

ANTISEPTIC HAND SANITIZER- alcohol gel
Laboratorios Jaloma S.A. de C.V.

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.

Antiseptic Hand Sanitizer

Drug Facts

Active ingredient

Ethyl alcohol 62%

Purpose

Antiseptic

Use

For hand washing to decrease bacteria on the skin

Warnings

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

Do not use

in the eyes

Stop use and ask a 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

Other information

- do not store above 110°F (43°C)
- may discolor certain fabrics, or may harm some wood finishes and plastics

Inactive ingredients

Water, glycerin, fragrance, tocopherol acetate, carbomer and triethanolamine.

Questions or comments?

+1 818 763 8698

Package Labeling: (65055-600-00)

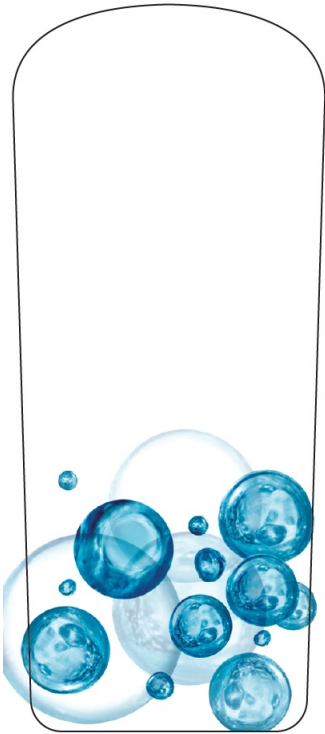


FRENTE



frente

vuelta



Drug Facts


Active ingredient	Purpose
Ethyl alcohol 62%Antiseptic	

Use
For hand washing to decrease bacteria on the skin

Warnings
For external use only
Flammable, keep away from fire or flame.
Do not use in the eyes ▶

LABORATORIOS JALOMA S.A. DE C.V.
AQUILES SERDÁN 438, Z.P. 44380.
GUADALAJARA, JALISCO, MEXICO.
MADE IN MEXICO

Lot No: _____
Exp Date _____
NDC: _____



Drug Facts
(continued)

Stop use and ask a doctor if

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- condition persists for more than 72 hours

Keep out of reach of children.
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Directions
wet hands thoroughly with product and allow to dry without wiping

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- may discolor certain fabrics, or may harm some wood finishes and plastics

▶

Drug Facts
(continued)

Inactive ingredients
Water, glycerin, fragrance, tocopherol acetate, carbomer and triethanolamine .

Questions or comments?
+1 818 763 8698

Package Labeling: (65055-600-01)



Formato de Especificación del producto.

Hand Sanitizer 120 ml reverso

REVERSO

frente

vuelta



Drug Facts

Active ingredient	Purpose
Ethyl alcohol 62%	Antiseptic

Use
For hand washing to decrease bacteria on the skin

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


Do not use in the eyes

Stop use and ask a doctor if
 irritation and redness develop
 condition persists for more than 72 hours

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Drug Facts (continued)

Directions
wet hands thoroughly with product and allow to dry without wiping

Other information
 do not store above 110°F (43°C)
 may discolor certain fabrics, or may harm some wood finishes and plastics

Inactive ingredients
Water, glycerin, fragrance, tocopherol acetate, carbomer and triethanolamine.

Questions or comments?
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Formato de Especificación del producto.

Hand Sanitizer 120 ml frente

FRENTE



Package Labeling: (65055-600-02)



Formato de Especificación del producto.

Hand Sanitizer 500 ml frente

FRENTE

60.5 mm

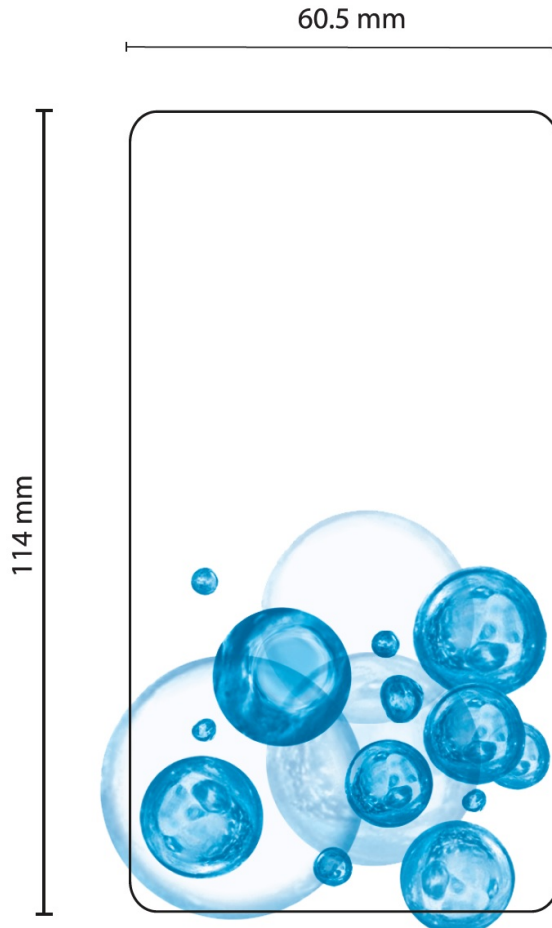




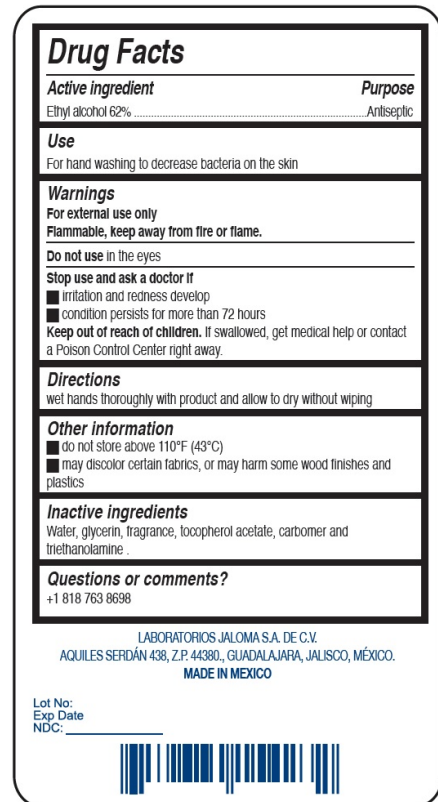
Formato de Especificación del producto.

Hand Sanitizer 60 ml reverso

REVERSO



frente



vuelta

ANTISEPTIC HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65055-600
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.62 mL in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65055-600-00	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2020	
2	NDC:65055-600-01	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2020	
3	NDC:65055-600-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/24/2020	

Labeler - Laboratorios Jaloma S.A. de C.V. (811122357)

Revised: 3/2020

Laboratorios Jaloma S.A. de C.V.