

## HAND SANITIZER- alcohol gel

### Actalys

*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.*

500ml NDC: 79032-206-15

Disinfectant gel for hand decontamination which contains a skinprotecting agent. Conditioned in a gelled texture, it allows a fast, convenient and effective use of the product.

**VIRUCIDE - PH NEUTRAL - FOR ALL SKIN TYPES  
DERMATOLOGICALLY TESTED**

**Instructions for use:** Apply the dose of gel (1ml) on the hands and rub until hands are dry, do not rinse.

**Precautions for use:** For external use, on healthy skin. Rinse with water in case of contact with eyes. Do not use if irritation occurs. Flammable product. Keep out of reach of children.  
Standards : EN1276 - EN1650 - PASTEUR EN14476

Highly flammable liquid and vapour. Causes severe eye irritation. In case of consultation with a doctor, keep container or label available. Keep out of reach of children. Read the label before use. Keep away from heat, hot surfaces, sparks, open flames and other sources of heat and ignition. Do not smoke. Keep container tightly closed. Store in a well-ventilated area. Keep in a cool place. Dispose of contents/container in accordance with local/regional/national/ international regulations.  
Danger. Biocide TP1 and TP2: Ready-to-use hand disinfectant (AL) in alcoholic scented gel. Biocidal active substance with % m/m: Ethanol (CAS No. 64-17-5) 56%. Inventory number : 38424

INCI Composition: Alcohol, Aqua, Carbomer, Perfume, Triethanolamine, Glycerin, Heterotheca inuloides flower extract.

Batch number: see on the package  
Preferably to be used before: see use-by date on the packaging.

**ACTALYS**  
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### Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

### Purpose

Antiseptic, Hand Sanitizer

### Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### Warnings

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

### Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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

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

#### **Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

#### **Other information**

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

Glycerin, Water, Carbomer, Trolamine, Arnica mexicana (Heterotheca inuloides, extract)

**Carton of 20 500ml bottles NDC: 79032-246-15**



**HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79032-206
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 mL in 500 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	4.5 mL in 500 mL
TROLAMINE (UNII: 9O3K93S3TK)	1 mL in 500 mL
WATER (UNII: 059QF0KO0R)	141.85 mL in 500 mL
HETERO THECA INULOIDES FLOWER (UNII: W9NZ9OZF68)	0.1 mL in 500 mL
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.75 mL in 500 mL

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:79032-206-15	20 in 1 BOX	07/30/2020	
1	NDC:79032-206-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	07/30/2020	

**Labeler** - Actalys (260814505)**Registrant** - Actalys (260814505)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Actalys		260814505	api manufacture(79032-206)

Revised: 7/2020

Actalys