

**PANION AND BF HAND SANITIZER- alcohol gel**  
**PANION & BF BIOTECH INC.**

*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.*

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**PANION & BF® Hand Sanitizer Gel**

***Drug Facts***

**Active Ingredient**

Ethyl Alcohol 75% v/v

**Purpose**

Antiseptic

**Use**

To help decrease bacterial on the skin that could potentially cause disease

**Warnings**

For external use only. Flammable. Keep away from heat or flame

**Do not use**

- In children less than 2 months of age
- On open skin wounds

**When using this product** keep out of eyes, ears, and mouth, in case of contact with eyes, rinse eyes thoroughly with water.

**Stop use and ask a doctor** if irritation or rash occurs. These may be signs of a serious condition.

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

**Directions**

- Place enough product on hands to cover all surfaces for at least 30 seconds. Then rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

**Other Information**

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive Ingredients**

Aqua, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Isononyl Isononanoate, O-Cymen-5-

OL, Triethanolamine, Tocopheryl Acetate

**USP**

Moisturization & Sanitization

**30 sec**

*Dual Action*

**99.99 % Germs Reduction**

PIC/S GMP Manufacturer

Made in Taiwan

**Packaging**



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<b>PANION AND BF HAND SANITIZER</b>			
alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78279-001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
O-CYMEN-5-OL (UNII: H41B6Q1I9L)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78279-001-18	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	
2	NDC:78279-001-49	225 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	
3	NDC:78279-001-99	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	
4	NDC:78279-001-23	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	
5	NDC:78279-001-35	360 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	
6	NDC:78279-001-28	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	
7	NDC:78279-001-30	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	
8	NDC:78279-001-32	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/30/2020	

**Labeler** - PANION & BF BIOTECH INC. (656381605)**Establishment**

Name	Address	ID/FEI	Business Operations
PANION & BF BIOTECH INC.		656381605	manufacture(78279-001)

Revised: 7/2020

PANION &amp; BF BIOTECH INC.