MOLCHEM HAND PURIFIER- benzalkonium chloride spray
MOL BELTING SYSTEMS, 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.

Warnings

For external use only.

When using this product keep out of eyes, ears and mouth. In case of contact with eyes, rinse thoroughly
with water.

Stop use and ask a doctor if irritation or rash occurs. This may be a sign of a serious condition.

Keep out of reach of children.

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

Other information

Store in dry place between 35° and 103°F

Directions

- Place enough product on hands to cover all surfaces. Rub hands together.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Uses

- To decrease bacteria on the skin.
- Recommended for repeated use.
- For use when soap and water are not available

Inactive ingredients

Deionized Water, Propylene glycol, Triethylene glycol, Phospholipids Complex, Organo Silane Quaternaries

Active ingredient

Benzalkonium Chloride 0.13%

Purpose

Antiseptic

Product label

MOLCHEM HAND PURIFIER

benzalkonium chloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80606-001
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**
DIMETHYLOCTADECYL(3-(TRIMETHOXYSILYL)PROPYL)AMMONIUM CHLORIDE (UNII: IQ36O85WQ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

TRIETHYLENE GLYCOL (UNII: 3P5SU53360)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80606-001-01	59.14 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/15/2021	
2	NDC:80606-001-02	236.58 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/15/2021	
3	NDC:80606-001-03	3785.41 mL in 1 DRUM; Type 0: Not a Combination Product	07/15/2021	
4	NDC:80606-001-04	18927.1 mL in 1 DRUM; Type 0: Not a Combination Product	07/15/2021	
5	NDC:80606-001-05	208198 mL in 1 DRUM; Type 0: Not a Combination Product	07/15/2021	
6	NDC:80606-001-06	1040987.75 mL in 1 JUG; Type 0: Not a Combination Product	07/15/2021	
7	NDC:80606-001-07	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/15/2021	

Labeler - MOL BELTING SYSTEMS, INC (147753685)

Establishment

Name	Address	ID/FEI	Business Operations
Mol Belting Systems Inc		147753685	pack(80606-001)

Revised: 6/2023 MOL BELTING SYSTEMS, INC