

ANTIBACTERIAL HANDWASH HOBBY- benzalkonium chloride liquid

Hobi Kozmetik Imalat Sanayi Ve Ticaret Anonim 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.

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antiseptic

USES

- Handwash to help decrease bacteria on skin
- Recommended for repeated use

WARNING

For external use only.

- do not use in or near eyes
- In case of eye contact, rinse thoroughly with water.

Stop use and ask a doctor if

- irritation occurs or rash appears and last

KEEP OUT OF REACH OF CHILDREN.

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

DIRECTIONS

- wet hands
- apply a small amount of product and work into lather
- rinse well and dry hands completely

Inactive Ingredients:

Water(Aqua),Sodium Laureth Sulfate,Cocamidopropyl Betaine,Coconut Monoethanol Amide,Sodium Chloride,Fragrance,Citric Acid,Methylchloroisothiazolinone,Methylisothiazolinone,D&C Red No.33,FD&C Blue No.1, FD&C Red No. 40, FD&C Yellow No. 5

Drug Facts

Active ingredient

Benzalkonium Chloride 0.31% w/w.....

Purpose

Antiseptic

Uses

- Handwash to help decrease bacteria on the skin
- Recommended for repeated use

Warnings

FOR EXTERNAL USE ONLY

When using this product

- Do not use in or near the eyes
- In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if Irritation or rash appears and lasts

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

Directions

- Wet hands ■ Apply a small amount of product and work into a lather
- Rinse well and dry hands completely

Inactive Ingredients

Water, Cocamidopropyl Betaine, Sodium Laureth Sulfate, Cocamide DEA, Lauryl Glucoside, Glycerin, Parfum, Citric Acid, Benzophenone-4, Sodium Chloride, Benzyl Alcohol, Methylchloroisoithiazolinone, Methylisothiazolinone, CI 42090.

Drug Facts	
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Warnings	
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ANTIBACTERIAL HANDWASH HOBBY

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73789-0440
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 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0K00R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	

COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SULISOBENZONE (UNII: 1W6L629B4K)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73789-0440-1	400 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333E	02/05/2020	

Labeler - Hobi Kozmetik Imalat Sanayi Ve Ticaret Anonim Sirketi (552240889)

Revised: 3/2020

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