#### B FREE GEL- ethyl alcohol gel ATAK FARMA KOZMETIK VE KIMYA SANAYI TICARET ANONIM SIRKETI

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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#### Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

#### **Purpose**

Antiseptic, Hand Sanitizer

#### Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### 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.

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#### **Directions**

- Place enough product on hands to cover all surfaces. 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**

water, glycerin, to copheryl acetate, Aloe, Fragrance

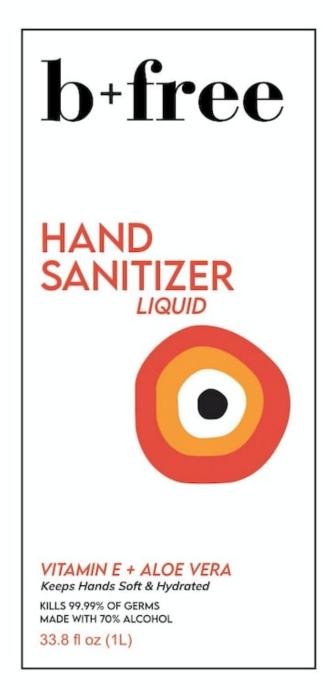
### Package Label - Principal Display Panel

500 mL NDC: 77418-200-01





1 L NDC: 77418-200-04



# **Drug Facts**

### Active ingredient

#### Purpose

Ethyl alcohol 70%.

Antiseptic

hand sanitizer to decrease bacteria on the skin • recommended for repeated use • for use when soap and water are not available

#### Warnings

Flammable, keep away from fire / flame. For external use only

### Do not use

in children less than 2 months of age • on open skin wounds

When using this product • do not get into eyes, In case of contact, rinse eyes thoroughly with water • do not inhale or ingest

#### Stop and ask doctor if

irritation and redness develop • condition persists for more than 72 hours

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

#### Directions

wet hands thoroughly with product and allow to dry without wiping.
 supervise children under 6 years of age when using this product to avoid swallowing

#### Other information

- store between 15-30°C (59-86°F)
  avoid freezing and excessive heat above 40°C (104°F)
  may discolor certain fabrics or surfaces

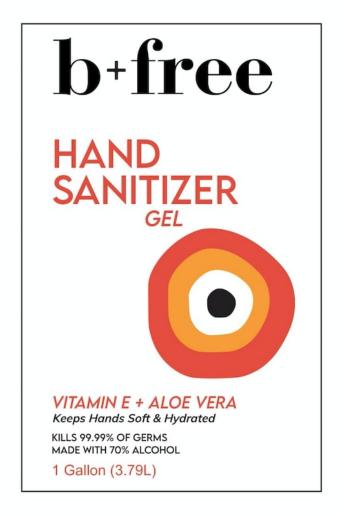
Inactive ingredients Water, Glycerin, Fragrance, Tocopheryl Acetate (VITAMIN E), Aloe Barbadensis Leaf Extract

Distributed by: b+free Company 34W Santa Clara St. San Jose, CA 95113, USA www.bfreecompany.com @bfreecompany



Lot No: 201020 Exp. Date: 10-2023

3.79 L NDC: 77418-100-02





100 mL NDC: 77418-200-03

### PIGY PACK LABEL







### **B FREE GEL**

ethyl alcohol gel

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77418-200		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
ASCORBYL TO COPHERYL MALEATE (UNII: D2G6259 XR5)		
ALOE (UNII: V5VD430 YW9)		
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)		
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		

]	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:77418-200- 01	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product $$	10/31/2020		
2	NDC:77418-200- 02	3790 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	10/31/2020		
3	NDC:77418-200- 03	$100\ mL$ in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	10/31/2020		
4	NDC:77418-200- 04	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	10/31/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	10/31/2020		

# Labeler- ATAK FARMA KOZMETIK VE KIMYA SANAYI TICARET ANONIM SIRKETI (566218248)

## **Registrant** - Atak farma kozmetik ve kimya sanayi ticaret anonim sirketi (566218248)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
ATAK FARMA KOZMETIK VE KIMYA SANAYI TICARET ANONIM SIRKETI		566218248	manufacture(77418-200)