

BUBBLE GUM- antibacterial hand sanitizer gel gel
Brands Internation Corp

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 - Ethyl Alcohol 62%

Purpose - Antiseptic

Use

- to decrease bacteria on the skin and clean hands
- recommended for repeated use

Warnings

for external use only

Flammable, keep away from fire or flame

Keep out of children. If accidentally swallowed, get medical help or contact a Poison Control Center right away

Do not get into eyes, If contact occurs, rinse thoroughly with water

Discontinue Use if irritation or redness develops, If irritation persists for more than 72 hours, consult a doctor

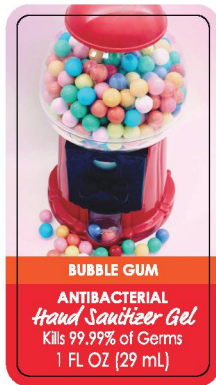
Directions

- apply to hands until thoroughly wet
- rub vigorously until dry
- supervise children in the use of this product

Other information

- may discolor certain fabrics or surfaces
- do not store above 110 F (43 C)

Water, Isopropyl Alcohol, Glycerin, Carbomer, Aminomethyl Prpanol, Fragrance, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Tocopheryl (Vitamin E) Acetate, Sunflower (Heilanthus Annuus) Seed Extract, Grapefruit (Citrus Grandis) Seed Extract, yellow 6 (CI 15985) Red 40 (CI 16035)

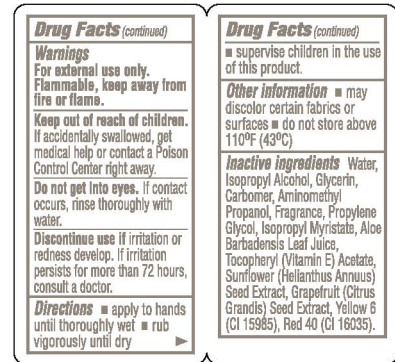


BACK
ADHESIVE SIDE

BACK LABEL



BACK LABEL INSIDE



BUBBLE GUM

antibacterial hand sanitizer gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 157-116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	620 mL in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
SUNFLOWER SEED (UNII: R9N3379M4Z)	
GRAPEFRUIT SEED OIL (UNII: 598D944HOL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50 157-116-01	29 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/10/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/10/2015	

Labeler - Brands Internation Corp (243748238)

Establishment

Name	Address	ID/FEI	Business Operations
Brands International Corp		243748238	manufacture(50 157-116)

Revised: 1/2015

Brands Internation Corp