059QF0K00R)	96.59 mL in 100 mL
POLYHEXANIDE (UNII: 322U039GMF)	0.26 mL in 100 mL
TRIETHOXYSYLILPROPYL STEARDIMONIUM CHLORIDE (UNII: XGN40YQC7B)	0.74952 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51706-808-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:51706-808-02	90 mL in 1 BOX; 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(51706-806, 51706-807, 51706-808)

Revised: 6/2020

Landy International