

## SAFETY DATA SHEET

According to regulation (EC) No. 1907/2006 and No. 453/2010

	<b>DESINCLOR COLORED ALCOHOLIC SOLUTION 2%</b>	Revision date: 01-06-2022 Replaces versión: 17-05-19 Page 1 of 11
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### 1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY/UNDERTAKING

**1.1. Product identification: DESINCLOR COLORED ALCOHOLIC SOLUTION OF CHLORHEXIDINE DIGLUCONATE 2%**

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

**Identified uses:** Antiseptic for healthy skin. Surgical rub of the hands.

**Uses advised against:** None different than those previously collected as identified use.

**1.3. Details of the supplier of the safety data sheet.**

IMARK-HOSPITAL, S.L.

Ctra. Ajalvir-Torrejón Km 3,300

Pol.Ind. Conmar naves 10 y 12

28864 Ajalvir (Madrid)

Tel. 918844033

Email of the person responsible for the security file:

info@imark-hospitals.com

**1.4. Emergency telephone number:**

00 34 91 884 40 33 (offices hours)

00 34 91 562 04 20 (Medical Services of Toxicological Information)

### 2. HAZARDS IDENTIFICATION

**2.1 Classification of the substance or mixture:**

Classification according to regulation (EC) No 1272/2008-605/2014 (CLP)

Eye irritation Cat 1.: H318

Aquatic Cat. chronic 3: H412

STOT-SE 3 Specific toxicity with dizziness and vertigo effects (Unique exposure) Cat.3: H336

Flammable liquid Cat. 2: H225

**2.2. Label elements:**



**Signal word:** Danger

Hazard statements:

H318: Causes serious eye damage.

H412: Harmful to aquatic life with long lasting effects.

H336: May cause drowsiness or dizziness.

H225: Highly flammable liquid and vapour.

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### Precautionary statements:

P101: If medical advice is needed, have product container or label at hand.

P102: Keep out of reach of children.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313: If eye irritation persists: Get medical advice/attention.

P261: Avoid breathing vapors/spray.

P271: Use only outdoors or in a well-ventilated area.

P304+P340: If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P312: Call a POISON CENTER or doctor/physician if you feel unwell.

P403+P233: Store in a well-ventilated place. Keep container tightly closed.

P405: Store locked up.

P210: Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P233: Keep container tightly closed.

P370+P378: In case of fire: Use extinguisher for extinction.

P403+P235: Store in a well-ventilated place. Keep cool.

P273: Avoid release to the environment.

P501: Dispose of contents/container in accordance with the current waste treatment legislation.

### **2.3. Other hazards:**

The product should only be used under medical prescription in children under 30 months. The use of alcoholic or aqueous based chlorhexidine skin solutions, as a skin disinfectant, has been associated with chemical burns in neonates.

Does not contain substances that meet the PBT criteria (persistent / bioaccumulative / toxic) and vPvB (very persistent / very bioaccumulable).

## **3. COMPOSITION / INFORMATION ON THE COMPONENTS**

### **3.1. Substances**

Not applicable (mixture)

### **3.2. Mixtures**

This product is a mixture

Description: Alcoholic solution of Chlorhexidine digluconate 2%

Composition per 100 g of product: 70% of propan-2-ol; 2% of Chlorhexidine Digluconate (10 g of Chlorhexidine Digluconate solution at 20% in 100 g).

Hazard statements according to (EC) No 1272/2008 (CLP) regulation

<u>Hazard ingredients</u>	<u>CAS RN</u>	<u>Concentration g/100 g</u>	<u>Hazard pictogram</u>	<u>Hazard statements</u>
Chlorhexidine digluconate solution 20%	18472-51-0	10	GHS05, GHS09	H318, H400, H410
Propan-2-ol. Isopropyl Alcohol	67-63-0	70	GHS02, GHS07	H-319, H225, H336
C9-11 Pareth-6	68439-46-3	<5	GHS05, GHS07	H302, H318

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### 4. FIRST AID MEASURES

#### 4.1. Description of first aid measures.

**Inhalation:** Take the person affected by the vapor to open space. If breathing is irregular or stops, practice an artificial respiration. If unconscious, place him in proper recovery position and seek medical help. Keep him/her covered with warm clothing while seeking medical attention.

**Skin contact:** Remove the contaminated clothes immediately and cover the affected area with lots of water, then wash with water and neutral soap or with another product suitable for cleaning the skin. If symptoms occur, see a doctor.

**Eye contact:** Remove contact lenses. Rinse the eye with plenty of clean, fresh water for at least 15 minutes, pulling the eyelids up, until the irritation subsides. Immediately medical attention is required.

