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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### 1.1 Product Identifier

**Material Name: Sodium Chloride 0.9% Irrigation/ Eye Wash Solution (Vioser S.A.)**

**Trade Name:** Not established

**Chemical Family:** Mixture

### 1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

#### Identified Use:

- α) Sodium chloride 0.9% Irrigation Solution is a sterile solution used for irrigation of body cavities, tissues, wounds, urethral catheters and generally irrigation wherein permitted to use a sterile and endotoxin-free electrolyte solution
- b) Sodium chloride 0.9% Eye Wash Solution is a sterile solution intended for washing, cleansing and for the irrigation of eyes that have been contaminated with particles or liquids.

### 1.3 Details of the Supplier of the Safety Data Sheet:

Vioser S.A.  
 9<sup>th</sup> km.National Road Trikala-Larissa,  
 Taxiarches ,Trikala  
 42100 Greece

### 1.4 Emergency telephone number:

Tel.: +30 24310 83441  
 Fax.: +30 24310 83550

## 2. HAZARDS IDENTIFICATION

### 2.1 Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### 2.2 Label Elements

**Signal Word:** Not Classified


**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

### 2.3 Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

#### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	GHS Classification	%
Sodium Chloride	7647-14-5	Not Listed	0.9
Water for injection	7732-18-5	Not Listed	q.s. to the corresponding volume

### 4. FIRST AID MEASURES

#### 4.1 Description of First Aid Measures

<b>Eye Contact:</b>	Due to the nature of this material first aid is not normally required. In case of effect, rinse with water for 15 minutes whilst lifting eyelid. Get medical attention if effects persist.
<b>Skin Contact:</b>	Due to the nature of this material first aid is not normally required. In case of effect, wash thoroughly with water.
<b>Ingestion:</b>	Due to the nature of this material first aid is not normally required. In case of ingestion, no action is required.
<b>Inhalation:</b>	Not an expected route of exposure. In case of inhalation, move individual to fresh air. Seek medical attention if effects persist.

#### 4.2 Most Important Symptoms and Effects, Both Acute and Delayed

<b>Symptoms and Effects of Exposure:</b>	No data available
<b>Medical Conditions Aggravated by Exposure:</b>	Not known

#### 4.3 Indication of the Immediate Medical Attention and Special Treatment Needed

<b>Notes to Physician:</b>	None
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### 5. FIRE FIGHTING MEASURES

**5.1 Extinguishing Media:** As for primary cause of fire, in case fire arises in vicinity

#### 5.2 Special Hazards Arising from the Substance or Mixture

<b>Hazardous Combustion Products:</b>	Not applicable Solution is water-based, therefore not flammable or explosive. Packaging is a Low Density Polyethylene and is not readily combustible but will give off CO, CO <sub>2</sub> and Carbon once on fire.
<b>Fire / Explosion Hazards:</b>	Not applicable

**5.3 Advice for Fire-Fighters** Fire fighters should wear approved self-contained breathing apparatus and full protective clothing.

### 6. ACCIDENTAL RELEASE MEASURES

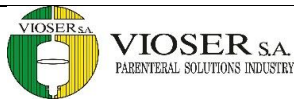
#### 6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Not applicable

#### 6.2 Environmental Precautions

None

#### 6.3 Methods and Material for Containment and Cleaning Up



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**Measures for Cleaning / Collecting:**

Wipe up with a damp cloth and place in container for disposal.

**Additional Consideration for Large Spills:**

None

6.4 Reference to other Sections Not applicable

## 7. HANDLING AND STORAGE

### 7.1 Precautions for Safe Handling

No special handling requirements for normal use of this material.

