

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## AQUA PURIFICATA

EN

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### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

|               |  |
|---------------|--|
| Product name: | Purified water<br>Aqua purificata<br>Water gezuiverd<br>Eau purifiée<br>Gereinigtes Wasser |
| N° CAS:       | 7732-18-5  |
| N° EC:        | 231-791-2  |

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

|                  |  |
|------------------|--|
| Identified uses: | Active Pharmaceutical Ingredient or Excipient. |
|------------------|--|

#### 1.3 Details of the supplier of the safety data sheet

|            |   |
|------------|---|
| Company:   | FRAVER NV<br>Keizershoek 336<br>2550 Kontich<br>Belgium |
| Telephone: | (+32) (0)3 457 11 76                                    |
| Email:     | info@magis-pharma.be                                    |
| Web page:  | www.magis-pharma.be                                     |

#### 1.4 Emergency telephone number

|                            |                         |                          |
|----------------------------|-------------------------|--------------------------|
| Public utility foundation: | Belgisch Antigifcentrum | Centre Antipoisons Belge |
| Telephone:                 | (+32) (0)70 245 245     | (Service 24/7)           |
| Web page:                  | www.antigifcentrum.be   | www.centreantipoisons.be |

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

The substance is not classified, according to the CLP regulation.

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

|                                       |                 |
|---------------------------------------|-----------------|
| Hazard pictogram(s):                  | Not applicable. |
| Signal word(s):                       | Not applicable. |
| Hazard statements:                    | Not applicable. |
| Precautionary statements:             | Not applicable. |
| Additional applicable label elements: | Not applicable. |

#### 2.3 Other hazards

Not available.

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### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

|                    |                          |
|--------------------|--------------------------|
| Product name:      | Purified water           |
| IUPAC name:        | Oxidane                  |
| Synonyms:          | Water<br>Distilled water |
| N° CAS:            | 7732-18-5                |
| N° EC:             | 231-791-2                |
| Molecular Formula: | H <sub>2</sub> O         |
| Content:           | 100 %                    |

#### 3.2 Mixtures

Not applicable.

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

|                     |  |
|---------------------|--|
| General notes:      | No special measures required.                                  |
| After inhalation:   | Supply fresh air and consult doctor in case of complaints.     |
| After skin contact: | Generally, the product does not irritate the skin.             |
| After eye contact:  | Immediately flush contaminated eyes with gently flowing water. |
| After ingestion:    | Rinse mouth with water. Do not induce vomiting.                |

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

Not available.

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

Not available.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

|                                 |   |
|---------------------------------|---|
| Suitable extinguishing media:   | Use fire fighting measures that suit the environment. |
| Unsuitable extinguishing media: | Not available.  |

#### 5.2 Special hazards arising from the substance/mixture

Not available.

#### 5.3 Advice for firefighters

|                                |                |
|--------------------------------|----------------|
| Surrounding fires:             | Not available. |
| Protection against fire:       | Not available. |
| Hazardous combustion products: | Not available. |

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### SECTION 6: ACCIDENTAL RELEASE MEASURES

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

##### For non-emergency personnel

Not available.

##### For emergency responders

Not available.

#### 6.2 Environmental precautions

Not available.

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

Absorb with liquid-binding material.

#### 6.4 Reference to other sections

Not available.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling: Not available.

Personal protection: Not available.

Technical protective measures: Not available.

Handling: Not available.

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

Storage: Store in cool, dry conditions in well-sealed recipients. Store between 2 °C and 8°C after opening of the packaging.

Conditions for safe storage, including any incompatibilities: Not available.

Storage – away from: Not available.

#### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

Not available.

#### 8.2 Exposure controls

##### Appropriate engineering control

Not available.

##### Individual protection measures

Eye/face protection: Goggles are recommended during refilling.

Skin protection: Not determined.