**Ingestion:** Request immediate medical treatment. NEVER cause vomiting. Never give anything by mouth to an unconscious person or with convulsions. Keep the patient at rest.

#### 4.2. Most important symptoms and effects, both acute and delayed.

Inhalation: can cause dizziness or fainting coughing nausea and headaches. Contact with skin can cause redness and in extended contact may cause skin to relapse.  
Contact with eyes can cause serious irritation, redness, pain, blurry vision.  
The accidental ingestion can cause gastrointestinal irritation and shut down central nervous system alongside nausea vomits vertigo and loss of consciousness.

#### 4.3. Indication of any immediate medical attention and special treatment needed.

The treatment should be directed to the control of the symptoms and the clinical conditions of the patient. In cases of doubt, or when symptoms of discomfort persist, seek medical attention. In case of aspiration inside the lungs, it can cause chemical pneumonia.

### 5. FIREFIGHTING MEASURES

#### 5.1. Methods of Extinguishment:

Extinguishing powder or CO<sub>2</sub>. In case of a serious fire also alcohol-resistant foam and water spray. Do not use for extinction: direct water jet. Direct water jet may not be effective in extinguishing fire as fire may spread.

#### 5.2. Special hazards arising from the substance or mixture:

The pressure can increase, and the container can explode in the case of heating or fire. The vapor is heavier than air and will expand through the floor. The vapors can accumulate in low, closed areas, travel a considerable distance to a source of ignition and produce a fire. The liquid residue that gets filtered through sewerage can cause a risk of fire or explosion. Because of the combustion or the thermic decomposition can form dangerous products: carbon monoxide, carbon dioxide. The exposure to the products of combustion or decomposition can prejudice your health. Carbon monoxide is highly toxic by inhalation. Carbon dioxide in sufficient amounts can behave as an asphyxiating gas. The product

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is toxic to aquatic life with long term effects. Avoid extinguishing water contaminated with this material to enter sewerage, drainage or water pipes.

### 5.3. Advice for firefighting personnel:

Special protection equipment for firefighters: Depending on the magnitude of the fire, full body protection equipment may be needed. If equipment is not available or not used, shut fire down from long distance.

Other recommendations: Refrigerate tanks, cisterns or containers near the source of heat or fire with water. Take into account the direction of the wind. Avoid that the products used in the fight against fire, go into drains, sewers or water courses.

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures:

Eliminate possible ignition points and electrostatic charges, ventilate the area. No Smoking. Avoid direct contact with the product. Avoid breathing vapors. Keep people without protection in a position opposite to the direction of the wind. Wear suitable respiratory protective equipment. Wear suitable clothing and gloves and eye / face protection. Avoid contact with the eyes, mucous membranes and sensitive areas of the skin. Contaminated clothing should be thoroughly cleaned.

### 6.2. Environmental precautions:

Absorb spills with sand, soil or other suitable absorbent material. Avoid the contamination of drains, surface or underground water, as well as soil. Avoid liquid to leak through water drain. In case of large spills, inform the authorities according with local legislation.

### 6.3. Methods and material for containment and cleaning up.

Proceed to collect the spillage with non-combustible absorbent materials (earth, sand, diatomaceous earth or vermiculite ...). Place the spill in an appropriate container for waste disposal..

### 6.4. Reference to other sections:

For contact information in case of emergency, see section 1.

For information on safe handling, see section 7.

For exposure control and individual protection measures, see section 8.

For the subsequent elimination of waste, see section 13.

## 7. HANDLING AND STORAGE

### 7.1. Precautions for safe handling.

Avoid any type of leak. Do not leave container open. Avoid contact in eyes, mucous membranes and sensitive skin areas. Do not eat, drink, smoke during its use. After use, wash hands and exposed skin.

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### 7.2. Conditions for safe storage, including any incompatibilities.

Protect from sunlight. Store at temperatures not exceeding 30°C. Keep in a cool place. The product must be stored isolated from heat and electrical sources. No smoking in storage area. If possible, avoid direct incidence of solar radiation. Store in a well ventilated place. Keep the container closed, in a dry and cool place. do not freeze.

### 7.3. Specific end uses.

Antiseptic for healthy skin. Biocide for human hygiene.

