LOLES- benzalkonium chloride soap
Diora Kimya Sanayi ve Ticaret Limited Sirketi

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.

Antibacterial Bar Soap for Personal Use

Benzalkonium Chloride.....0.10%

Antimicrobial. Antibacterial Bar Soap.

- For washing to decrease bacteria on the skin
- Recommended for repeated use

For external use only.

When using this product, do not use in or near the eyes. If contact occurs, rinse thorougly with water.

Stop use and ask doctor if irritation or rash appears and lasts.

Keep out of reach of children. if swallowed, get medical help or contact a Poison Control Center right away.

- Wet bar with water, wash skin and rinse

Sodium Palmate, Sodium Palm Kernelate, Aqua (Water), Fragrance (Parfum), Glycerin, Palm Acid, Sodium Chloride, Tetrasodium EDTA, Tetrasodium Etidronate, Avena Sativa (Oat) Kernel Flour, Tocopheryl Acetate (Vitamin E)

LOLES

benzalkonium chloride soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73485-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.02 g in 100 g
SODIUM PALMATE (UNII: S0A6004K3Z)	65 g in 100 g
WATER (UNII: 059QF0KO0R)	15 g in 100 g

SODIUM PALM KERNELATE (UNII: 6H91L1NXTW)	16 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	1.5 g in 100 g
EDETATE SODIUM (UNII: MP1J8420LU)	0.02 g in 100 g
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.48 g in 100 g
ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4)	0.02 g in 100 g
FRAGRANCE 13576 (UNII: 5EM498GW35)	0.86 g in 100 g
PALM ACID (UNII: B6G0Y5Z616)	0.5 g in 100 g
AVENA SATIVA LEAF (UNII: 206PI19V7R)	0.5 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73485-004-01	200 g in 1 BOX; Type 0: Not a Combination Product	12/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/01/2022	

Labeler - Diora Kimya Sanayi ve Ticaret Limited Sirketi (533104358)

Registrant - US Naturals Corp (081035629)

Establishment

Name	Address	ID/FEI	Business Operations
Diora Kimya Sanayi ve Ticaret Limited Sirketi		533104358	manufacture(73485-004)

Revised: 12/2022 Diora Kimya Sanayi ve Ticaret Limited Sirketi