

**LAB AMAROS CAMELLIA SANITIZER- ethanol gel**  
**AMAROS CO., LTD.**

*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**

Ethanol 62.0% v/v

**INACTIVE INGREDIENTS**

Water, Propylene Glycol, Glycerin, Dimethicone, Carbomer, Triethanolamine, Tocopheryl Acetate, Menthol

**PURPOSE**

SANITIZER

**WARNINGS**

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

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Do not use

- in children less than 2 months of age
  - on open skin wounds
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When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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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**

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

**Uses**

- Hand sanitizer to decrease the bacteria on the skin.
- Recommended for repeated use.

**Directions**

- Take an appropriate amount on your hands and rub thoroughly to dry.

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



## LAB AMAROS CAMELLIA SANITIZER

ethanol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60899-120
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	310 mL in 500 mL

**Inactive Ingredients**

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Glycerin (UNII: PDC6A3C0OX)	
Dimethicone (UNII: 92RU3N3Y1O)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
Menthol (UNII: L7T10EIP3A)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60899-120-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2021	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2021	

**Labeler** - AMAROS CO., LTD. (690338801)**Registrant** - AMAROS CO., LTD. (690338801)**Establishment**

Name	Address	ID/FEI	Business Operations
AMAROS CO., LTD.		690338801	manufacture(60899-120)

Revised: 5/2021

AMAROS CO., LTD.