

SALOON ANTIBACTERIAL HAND WASH OCEAN- benzalkonium chloride solution

TIBET İTHALAT İHRACAT VE KOZMETİK SANAYİ ANONİM ŞİRKETİ

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.

Saloon Antibacterial Hand Wash Ocean

Drug Facts

Active Ingredient:

Benzalkonium chloride %0,13

Purpose

Antibacterial

Use

For handwashing to decrease bacteria on the skin.

Warnings

For external use only.

When using this product

- Do not use in the eyes.

Stop use and ask a doctor if

- Irritation and redness develop. If condition persists for more than 72 hours consult a doctor.

Keep out of reach of children.

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

Directions

- Wet hands and forearms. Apply 5 milliliters (2 full pumps) to hands and forearms. Scrub thoroughly for 60 seconds. Rinse and repeat.

Inactive Ingredients

Water, Glycerin, PEG-4 Rapeseedamide, Cocamidopropylamine Oxide,

Lauramidopropylamine Oxide, Myristamidopropylamine Oxide, Lauryl Glucoside, Cetrimonium Chloride, PEG 120 Methyl Glucose Dioleate, Sodium PCA, Cocamine Oxide, Lauramine Oxide, Malic Acid, Tetrasodium EDTA, Sodium Benzoate, Potassium sorbate, Parfum, Acid Blue 9, Acid Red 33.

Package Labeling:

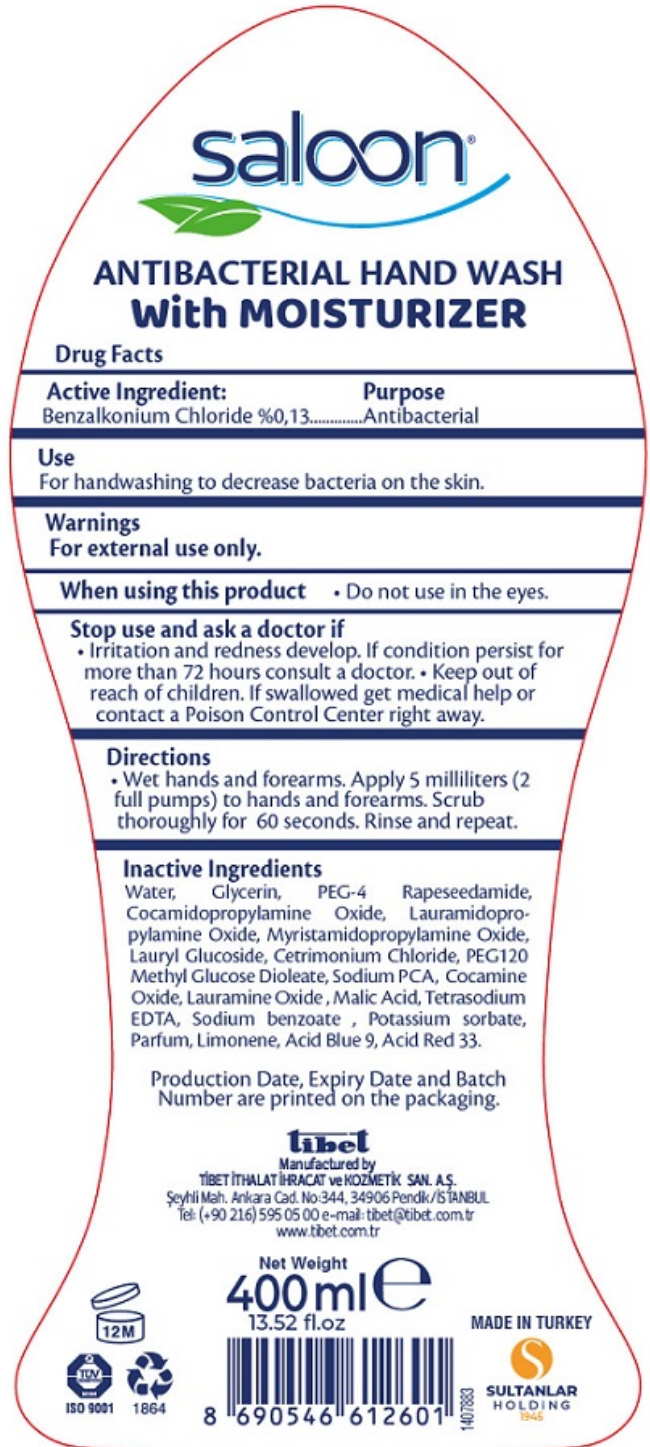


Ihracat Antibakteriyel Sıvı Sabun 400 ml

53 x 121 mm /



CMYK



SALOON ANTIBACTERIAL HAND WASH OCEAN

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81608-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-4 RAPESEEDAMIDE (UNII: 89575CN928)	
COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)	
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	
MYRISTAMIDOPROPYLAMINE OXIDE (UNII: 3HSF539C9T)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
COCAMINE OXIDE (UNII: QWA2IZI6FI)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
MALIC ACID (UNII: 817L1N4CKP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA05BB0L)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81608-003-00	400 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2021	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph not final	part333E	04/01/2021	

Labeler - TIBET ITHALAT IHRACAT VE KOZMETIK SANAYI ANONIM SIRKETI (643295637)

Revised: 4/2021

TIBET ITHALAT IHRACAT VE KOZMETIK SANAYI ANONIM SIRKETI