### 7.2 Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.  
**Incompatible Materials:** None

Specific end use(s): See section 1.2 Identified Use

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Control Parameters

EU Limit None  
GR Limit None


### 8.2 Exposure Controls

**Engineering Controls:** Not applicable  
**Eye/Face Protection:** Not required under normal conditions of use.  
**Skin Protection:** Not required for the normal use of this product.  
**Respiratory protection:** Not required under normal conditions of use.  
**Environmental Controls:** Not applicable.No environmental issues from the product's use is expected

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 information on basic physical and chemical properties

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colorless
<b>Odor:</b>	None	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	5.0-7.0		
<b>Kinematic Viscosity</b>	No data available		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient n-octanol/water</b>	Not applicable		
<b>Decomposition Temperature (°C):</b>	No data available		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Vapor Density:</b>	No data available		
<b>Viscosity:</b>	No data available		

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**Particle Characteristics** Not applicable

**Flammability:**

<b>Autoignition Temperature (°C):</b>	No data available
<b>Flammability):</b>	No data available
<b>Flash Point (°C):</b>	No data available
<b>Upper Explosive Limits ((% by Vol.):</b>	No data available
<b>Lower Explosive Limits (% by Vol.):</b>	No data available

**9.2 Other information**

**9.2.1 Physical hazard classes:** not applicable

**10. STABILITY AND REACTIVITY**

<b>10.1 Reactivity:</b>	No data available
<b>10.2 Chemical Stability:</b>	Stable under recommended storage and handling conditions
<b>10.3 Possibility of Hazardous Reactions</b>	No data available
<b>10.4 Conditions to Avoid:</b>	Avoid heat and do not freeze
<b>10.5 Incompatible Materials:</b>	Avoid Contact with agents, that could deteriorate the container
<b>10.6 Hazardous Decomposition Products:</b>	No data available

**11. TOXICOLOGICAL INFORMATION**

**Information on Hazard Classes as defined in Regulation (EC) No 1272/2008**

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**Short Term:** Mild eye irritant in experimental animals (based on components)

**Acute Toxicity: (Species, Route, End Point, Dose) : Not classified as harmful**

**SODIUM CHLORIDE**

Rat	Sub-tenon injection (eye)	LC50	0/1hr	> 42 g/m <sup>3</sup>
Rat	Oral	LD 50	3g/kg	
Mouse	Oral	LD 50	4g/kg	
Rabbit	Dermal	LD 50	> 10g/kg	

**Skin Corrosion/Irritation: (Study Type, Species, Severity)**

**SODIUM CHLORIDE**

Skin Irritation	Rabbit	Mild
Eye Irritation	Rabbit	Mild

<b>Respiratory or skin sensitization</b>	No data available
<b>Serious eye damage irritation</b>	No data available
<b>Germ cell mutagenicity</b>	Not applicable
<b>Carcinogenicity</b>	Not applicable



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<b>Reproductive toxicity</b>	Not applicable
<b>STOT-single exposure</b>	Not applicable
<b>STOT-repeated exposure</b>	Not applicable
<b>Aspiration hazard</b>	Not applicable

#### 11.2 Information on other hazards

11.2.1. **Endocrine disrupting properties** Not applicable

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** No harmful effects to aquatic organisms are expected.

**12.1 Toxicity:** No data available

**12.2 Persistence and Degradability:** No data available


**12.3 Bio-accumulative Potential:** No data available

**12.4 Mobility in Soil:** No data available

**12.5 Results of PBT and vPVP assessment** No data available

**12.6 Endocrine disrupting properties** Not applicable

**12.7 Other adverse effects** No data available

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### 13. DISPOSAL CONSIDERATIONS

**13.1 Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, RID , ADN, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

#### 15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

##### SODIUM CHLORIDE


CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

##### Water for injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present

The mixture is not subjected to Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (22), Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (23) or Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals.

**15.2 Chemical safety assessment** Not applicable

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## 16. OTHER INFORMATION

<b>Data Sources:</b>	Publicly available toxicity information.
<b>Reasons for Revision:</b>	Updated to New Format according to (EU) 2020/878 Regulation
<b>Revision date:</b>	19 October 2021
<b>Prepared by:</b>	Vioser S.A.

**End of Safety Data Sheet**

Vioser S.A. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.