

ADVANCED ALCOHOL GEL SANITIZER- alcohol gel
Betco Corporation, Ltd

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.

Advanced Alcohol Gel Sanitizer

Active Ingredient

Active Ingredient

Ethyl Alcohol 70%

Uses

Uses

- Hand sanitizer to reduce microorganisms on the skin.
- Use this product when soap and water are not available.

Purpose

Purpose

Antiseptic

Warnings

Warnings

- For external use only.
- Avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- FLAMMABLE. This product contains ethyl alcohol. Keep away from sources of ignition.
- Discontinue use if irritation or redness develops.
- If irritation persists for more than 72 hours, consult a physician.
- KEEP OUT OF REACH OF CHILDREN.
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Directions

- Read the entire label before using this product.
- Place enough product on your palm to thoroughly cover your hands.
- Rub hands together briskly until dry.

Inactive Ingredients

Inactive Ingredients

Water, PEG/PPG-8/3 Laurate, Glycerin, Carbomer, Tetrahydroxypropylethyldiamine, Fragrance.

Warnings

KEEP OUT OF REACH OF CHILDREN.

Principal Display Panel

Drug Facts		Datos del Producto	
Active Ingredient	Purpose	Ingrediente Activo	Propósito
Ethyl Alcohol 70%	Antiseptic	Alcohol etílico 70%	Antiséptico
Uses		Usos	
<ul style="list-style-type: none"> Hand sanitizer to reduce microorganisms on the skin. Use this product when soap and water are not available. 		<ul style="list-style-type: none"> Desinfectante para las manos destinado a reducir la cantidad de microorganismos de la piel. Útilice este producto cuando el jabón y el agua no están disponibles. 	
Warnings		Advertencias	
<ul style="list-style-type: none"> For external use only. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. FLAMMABLE. This product contains ethyl alcohol. Keep away from sources of ignition. Discontinue use if irritation or redness develops. If irritation persists for more than 72 hours, consult a physician. KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away. 		<ul style="list-style-type: none"> Solo para uso externo. Evite el contacto con los ojos. En caso de contacto, enjuague los ojos con agua. INFLAMABLE. Este producto contiene alcohol etílico. Manténcelo alejado de las fuentes de ignición. Evite el contacto con la piel si se desarrolla una irritación o enrojecimiento. Si la irritación persiste durante más de 72 horas, consulte a un médico. ¡MANTÉNGA ESTE PRODUCTO FUERA DEL ALCANCE DE LOS NIÑOS. En caso de ingestión, obtenga asistencia médica o diríjase a un Centro de toxicología de inmediato. 	
Directions		Instrucciones	
<ul style="list-style-type: none"> Read the entire label before using this product. Place enough product on your palm to thoroughly cover your hands. Rub hands together totally until dry. 		<ul style="list-style-type: none"> Lea la etiqueta completa antes de usar este producto. poner suficiente cantidad del producto en la palma de la mano para cubrir las manos completamente. Frotase las manos vigorosamente hasta que se sequen. 	
Inactive Ingredients		Instrucciones	
Water, PEG/PPG-8/3 Laurate, Glycerin, Carbomer, Tetrahydroxypropylethyldiamine, Fragrance.		<ul style="list-style-type: none"> Lea la etiqueta completa antes de usar este producto. poner suficiente cantidad del producto en la palma de la mano para cubrir las manos completamente. Frotase las manos vigorosamente hasta que se sequen. 	
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Advanced Alcohol Gel Sanitizer

Ethanol Based Gel Hand Sanitizer with Aloe
Gel de etanol sanitizador para manos con Aloe

KILLS 99.99% of Germs

HAND SANITIZER 796

18.5 fl. oz. (1.16 pt.) 550 mL

ADVANCED ALCOHOL GEL SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6560 1-796
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	1 mL in 0.7 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
DIMETHICONE PEG-8 LAURATE (UNII: 72MF9C2A18)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETOL (UNII: Q4R969U9FR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:6560 1-796-19	900 mL in 1 BAG; Type 1: Convenience Kit of Co-Package	08/01/2019	
2	NDC:6560 1-796-29	1000 mL in 1 BAG; Type 0: Not a Combination Product	08/01/2019	

3	NDC:65601-796-57	550 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2019	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/01/2019	

Labeler - Betco Corporation, Ltd (024492831)

Registrant - Betco Corporation, Ltd (024492831)

Establishment

Name	Address	ID/FEI	Business Operations
Betco Corporation, Ltd		024492831	manufacture(65601-796) , label(65601-796)

Revised: 8/2019

Betco Corporation, Ltd