

**BABYLISS PRO PROTECT HAND SANITIZER- alcohol gel**  
**MaKMaC 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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**BABYLISS PRO PROTECT HAND SANITIZER**

***Drug Facts***

***Active Ingredient***

Ethyl Alcohol 70% V/V

***Purpose***

Antiseptic

***Use***

Antibacterial hand sanitizing gel to help kill bacteria and germs as antiseptic on the skin. For use when soap and water are not available.

***Warnings***

**Flammable. Keep away from fire or flame.**

**For external use only**

**When using this product**

keep out of eyes and mouth. In case of contact with eyes, immediately rinse eyes thoroughly with water.

**Stop use and ask doctor if**

irritation, rash or allergy 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***

Apply. Put enough product on hands to cover all surfaces. Rub hands together, until hands feel dry. This should take around 20 seconds. Recommended for repeated use. Supervise children under 6 years of age when using this product to avoid swallowing.

***Other information***

Store between 59-86°F (15-30°C)

Avoid freezing and excessive heat above 104°F (40°C)

***Inactive ingredients***

Deionized Water. Carbomer. Panthenol. DMDM Hydantoin. Disodium EDTA. Triethanolamine.

## Package Labeling

# BaByliss<sup>PRO</sup>

# PROTECT™



HAND SANITIZER

70% ALCOHOL

KILLS MORE THAN 99.9% OF GERMS

OF FDA ORGANISMS IN THE TECHNICAL FINAL MONOGRAPH OF TOPICAL ANTIMICROBIAL DRUG PRODUCTS

16.5 fl oz (488 mL)

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<b>Warnings</b>	
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<b>For external use only</b>	
When using this product keep out of eyes and mouth. In case of contact with eyes, immediately rinse eyes thoroughly with water.	
Stop use and ask doctor if irritation, rash or allergy 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.	
<b>Directions</b>	
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BaBylissPRO World Headquarters: Paris, France.  
BaBylissPRO: Glendale, AZ 85307  
Made in Mexico. Model BHS16 20BA073510 Non-sterile Solution



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## BABYLIS PRO PROTECT HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78080-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
PANTHENOL (UNII: WV9CM0O67Z)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
EDETATE DISODIUM ANHYDRO US (UNII: 8NLQ36F6MM)	
TROLAMINE (UNII: 9O3K93S3TK)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78080-002-00	12 in 1 BOX	09/25/2020	
1		488 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/25/2020	

**Labeler** - MaKMaC Inc (128886705)

Revised: 9/2020

MaKMaC Inc