

**HAND SANITIZER- ethanol alcohol gel**  
**HAND SANITIZING WIPES- ethanol alcohol cloth**  
**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.*

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**Hand Sanitizer**

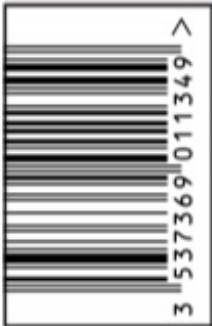
**5L NDC:79032-202-50**



# HAND SANITIZER



**WASHES AND DISINFECTS HANDS  
ELIMINATES BACTERIA - DRIES INSTANTLY**



Hydro-alcoholic gel for hands decontamination, containing a hand-protecting agent. Its gel-texture allows a fast, practical and effective use of the product Disinfecting solution, no foaming, without rinsing, nor wiping, without residues, eliminates the odors and the bacterial proliferation.

**VIRICIDE – NEUTRAL PH – ALL SKIN TYPES  
TESTED UNDER DERMATOLOGICAL CONTROL**

Method of use: Apply the dose of gel (1 ml) on hands and scrub until hands are dry. Do not rinse.

Precautions: For external use on healthy skin. If in eyes, rinse with water. If irritation occurs, discontinue use. Flammable. Keep out of reach of children.

Compliant with norms: EN1276 - EN1650 - PASTEUR EN14476

Highly flammable liquid and vapor. Causes serious eye irritation. If medical advice is needed, have product container or label at hand. Keep out of reach of children. Before use, read the label and information concerning the product. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Store in a well ventilated place. Keep cool. Dispose of the contents and container in appropriate collectors in accordance with local/regional/national/international regulations.



Danger: Biocide TP1 and TP2: ready to use alcohol-based and scented hand sanitizer.  
Active biocidal substance with% m / m: ethanol (CAS N ° 64-17-5) 56%. Inventory number: 38424  
Composition INCI : Alcohol, Aqua, Carbomer, Parfum, Triethanolamine, Glycerin, Heterotheca isu-  
loides flower extract.



**5L<sup>e</sup>  
169 Fl.oz**



**ACTALYS - Z.A. du Haut des Tappes BP 70 065 - 54310 HOMÉCOURT**  
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79032-202-51 Outer Carton Image



### **Inactive Ingredients**

Water, Carbomer, Parfum, Triethanolamine, Glycerin, Heterotheca Inuloides Flower Extract

### **Active ingredient - Alcohol**

Active Biocidal substance with % m/m: Ethanol (CAS N 64-175-) 56%

### **Purpose**

Hydro-Alcoholic gel for hands decontamination, containing a hand-protecting agent. Its gel-texture allows a fast, practical, and effective use if the product disinfecting solution no foaming, without rinsing, nor wiping, without residues, eliminates the odors of bacterial proliferation.

### **Dosage**

Apply the does of gel (1ml) on hands and scrub until hands are dry. Do not rinse

### **Usage**

Apply the dose of gel (1 ml) on hands and scrub imtil the hands are dry. Do not rinse

### **Warnings - Flammable**

Highly flammable liquid and vapor. Causes serious eye irritation. if medical advise is needed have product contianer or label at hand. Before use, read the label and information concerning the product. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking, store in well ventilated place. Keep cool. Dispose of the contents in apporopriate collectors in accordance with local/regional/national/international regulations.

**Warnings - Biocide**

Danger: Biocode TP1 and TP2: ready to use alcohol-based and scented hand sanitizer.

Active biocidal substance with % m/m: ethanol(CAS N 64-17-5) 56% Inventory number:38424

**Keep out of reach of Children**

Keep out of reach of Children

**Discontinue use**

If irritation occurs, discontinue use

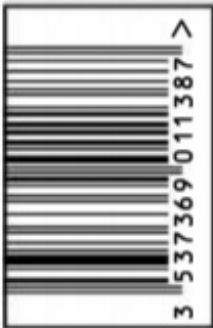
**1L NDC 79032-213-11**



# HAND SANITIZER



**HAND WASHING AND DISINFECTION  
ELIMINATES BACTERIA - DRIES INSTANTLY**



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Disinfectant gel for hand decontamination which contains a skin-protecting 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 gas fumes. 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 : 30424  
INCI Composition: Alcohol, Aqua, Carbomer, Parfum, Isoethanolamine, Glycerin, Heterotheca inuloides flower extract.



