

**HAND SANITIZER- alcohol gel**  
**Monarch Global Brands, 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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**Hand Sanitizer**

***Active Ingredient***

Ethyl Alcohol 62% v/v. Purpose: Antibacterial

***Purpose***

Antibacterial, Hand Sanitizer

***Use[s]***

- Hand Sanitizer to reduce bacteria on the skin
- Recommended for repeated use

***Warnings***

**Flammable.**, keep away from fire and flame

**For external use only**

**When using this product**

do not use in or near the eyes. If contact occurs, rinse thoroughly with water.

***Stop use and consult doctor***

if irritation occurs or rash appears and lasts.

***Keep out of reach of Children.***

If swallowed, get medical help or call a Poison Control Center.

***Directions***

- Place enough product in your palm to cover your hands
- Rub hands together briskly until dry
- Children under 6 years of age should be supervised when using this product

***Other information***

- Store below 106F (41C)
- May discolor certain fabrics or surfaces
- Avoid freezing and heat above 105F (40C)

***Inactive ingredients***

water, glycerin, triethanolamine, carbomer, Aloe Barbadensis Leaf extract, Tocopheryl Acetate

**Questions or Comments?**

215 482 6100

info@monarchbrands.com

**Package Label - Principal Display Panel**

237mL NDC: 80330-007-01

Papillon

HAND SANITIZER

WITH ALOE

62% ETHYL

ALCOHOL

CDC RECOMENDED

FORMULA

ETHYL ALCOHOL ANTISEPTIC

TOPICAL SOLUTION

8 oz. (237ml)

179mm

85mm

<b>Drug Facts</b>	 <b>Papillon</b> <sup>TM</sup> <b>HAND SANITIZER</b> WITH ALOE <b>62% ETHYL</b> <b>ALCOHOL</b> <b>CDC RECOMENDED</b> <b>FORMULA</b> <b>ETHYL ALCOHOL ANTISEPTIC</b> <b>TOPICAL SOLUTION</b> 8oz.(237ml)
<b>Active ingredient.....Purpose</b> Ethyl Alcohol 62%.....Antibacterial	
<b>Use[s]</b> • Hand Sanitizer to reduce bacteria on the skin • Recommended for repeated use	
<b>Warnings</b> <b>Flammable.</b> Keep away from fire and flame.	
<b>For external use only</b>	
<b>When using this product</b> do not use in or near the eyes. If contact occurs, rinse thoroughly with water.	
<b>Stop use and consult doctor</b> if irritation occurs or rash appears and lasts.	
<b>Keep out of the reach of children.</b> If swallowed, get medical help or contact a Poison Control Center.	
<b>Directions</b> • Place enough product in your palm to cover your hands • Rub hands together briskly until dry • Children under 6 years of age should be supervised when using this product	
<b>Other Information</b> • Store below 106°F (41°C) • May discolor certain fabrics or surfaces • Avoid freezing and heat above 105°F (40°C) 	
<b>Inactive Ingredients</b> Ethanol, Water (Agua), Glycerin, Triethanolamine Carbomer, Aloe Barbadensis Leaf Extract, Tocopheryl Acetate.	
<b>Questions or Comments?</b> 215 482 6100 info@monarchbrands.com	

Distributed by:  
**MONARCH**  
BRANDS  
11350 Norcom Road  
Philadelphia PA 19154  
RN #100823  
HS-ETL-8OZ  
Made in China

lot#:  
Pro.:  
Exp.:  


355mL NDC: 80330-007-02

Papillon

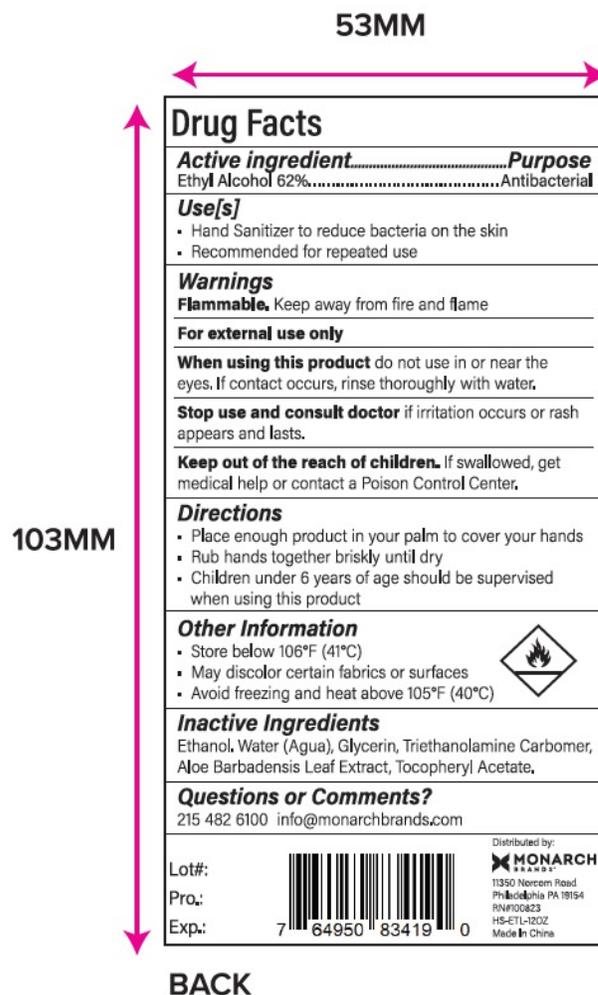
HAND SANITIZER

WITH ALOE

62% ETHYL

ALCOHOL

CDC RECOMENDED  
 FORMULA  
 ETHYL ALCOHOL ANTISEPTIC  
 TOPICAL SOLUTION  
 12 oz. (355ml)



3785mL NDC: 80330-007-03

Papillon  
 HAND SANITIZER  
 WITH ALOE  
 62% ETHYL  
 ALCOHOL  
 CDC RECOMENDED  
 FORMULA  
 ETHYL ALCOHOL ANTISEPTIC  
 TOPICAL SOLUTION  
 1 U.S. Gallon



## HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80330-001(NDC:74742-007)
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80330-001-01	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2020	
2	NDC:80330-001-02	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2020	
3	NDC:80330-001-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final

part333A

08/27/2020

**Labeler** - Monarch Global Brands, Inc. (014623185)

Revised: 8/2020

Monarch Global Brands, Inc.