

BT21 HAND SANITIZER- alcohol gel
BALLON BLANC

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

Alcohol (70%)

INACTIVE INGREDIENTS

Water, Triethanolamine, Glycerin, Carbomer, Polysorbate 20, Tocopheryl Acetate, Perfume

PURPOSE

Antiseptic

WARNINGS

For external use only

Do not use if you are allergic to any of the ingredients

When using this product Avoid contact with eyes. in case of contact, rinse eyes thoroughly with water. Avoid contact with broken, irritate. or itching skin.

Stop use and ask a doctor if irritation or redness develops and condition persists for more than 72 hours.

Keep out of reach of children. if swallowed, get medical help or contact a Poison Control Center(1-800-222-1222) right away.

If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

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Uses

Hand sanitizer for decreasing bacteria on skin

Directions

Apply the appropriate amount of the product onto your hands and spread it thoroughly.

Rub hands together until it dries.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



접착부분	
Drug Facts	
Active Ingredient -----	Purpose
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BT21 HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78967-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	42 mL in 60 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
Glycerin (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78967-020-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part333A	09/01/2020	
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Labeler - BALLON BLANC (089595089)

Registrant - BALLON BLANC (089595089)

Establishment

Name	Address	ID/FEI	Business Operations
MYUNG COSMETIC		688222692	manufacture(78967-020)

Revised: 9/2020

BALLON BLANC