## 8. EXPOSURE CONTROL / PERSONAL PROTECTION

### 8.1. Control parameters.

Limits of professional exposure (VLA) of isopropyl alcohol

INSHT 2014 (RD. 39/1997)	YEAR	VLA-ED	VLAC-EC
Isopropyl alcohol	2011	200ppm;500mg/m <sup>3</sup>	400ppm; 1000 mg/m <sup>3</sup>

VLA= Environmental Limit Value ED = Daily Exposure EC= Short duration exposure

Level without a derivative effect (DNEL):

	Inhalation DNEL	Coetaneous DNEL	Oral DNEL
Level without a derivative effect, workers: Isopropyl Alcohol	-(a)500(c)mg/m <sup>3</sup>	-(a)888(c)mg/kg/bw/d	-(a)-(c)

Level without a derivative effect, general population:

Isopropyl Alcohol	-(a)89.0(c)	-(a)c319(c)	-(a)26.0(c)
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(a) Acute, short duration exposure (c) Chronic, prolonged or repeated exposure

### 8.2. Exposure controls

#### Appropriate technical controls.

When using the product ensure adequate ventilation and follow the principles of good occupational hygiene to control personal exposures. For this, good local ventilation must be carried out and a good general extraction system must be available. Avoid inhaling vapors. It is recommended to install emergency ocular sources near the area of use. It is recommended to install emergency showers near the area of use.

#### Individual protection measures, such as personal protective equipment.

Eye / face protection:

Face shield. Safety glasses with side protections against splashing liquids. Complete protection of the eyes. Contact lenses can pose an additional danger. Have an eyewash bottle containing clean water available.

Skin protection:

Wear suitable gloves. Preferred protection: nitrile gloves.

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### Respiratory protection:

The facilities, conditions of use and the amount of material handled will determine the type of personal protective equipment required.

Adequate protection for the respiratory tract at low concentrations: mask with type A filters (brown) for gases and vapors of organic compounds.

### **Environmental exposure controls.**

The work procedures to be followed and the degree of potential exposure should be taken into consideration, as this may determine whether a higher level of protection is required.

Avoid any spillage in the environment. Avoid emissions to the atmosphere.

Avoid ground contamination.

## **9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	Liquid
Color	Orange
Odor	Characteristic
pH	6,50 – 8,00
Density	0.872 g / cm <sup>3</sup>
Fusion point	Not available
Melting point	Not available
Boiling point	Not available
Solubility (water)	Soluble

## **10. STABILITY AND REACTIVITY**

### **10.1. Reactivity**

Due to the cationic nature of the Chlorhexidine salts, they are chemically incompatible with anionic compounds and detergents. Keep away from sulfates, borates, bicarbonates, chlorides ...

### **10.2. Chemical stability**

Stable under normal conditions of handling and storage.

### **10.3. Possibility of hazardous reactions**

Possible dangerous reaction with oxidizing agents.

### **10.4. Conditions to avoid**

Keep away from heat, sources of ignition and direct sunlight. In case of soft heating it decomposes, producing dangerous peroxides. Do not freeze.

### **10.5. Incompatible materials**

Keep away from oxidizing agents and strongly alkaline or acidic materials in order to avoid exothermic reactions.

Chemically incompatible with anionic compounds.

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### 10.6. Hazardous decomposition products

Combustion or thermal decomposition, emits toxic and irritants vapors.

## 11. TOXICOLOGICAL INFORMATION

See section 2

### 11.1. Information on toxicological effects:

#### Acute toxicity.

No experimental toxicological data (ingestion and inhalation) of the preparation as such are available. The toxicological information provided below, corresponds to the components:

#### Ingestion:

Chlorhexidine digluconate solution: LD50 oral (rat) >2000 mg/kg. The accidental ingestion can cause harm to human health. It may cause gastrointestinal irritation.

Isopropyl Alcohol: DL50 oral (rat) 5045 mg/kg

Inhalation: No information available. Can be harmful by inhalation.

Chlorhexidine digluconate solution: No available information. Can be harmful by inhalation.

Isopropyl Alcohol: CL50>72600 mg/m<sup>3</sup>

#### Skin contact:

The product is classified as a mild skin irritation (rabbits). Indication of primary irritation: 0,99 that corresponds to a mild response.

#### Eye contact

Eye irritant cat 2. Causes serious eye irritation.

#### **Skin corrosion/irritation**

The skin exposure of albino rabbit skin to the product showed no irritating effect with a primary index (IPI) of zero. Do not use on people sensitive to its components, or in large areas of the skin, or for a long time, or with non-breathable fabrics. Can cause skin or allergic reactions.

#### **Ocular corrosion/irritation**

Ocular irritant Cat2. Causes serious eye irritation

#### **Respiratory or skin sensitization**

Rare cases of allergic reactions to chlorhexidine have been reported. This product is not considered a skin sensitizer.

#### **Mutagenicity**

There is no evidence of a mutagenic potential

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### Carcinogenicity

There is no evidence that this product represents a carcinogenic risk under normal conditions of handling and use

### Reproductive toxicity

No evidence of toxicity for reproduction or development.

