

HEALTHY SPIRIT- alcohol gel
K2 HEALTH PRODUCTS LLC

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

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

Do not freeze. For external use only.

Do not use

- in children less than 2 months of age
- in ears or mouth

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

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

Keep out of reach of children.

Children should be supervised when using this product.

Directions

Apply a small amount into palms and spread on both hands. Rub into skin until dry.

Inactive ingredients

Isopropyl alcohol, Hydroxyethyl cellulose, glycerin, methylparaben, propylparaben, Propylene glycol, Dmdm hydantoin, FD&C Blue no 1

Package Label - Principal Display Panel



Drug Facts / Información del Medicamento	
Active Ingredient / Ingrediente activo	Purpose(s) / Propósito(s):
Benzalkonium chloride / Cloruro de benzalconio 0.13%	Antiseptic / Antiséptico
Use / Uso:	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. / Desinfectante de manos para ayudar a reducir las bacterias que potencialmente pueden causar enfermedades. Se utiliza cuando no se dispone de agua y jabón.	
Warnings / Advertencias:	
Do not freeze. For external use only / No congelar. Solo para uso externo.	
Do not use / No utilice:	
- in children less than 2 months of age / en niños menores de 2 años. - in ears or mouth / en nariz y boca.	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. / Quando use este producto , manténgase alejado de los ojos, los oídos y la boca. En caso de contacto con los ojos, enjuague los ojos con abundante agua.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. / Deje de usar y pregunte a un médico si se produce irritación o sarpullido. Estos pueden ser signos de una afección grave.	
Keep out of reach of children. / Manténgase alejado de los niños	
Children should be supervised when using this product. / Supervisar a los niños cuando usen este producto.	
Directions / Instrucciones:	
Apply a small amount into palms and spread on both hands. Rub into skin until dry. / Aplique una pequeña cantidad en las palmas de las manos y extienda en ambas manos. Frota la piel hasta que se seque.	
Inactive Ingredients / Ingredientes Inactivos:	
Water (agua), isopropyl alcohol, hydroxyethylcellulose, glycerin, methylparaben, propylparaben, propylene glycol, DMDM Hydantoin, FD&C Blue no. 1 / Agua (agua), alcohol isopropílico, hidroxietilcelulosa, glicerina, metilparabeno, propilparabeno, propilenglicol, FD&C Azul no. 1	
Questions? / Preguntas?	
For USA call: (888) 451-5144 / Para Estados Unidos marca: (888) 451-5144.	

MANUFACTURED FOR/HECHO PARA:
 K2 Health Products, LLC | Brooklyn, NY 11208. EXPIRATION DATE/FECHA DE CAD.

HEALTHY SPIRIT

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73745-001
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
WATER (UNII: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73745-001-01	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
2	NDC:73745-001-02	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/19/2020	
3	NDC:73745-001-03	3000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/12/2020	

Labeler - K2 HEALTH PRODUCTS LLC (800616612)

Revised: 5/2020

K2 HEALTHPRODUCTS LLC