

ADVANCED ALCOHOL GEL SANITIZER II- 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 II

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, Diisopropanolamine, PEG-6 (and) AMP- Acrylates/Vinyl Isodecanoate Crosspolymer, Glycerin, PEG/PPG-8/3 Laurate, Aloe Barbadensis Leaf Juice

Warnings

KEEP OUT OF REACH OF CHILDREN.

Principal Display Panel

<p>Drug Facts</p> <p>Active Ingredient Ethyl Alcohol 70% Purpose Antiseptic</p> <p>Uses</p> <ul style="list-style-type: none"> Hand sanitizer to reduce microorganisms on the skin. Use this product when soap and water are not available. <p>Warnings</p> <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. <p>Directions</p> <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 briskly until dry. <p>Inactive Ingredients Water, Diisopropanolamine, PEG-6 (and) AMP- Acrylates/Vinyl Isodecanoate Crosspolymer, Glycerin, PEG/PPG-8/3 Laurate, Aloe Barbadensis Leaf Juice</p> <p>Questions? 888-GO BETCO (888-462-3826)</p>	<p>Datos del Producto</p> <p>Ingrediente Activo Alcohol etílico 70% Propósito Antiséptico</p> <p>Usos</p> <ul style="list-style-type: none"> Desinfectante para las manos destinado a reducir la cantidad de microorganismos de la piel. Utilice este producto cuando el jabón y el agua no están disponibles. <p>Advertencias</p> <ul style="list-style-type: none"> Sólo para uso externo. Evite el contacto con los ojos. En caso de contacto, enjuáguese los ojos con agua. INFLAMABLE. Este producto contiene alcohol etílico. Mantener alejado de las fuentes de ignición. Deje de usarlo si se desarrolla una irritación o enrojecimiento. Si la irritación persiste durante más de 72 horas, consulte a un médico. MANTENER FUERA DEL ALCANCE DE LOS NIÑOS. En caso de ingestión, obtenga asistencia médica o diríjase a un Centro de toxicología de inmediato. <p>Instrucciones</p> <ul style="list-style-type: none"> Lea toda la etiqueta antes de usar este producto. Peque suficiente cantidad del producto en la palma de la mano para cubrir las manos completamente. Frotase las manos vigorosamente hasta que se sequen. 	 <p>Advanced Gel Sanitizer Ethanol Based Gel Hand Sanitizer HAND SANITIZER 797 1 gal. (3.78 L)</p>
--	--	---

ADVANCED ALCOHOL GEL SANITIZER II

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65601-797
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PEG-8 LAURATE (UNII: 762O8IWA10)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIISOPROSPANOLAMINE (UNII: 0W44HYL8T5)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
WATER (UNII: 059QF0KO0R)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65601-797-55	208 198 mL in 1 DRUM; Type 0: Not a Combination Product	05/14/2020	
2	NDC:65601-797-04	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/14/2020	

Labeler - Betco Corporation, Ltd (024492831)**Registrant** - Betco Corporation, Ltd (024492831)**Establishment**

Name	Address	ID/FEI	Business Operations
Betco Corporation, Ltd		024492831	manufacture(65601-797) , label(65601-797)

Revised: 5/2020

Betco Corporation, Ltd