Hand protection: Protective gloves that satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

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Respiratory protection: Fresh air mask.  
Thermal hazards: Not determined.  
**Environmental exposure control**  
Not available.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

Appearance: Colourless fluid  
Odour: Odourless  
Odour threshold: Not available.  
pH: 6.0–8.0 (25 °C)  
Melting/freezing point: 0 °C (32 °F)  
Initial boiling point: 100 °C (212 °F)  
Boiling range: Not available.  
Flash point: Not available.  
Evaporation rate: Not available.  
Flammability (solid/gas): Not available.  
Upper/lower flammability or explosive limits: Not available.  
Vapour pressure: Not available.  
Vapour density: Not available.  
Relative density: 1.000 g/cm<sup>3</sup> (3,98 °C)  
Solubility: Not available.  
Solubility in water: Not available.  
Partition coefficient (n-octanol/water): Not available.  
Auto-ignition temperature: Not available.  
Decomposition temperature: Not available.  
Viscosity: Not available.  
Explosive properties: Not available.  
Oxidising properties: Not available.

#### 9.2 Other information

Not available.

### SECTION 10: STABILITY AND REACTIVITY

#### 10.1 Reactivity

Not available.

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### 10.2 Chemical stability

Not available.

### 10.3 Possibility of hazardous reactions

No hazardous reactions known.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

Not available.

### 10.6 Hazardous decomposition products

No hazardous decomposition products known.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

|  |                |
|--|----------------|
| Acute toxicity:                              | Not available  |
| Skin corrosion/irritation:                   | Not available. |
| Serious eye damage/irritation:               | Not available. |
| Respiratory/skin sensitisation:              | Not available. |
| Germ cell mutagenicity:                      | Not available. |
| Carcinogenicity:                             | Not available. |
| Reproductive toxicity:                       | Not available. |
| Summary of evaluation of the CMR properties: | Not available. |
| STOT-single exposure:                        | Not available. |
| STOT-repeated exposure:                      | Not available. |
| Aspiration Hazard:                           | Not available. |
| Other:                                       | Not available. |

### 11.2 Additional information on potential adverse human health effects and symptoms

|               |   |
|---------------|---|
| Eye contact:  | Not available.                          |
| Skin contact: | Not available.                          |
| Inhalation:   | May cause respiratory tract irritation. |
| Ingestion:    | Not available.                          |
| Aspiration:   | Not available.                          |

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not available.

### 12.2 Persistence and degradability

Not available.

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### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not applicable.

### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Recommendation: Smaller quantities can be disposed of with household waste. Considering local regulations, the product may be disposed of as wastewater after neutralisation. For uncleaned packaging: Disposal must be made according to official regulations.

## SECTION 14: TRANSPORT INFORMATION

### Transport information according to ADR/RID/IMDG/ICAO/IATA

#### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not dangerous goods.

#### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : No classified.

#### 14.6 Special precautions for user

Not available.

#### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

#### 14.8 Additional transport information

Not dangerous.

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### SECTION 15: REGULATORY INFORMATION

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

Not applicable.

#### 15.2 Chemical safety assessment

Not available.

### SECTION 16: OTHER INFORMATION

#### 16.1 Changes since the previous version

Not applicable.

#### 16.2 Abbreviations and acronyms used

|              |   |
|--------------|---|
| ADR:         | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| CAS:         | Chemical Abstracts Service (division of the American Chemical Society)              |
| EC (number): | European Community (number)   |
| IATA:        | International Air Transport Association   |
| ICAO:        | International Civil Aviation Organization   |
| IMDG:        | International Maritime Code for Dangerous Goods                                     |
| IUPAC:       | International Union of Pure and Applied Chemistry                                   |
| PBT:         | Persistent, Bioaccumulative and Toxic substance                                     |
| RID:         | Regulations Concerning the International Transport of Dangerous Goods by Rail       |
| STOT:        | Specific Target Organ Toxicity  |
| UN (number): | United Nations (number)   |
| vPvB:        | very Persistent and very Bioaccumulative  |

#### 16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

#### 16.4 Method of classification in case of mixture

Not applicable.

#### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

#### 16.6 Training advisement

Not available

#### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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### 16.8 Department issuing MSDS

Quality Department

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