

CLEANSE- benzalkonium chloride 0.13% solution**Medline Industries, Inc.**

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

Antibacterial

Use

for handwashing to decrease bacteria on the skin

Warnings

For external use only: hands only

When using this product

- avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

- irritation or redness develops
- condition persists for more than 72 hours

Keep out of reach of children.

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

Directions

- wet hands
- apply palmful to hands
- scrub thoroughly
- rinse thoroughly

Inactive ingredients

benzophenone-4, cocamidopropyl betaine, citric acid, disteareth-75 IPDI, fragrance, glycerin, lauramine oxide, lauramidopropylamine oxide, myristamidopropylamine oxide, PEG-150 distearate, red 40, red 33, sodium benzoate, sodium chloride, tetrasodium EDTA, water, yellow 5

Questions?

Call 1-800-MEDLINE

www.medline.com

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Drug Facts

Active ingredient

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Uses for handwashing to decrease bacteria on the skin

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REF HHABSPG

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CLEANSE

benzalkonium chloride 0.13% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-177
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
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
EDETATE SODIUM (UNII: MP1J8420LU)				
GLYCERIN (UNII: PDC6A3C0OX)				
DISTEARETH-75 ISOPHORONE DIISOCYANATE (UNII: 5365FJ30SC)				
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)				
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)				
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)				
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)				
DMDM HYDANTOIN (UNII: BYR0546TOW)				
SULISOBENZONE (UNII: 1W6L629B4K)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-177-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/2016	
2	NDC:53329-177-08	221 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/2016	
3	NDC:53329-177-84	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/19/2016	
4	NDC:53329-177-25	3790 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/2016	
5	NDC:53329-177-06	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/2016	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	08/19/2016	

Labeler - Medline Industries, Inc. (025460908)