

WOLKE HAND SANITIZER- alcohol gel
Hidro Soluciones Integrales, 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.

Wolke Hand Sanitizer

Drug Facts

Active Ingredient

Alcohol 70% v/v

Purpose

Antiseptic

Uses

To decrease bacteria on the skin when water, soap & towel are not available - Recommended for repeated use.

Warnings

- ***For external use only.***

Flammable - □Keep away from fire or flame.

When using this product

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

Do not use

on broken or irritated skin.

Stop use and ask a doctor if

irritation or redness develop and last more than 72 hours.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply enough product to wet hands. Rub hands together until dry. Supervise children in use of this product.

Other information

- Do not store above 105 °F (40 °C).
- May discolor certain wood surfaces.

Inactive Ingredients:

Purified water, carbomer, triethanolamine, glycerin.

Package Labeling: 250ml



WOLKE™

HAND SANITIZER



KILLS 99.99% OF GERMS

MOISTURIZING GEL

70% ALCOHOL

8.4 FL. OZ (250ml.)



Drug Facts	
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Alcohol 70% v/v	Antiseptic
Uses	
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• Do not store above 105 °F (40 °C). • May discolor certain wood surfaces.	
Inactive Ingredients: Purified water, carbomer, triethanolamine, glycerin.	

Made in Mexico

**Distributed by: Hidro Soluciones Integrales S.A. de C.V.
Paseo de Italia 3, Lomas Verdes, Naucalpan de Juarez 53125**

Package Labeling: 500ml



HAND SANITIZER



KILLS 99.99% OF GERMS

MOISTURIZING GEL

70% ALCOHOL

16.9 FL. OZ (500 ml.)



Drug Facts

Active Ingredient	Purpose
Alcohol 70% v/v	Antiseptic

Uses

To decrease bacteria on the skin when water, soap & towel are not available - Recommended for repeated use.

Warnings - For external use only.

Flammable - Keep away from fire or flame.

When using this product keep out of eyes. In case of contact with eyes, rinse thoroughly with water. Do not use on broken or irritated skin.

Stop use and ask a doctor if irritation or redness develop and last more than 72 hours.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions - Apply enough product to wet hands. Rub hands together until dry. Supervise children in use of this product.

Other information

- Do not store above 105 °F (40 °C).
- May discolor certain wood surfaces.

Inactive Ingredients: Purified water, carbomer, triethanolamine, glycerin.

Made in Mexico

**Distributed by: Hidro Soluciones Integrales S.A. de C.V.
Paseo de Italia 3, Lomas Verdes, Naucalpan de Juarez 53125**

Package Labeling: 900ml



WOLKE™

HAND SANITIZER



KILLS 99.99% OF GERMS

MOISTURIZING GEL

70% ALCOHOL

30.4 FL. OZ (900 ml.)



WOLKE™

Drug Facts

Active Ingredient	Purpose
Alcohol 70% v/v	Antiseptic

Uses
To decrease bacteria on the skin when water, soap & towel are not available - Recommended for repeated use.

Warnings - For external use only.

Flammable - Keep away from fire or flame.

When using this product keep out of eyes. In case of contact with eyes, rinse thoroughly with water. Do not use on broken or irritated skin.

Stop use and ask a doctor if irritation or redness develop and last more than 72 hours.

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

Directions - Apply enough product to wet hands. Rub hands together until dry. Supervise children in use of this product.

Other information

- Do not store above 105 °F (40 °C).
- May discolor certain wood surfaces.

Inactive Ingredients: Purified water, carbomer, triethanolamine, glycerin.

Made in Mexico

Distributed by: Hidro Soluciones Integrales S.A. de C.V.
Paseo de Italia 3, Lomas Verdes, Naucalpan de Juarez 53125

WOLKE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78207-000
Route of Administration	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: 059QF0KO0R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78207-000-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	
2	NDC:78207-000-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	
3	NDC:78207-000-03	900 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/25/2020	

Labeler - Hidro Soluciones Integrales, S.A. de C.V. (951577999)

Revised: 6/2020

Hidro Soluciones Integrales, S.A. de C.V.