

HAND SANITIZER KIDS- benzalkonium chloride gel
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, hydroxypropyl methylcellulose, PEG-12 dimethicone, fragrance, DMDM hydantoin, FD&C Yellow No.5, FD&C Yellow No. 6, FD&C Blue No. 1 , FD&C Red No. 40.

Principal display panel



THE FUN-LOVING CEREZONA, PERONDO, MANGAZO AND PACHITA WILL TEACH CHILDREN TO KEEP THEIR HANDS FREE OF GERMS; WITH MOISTURIZING ACTIVE INGREDIENTS, TRICLOSAN AND ALCOHOL FREE.

LOS DIVERTIDOS CEREZONA, PERONDO, MANGAZO Y PACHITA ENSEÑARÁN A LOS NIÑOS A MANTENER SUS MANOS LIBRES DE GÉRMENES, CON INGREDIENTES HUMECTANTES, LIBRE DE ALCOHOL Y TRICLOSAN.

99.99%
EFFECTIVENESS

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

DRUGS FACTS	
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1.800.500
Harmonia
4276664



QUESTIONS?
info@myminicare.com
www.myminicare.com
Ph: +1 (302) 3001126

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 KIDS

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73360-002
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)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73360-002-01	4 in 1 CARTON	09/20/2019	
1		28 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:73360-002-02	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(73360-002)

Revised: 12/2022

Harmonia de Venezuela CA