**1Le  
33,8 Fl.oz**



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

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### **Inactive Ingredients**

Water, Carbomer, Parfum, Triethanolamine, Glycerin, Heterotheca Inuloides Flower Extract

### **Active Ingredients**

Active Biocidal substance with % m/m: Ethanol (CAS N 64-175-) 56%

### **Purpose**

Hydro-Alcoholic gel for hands decontamination, containing a hand-protecting agent. Its gel-texture allows a fast, practical, and effective use if the product disinfecting solution no foaming, without rinsing, nor wiping, without residues, eliminates the odors of bacterial proliferation.

### **Dosage**

Apply the does of gel (1ml) on hands and scrub until hands are dry. Do not rinse

### **Usage**

Apply the dose of gel (1 ml) on hands and scrub imtil the hands are dry. Do not rinse

### **Warning - Flammable**

Highly flammable liquid and vapor. Causes serious eye irritation. if medical advise is needed have product contianer or label at hand. Before use, read the label and information concerning the product. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking, store

in well ventilated place. Keep cool. Dispose of the contents in appropriate collectors in accordance with local/regional/national/international regulations.

## Warning - Biocide

Danger: Biocode TP1 and TP2: ready to use alcohol-based and scented hand sanitizer.

Active biocidal substance with % m/m: ethanol(CAS N 64-17-5) 56% Inventory number:38424

## Keep out of reach of Children

Keep out of reach of Children

## Discontinue Use

If irritation occurs, discontinue use

## 130 sheet package NDC:79032-209-13

The HAND SANITISING wipe cleans, disinfects, deodorizes, allows the destruction of microbes, germs, bacteria and facilitates their total elimination. HAND SANITISING is a bactericidal, fungicidal, virucidal wipe for an effective disinfection. HAND SANITISING - by its composition - ensures you a total protection of your hands with components such as glycerin and arnica.

**APPLICATION FIELDS :**  
Hospital hygiene, medical practice, pharmaceutical industry, veterinary practice, community, canteen, catering, kitchen, food industry, food processing industry, large surface laboratory, meat-cutting room, milking room, slaughterhouse, dairy. All areas for which effective disinfection is mandatory.

**INSTRUCTIONS:**  
Take a wipe out of the bucket. Take care to close the lid properly afterwards to avoid drying. Unfold the wipe and apply to the surface to be decontaminated. The contact time for a perfect disinfection is 5 minutes. To avoid viruses, the contact time is 15 minutes.



The label features a blue header with '130 WIPES' and a 'BACTERICIDAL' warning symbol. The main title 'Hand Sanitising' is in large blue letters. Below it are icons for a hand, a telephone, a computer, and a toilet. A blue box contains three bullet points: 'CLEANING WIPES WITH VERY HIGH DISINFECTING POWER FOR HANDS AND SURFACES', 'CONTAINS SKIN SOFTENING AGENTS', and 'FAST AND EFFECTIVE SOLUTION FOR TOTAL DISINFECTION'. On the right, there is a 'COMPLIANCE AND STANDARDS' section with various EN standards, a 'WARNING' symbol, a barcode, and a 'WARNING' text box with a person icon. At the bottom right, there is an 'INGI' list and contact information for ACTALYS.

**COMPLIANCE AND STANDARDS :**  
EN 1276 - EN 13697 BACTERICIDE Pseudomonas Aeruginosa strains CIP 103467 - Escherichia Coli CIP 54-127 - DSM 682, Staphylococcus Aureus CIP 4-83 - DSM 799 Salmonella Choleraesuis ATCC 10708 in pure form. Enterococcus Hirae DSM 3320 concentration 50% Mandatory contact time 5 minutes. EN 1650 - EN 13697 FUNGICIDE Candida Albicans strains CIP 4872 - DSM 1386 Aspergillus Niger ATCC 16404 - DSM 1988 in pure form. Mandatory contact time 15 minutes. EN 14476 VIRUCIDE H1N1 virus in pure form contact time 30 seconds.  
TP1 - TP2 - TP4: disinfection of healthy hands, surfaces in contact or not with foodstuffs. CASE 64-17-5 Ethanol 56.00% m/m.<sup>(75% v/v)</sup>

