

HAND SANITIZER- benzalkonium chloride lotion
Harmonia de Venezuela CA

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.

Drug Facts

Active Ingredient

Purpose

Benzalkonium Chloride (0.1 %)------ Antimicrobial

Uses

For hand sanitizing to decrease bacteria on the skin.

Warnings

For external uses only. / When using this products avoid contact of eyes. In case of eye contact, flush eyes with water. / **Stop use and ask a doctor if** irritation or redness develops, or if conditions 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

Apply a small amount into palm of hands and rub hands together briskly until dry.

Inactive Ingredients

water, glycerin, stearic acid, cetostearyl alcohol, mineral oil, propylene glycol, trietanolamine, benzophenone-3, polysorbate 60, PEG 12-dimethicone, glyceryl stearate, fragrance, imidazolidinyl urea, propyl paraben, carbomer, tocopheryl acetate, tetrasodium EDTA, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Blue No. 1 , FD&C Red No. 40.

Principal display panel



COMBINES THE EFFECTIVENESS OF A POWERFUL SANITIZER,
THE PLEASANT MOISTURIZING SENSATIONS OF A FAST-ABSORBING LOTION,
AND THE INTENSITY OF ITS FRUITY FRAGRANCES THAT LAST FOR LONGER.

LA INNOVADORA FÓRMULA DE MINI CARE COMBINA LA EFECTIVIDAD
DE UN PODEROSO ANTIBACTERIAL, LA AGRADABLE SENSACION HUMECTANTE
DE UNA LOCION DE RÁPIDA ABSORCIÓN, Y LA INTENSIDAD DE SUS FRAGRANCIAS FRUTALES
QUE PERDURAN POR MÁS TIEMPO.



KILLS 99.99% OF GERMS IN LESS THAN 30 SECONDS / ELIMINA EL 99.99% DE LOS GÉRMESES EN MENOS DE 30 SEGUNDOS.

| DRUGS FACTS | |
|--|---------------|
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QUESTIONS?
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LOT:
EXP:



MANUFACTURED BY HARMONÍA®, DIST. BY HARMONÍA & CO LLC, LEWES, DELAWARE 19958, USA. TRADE MARK USED AND DISTRIBUTED WITH APPROVAL OF HARMONÍA & CO LLC. NSO PC-C-57:125-VE. MADE IN VENEZUELA.

HAND SANITIZER

benzalkonium chloride lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73360-001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |

| |
|---|
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) |
| MINERAL OIL (UNII: T5L8T28FGP) |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) |
| TROLAMINE (UNII: 9O3K93S3TK) |
| OXYBENZONE (UNII: 95OOS7VE0Y) |
| POLYSORBATE 60 (UNII: CAL22UVI4M) |
| PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95) |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) |
| IMIDUREA (UNII: M629807ATL) |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) |
| CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| EDETATE SODIUM (UNII: MP1J8420LU) |

| Packaging | | | | |
|------------------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:73360-001-01 | 4 in 1 CARTON | 09/20/2019 | |
| 1 | | 28 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:73360-001-02 | 28 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/20/2019 | |

| Marketing Information | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 09/20/2019 | |

Labeler - Harmonia de Venezuela CA (817307290)

| Establishment | | | |
|--------------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Harmonia de Venezuela CA | | 817307290 | manufacture(73360-001) |

Revised: 12/2022

Harmonia de Venezuela CA