

WINNING HANDS ALCOHOL FREE- benzalkonium chloride soap
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.

Winning Hands Alcohol Free

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☐Active Ingredient

Benzalkonium Chloride 0.13%

Winning Hands Alcohol Free

Uses

- Use in a variety of public facilities.
- Use this product when soap and water are not available.

Winning Hands Alcohol Free

Warnings

- **For external use only.**
- Avoid contact with eyes.
- Children under the age of 6 should be supervised by an adult when using this product.
- Discontinue use if irritation or redness develops.
- If irritation persists for more than 72 hours, consult a physician.
- **KEEP OUT OF REACH OF CHILDREN.**

Winning Hands Alcohol Free

Directions

- ☐**Read the entire label before using this product.**
- ☐Dispense product onto dry hands. Rub hands together until hands are dry.
- Use as needed between hand washes to reduce bacteria on the skin.

Winning Hands Alcohol Free

Inactive Ingredients

Deionized ☐Water, Sodium PCA, PEG/PPG-8/3 Laurate, Dimethicone, DMDM Hydantoin, PEG-3 Cocamide, Fragrance, Iodopropynyl Btylcarbamate, D&C Green #5.

Winning Hands Alcohol Free

Questions or Comments?Phone: (800) 777-9343

MDS information:☐(800) 891-4965

Winning Hands Alcohol Free

Purpose

Antiseptic

Winning Hands Alcohol Free

KEEP OUT OF REACH OF CHILDREN

Winning Hands Alcohol Free

Winning Hands Alcohol Free

Nondrying-Nonflammable Alcohol Free Foaming Hand Sanitizer

Net Contents: 1 gallon (U.S./E.U.) 3.78 L



Drug Facts	
Active Ingredient Benzalkonium Chloride 0.13%	Purpose Antiseptic
Uses • Use in a variety of public facilities. • Use this product when soap and water are not available.	
Warnings • For external use only. • Children under the age of 6 should be supervised by an adult when using this product. • Discontinue use if irritation or redness develops. • If irritation persists for more than 72 hours, consult a physician. KEEP OUT OF REACH OF CHILDREN.	
Directions • Read the entire label before using this product. • Dispense product onto dry hands. Rub hands together until hands are dry. • Use as needed between hand washes to help reduce bacteria on the skin.	
Inactive Ingredients Deionized Water, Sodium PCA, PEG/PPG-8/3 Laurate, Dimethicone, DMDM Hydantoin, PEG-3 Cocamide, Fragrance, Iodopropinyl Butylcarbamate, D&C Green #5.	
Questions or Comments? Phone: (800) 777-9343 MSDS Information Phone: (800) 891-4965	
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MSDS No. 792 0275210	

Datos del Producto	
Ingrediente Activo Cloruro de benzalconio 0.13%	Propósito Antiséptico
Usos • Para usar en diversos establecimientos públicos. • Utilice este producto cuando el jabón y el agua no están disponibles.	
Precauciones • Solo para uso externo. • Los niños menores de 6 años deben ser supervisados por un adulto cuando usen este producto. • 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.	
Instrucciones • Lea toda la etiqueta antes de usar este producto. • Reparta producto sobre las manos secas. Frota las manos entre sí hasta que estén secas. • Use según necesidad entre los lavados de manos para ayudar a reducir la cantidad de bacterias de la piel.	
Ingredientes Inactivos Agua desionizada, PCA de sodio, PEG/PPG-8/3 Laurate, Dimeticona, DMDM Hidantoina, PEG-3 Cocamida, Fragancia, Iodopropinil butilcarbamate, D&C Verde #5.	
¿Preguntas o comentarios? Teléfono: (800) 777-9343 Información de la Hoja de Datos sobre Seguridad del Material (MSDS) Teléfono: (800) 891-4965	

WINNING HANDS ALCOHOL FREE

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65601-752
Route of Administration	Topical		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PEG-6 COCAMIDE (UNII: YZ6NLA401E)	
IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65601-752-04	3780 mL in 1 JUG; Type 0: Not a Combination Product	11/12/2012	01/01/2016
2	NDC:65601-752-54	1000 mL in 1 BAG; Type 0: Not a Combination Product	11/12/2012	01/01/2016
3	NDC:65601-752-55	207900 mL in 1 DRUM; Type 0: Not a Combination Product	11/12/2012	01/01/2016

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/12/2012	

Labeler - Betco Corporation, Ltd. (070307547)

Registrant - Betco corporation, Ltd. (070307547)

Establishment

Name	Address	ID/FEI	Business Operations
Betco Corporation, Ltd.		070307547	manufacture(65601-752)

Revised: 9/2016

Betco Corporation, Ltd.