**Hazard statements:** H225 Highly flammable liquid and vapour. H319 Causes severe eye irritation. **Cautionary statements:** P102 Keep out of reach of children. P210 Keep away from heat, hot surfaces, sparks, open flames and all other sources of ignition. Do not smoke. P211 Use explosion-proof electrical/ventilating/lighting equipment. P233 Take precautionary measures against electrostatic discharge. P280 Wear eye protection/face protection. P305+P351+P338 If in eyes: Rinse copiously with water for several minutes. Remove contact lenses, if present and easily removable. Continue rinsing. P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**INGI :** Alcohol, Aqua, Glycerin, Perfume, Heterotheca inuloides flower extract

**Inventory number :** 63788

**ACTALYS - Z.A. DU HALIT DES TAPPEES - BP 70065 - 54310 HOMÉCOURT**  
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MAIL: lobo@actalys.eu - www.actalys.eu

## Outer Carton Image NDC:79032-209-23



## Active Ingredient

Ethanol 56% m/m CASE 64-17-5

## Inactive Ingredients

Water, Glycerin, Perume, Heterotheca inuloides flower extract, Triethanolamine

## Purpose

The Hand sanitizing wipe cleans, disinfects, deodorizes, allows the destruction of microbes, germs, bacteria, and facilitates their total elimination. Hand sanitizing is a bactericidal, fungicidal, virucidal wipe for an effective disinfection. Hand sanitizing - by its composition - ensures you a total protection of your hands with components such as glycerin and arnica

## Dosage

Take a wipe out of the bucket. Take care to close the lid properly afterwards to avoid drying. unfold the wipe and apply to the surface to be decontaminated. the contact time for a perfect disinfection is 5 minutes. to avoid viruses, the contact time is 15 minutes.

## Usage

Take a wipe out of the bucket. Take care to close the lid properly afterwards to avoid drying. unfold the wipe and apply to the surface to be decontaminated. the contact time for a perfect disinfection is 5 minutes. to avoid viruses, the contact time is 15 minutes.

## Warning - Flammable

Highly Flammable liquid and vapor. Keep away from heat, hot surfaces, sparks, open flames, and all other sources of ignition. Do not smoke. Use explosion-proof electrical/ventilating/lighting equipment. Take precautionary measures against electrostatic discharge.

## Warning - Eye Irritant

Causes severe eye irritation. Wear eye protection/face protection.

If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easily removable. Continue rinsing

## Keep out of reach of Children

Keep out of reach of Children

## Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

## HAND SANITIZER

ethanol alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79032-202
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety



Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	3.5 L in 5 L	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
HETERO THECA INULOIDES FLOWER (UNII: W9NZ9OZF68)		0.1 L in 5 L		
TROLAMINE (UNII: 9O3K93S3TK)		0.01 L in 5 L		
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)		0.75 L in 5 L		
GLYCERIN (UNII: PDC6A3C0OX)		0.045 L in 5 L		
WATER (UNII: 059QF0KO0R)		1.4185 L in 5 L		
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79032-202-51	4 in 1 BOX	07/20/2020	
1	NDC:79032-202-50	5 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/15/2020		

## HAND SANITIZING WIPES

ethanol alcohol cloth

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79032-209
Route of Administration	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	0.566
<b>Inactive Ingredients</b>			
Ingredient Name		Strength	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)		0.56	
HETERO THECA INULOIDES FLOWER (UNII: W9NZ9OZF68)		0.001	
GLYCERIN (UNII: PDC6A3C0OX)		0.011	
WATER (UNII: 059QF0KO0R)		0.289	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79032-209-23	6 in 1 BOX	07/20/2020	
1	NDC:79032-209-13	1 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/20/2020	

## HAND SANITIZER

ethanol alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79032-213
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 L in 1 L

### Inactive Ingredients

Ingredient Name	Strength
HETEROTHECA INULOIDES FLOWER (UNII: W9NZ9OZF68)	0.0002 L in 1 L
TROLAMINE (UNII: 9O3K93S3TK)	0.002 L in 1 L
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.0015 L in 1 L
WATER (UNII: 059QF0KO0R)	0.2837 L in 1 L
GLYCERIN (UNII: PDC6A3C0OX)	0.009 L in 1 L

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79032-213-11	12 in 1 BOX	07/20/2020	
1	NDC:79032-213-10	1 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/20/2020	

**Labeler** - Actalys (260814505)

### Establishment

Name	Address	ID/FEI	Business Operations
Actalys		260814505	api manufacture(79032-202, 79032-213, 79032-209)

Revised: 7/2020

Actalys