### Specific target organ systemic toxicity (STOT) - single exposure (SE) and / or repeated exposure (RE):

STOT SE 3. Specific toxicity with dizziness and vertigo effects. (Unique exposure)

Cat3. Neurological effects. Organs affected: SNC.

May cause dizziness or vertigo by inhalation

### Delayed, immediate and chronic effects due to short and long term exposure:

Short term exposure: The exposure to vapors above the occupational limit can produce adverse effects to the health, such as irritation of mucous membrane or respiratory, kidneys, liver, and central nervous system. The splashes in the eyes can cause eye irritation and reversible damage. If ingested it may cause irritation in throat or other effects that are described in the exposure to vapors.

Can be absorbed by inhaling vapor, through the skin or by ingestion.

Prolonged or repeated exposure: Repeated or prolonged contact can cause the removal of the skin's natural fat, resulting in non-allergic contact dermatitis and skin irritation.

## 12. ECOLOGICAL INFORMATION

### 12.1. Ecotoxicity

No experimental ecological data are available for the preparation.

The following ecological information generated corresponds to the components.

Chlorhexidine Digluconate solution:

EC50

Acute toxicity (fish): 2,08 mg/l (Chlorhexidine digluconate 20%)

Acute toxicity (daphnia magna): 0,087 mg/l (chlorhexidine digluconate 20%)

Acute toxicity (Algae): 0,081 mg/l (Chlorhexidine digluconate 20%)

(Factor M=10 for acute toxicity)

NOEC

Daphnia magna: 0,0206 mg/l (chlorhexidine digluconate 20%)

(Factor M=1 for chronic toxicity)

Isopropyl Alcohol:

CL50 (fish): 9,640 mg/l 96 hours

CE50 (daphnia): 13.300mg/l 48hours

CE50 (algae): >1.000 mg/l 72hours

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### 12.2. Persistence and Degradability

Chlorhexidine Digluconate solution, it is not easily degradable.  
Isopropyl alcohol, easily degradable.

### 12.3. Bioaccumulative potential

Not available.

### 12.4. Mobility in soil

Not available.

### 12.5. Results of PBT and vPvB assessment

Does not contain substances that meet the PBT / vPvB criteria

### 12.6. Other adverse effects

Toxic to aquatic life with long term effects.

## 13. DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

Take all necessary measures to avoid waste production as much as possible. Deposit in an authorized landfill or incinerate under controlled conditions, using an incinerator designed for the disposal of hazardous chemical waste. Do not discharge into drains or the environment.  
The disposal of the product and empty containers must be carried out in accordance with the local and national legislations in force

## 14. TRANSPORT CONSIDERATIONS

**14.1. UN number:** UN 1993

**14.2. UN proper shipping name:** Flammable liquid N.E.P. (contains isopropyl alcohol)

**14.3. Transport hazard class and packing group:** 3 / II

### 14.4.

Classification for Road transport (ADR) :

Class: 3

Packing group: II

Classification code: F1

Labels: 3

Limited and excepted quantities: 1 L (see total exemptions ADR 3.4)



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Classification for SEA transport(IMDG)

Class: 3

Packing group: II



Classification for Air transport IATA/ICAO

Class: 3

Packing group / Container: II



### Additional data for transport (ADR)

Excepted amounts (EQ): E2

Limited quantities (LQ): 1L

Transport category: 2

Restriction code in tunnel. D/E

### 14.5. Dangers for the environment

Harmful to aquatic life with long term effects.

Not marked. Special provision for signaling hazardous raw materials for the environment.

### 14.6. Particular precautions for users

Make sure that the people who transport the product know what to do in case of accident or spill.  
Always transport in closed containers that are upright.

## 15. REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/ legislation specific for the substance or mixture

The regulations applicable to this product are usually mentioned throughout this safety data sheet.  
Biocide for human hygiene.

### 15.2. Chemical safety assessment.

It's a mix

## 16. OTHER INFORMATION

Revision according to Regulation (EC) No 1907/2006 and Regulation No 453/2010

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**Full text of H-statements and P-statements referred to under sections 2 and 3.**

H-statements:

H319: Causes serious eye irritation.

H412: Harmful to aquatic life with long lasting effects.

P- statements:

P264: Wash thoroughly after handling.

P280: Wear eye protection.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313: If eye irritation persists: Get medical advice/attention.

P101: If medical advice is needed, have product container or label at hand.

P102: Keep out of reach of children.

P273: Avoid release to the environment.

P501: Dispose of contents / container according to legal regulations

**16.2.** The information contained in this document corresponds to our current knowledge, corresponds to a description of the established safety requirements of the product and should not be interpreted as a guarantee of the properties of the product. Therefore, it is the responsibility of the user to observe the corresponding regulations and regulations, under current legislation.