

**HAND SANITIZER WOLKE- 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.*

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**HAND SANITIZER WOLKE**

***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:**



**HAND SANITIZER WOLKE**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78207-001
<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 HO MO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78207-001-01	3700 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/01/2020	

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

Revised: 8/2020

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