



## STERILE HIGH PURITY WATER – 900ML TRIGGER SPRAY (105669) WFI QUALITY FOR CLEANING PURPOSES ONLY

STERILE HIGH PURITY WATER IS ONE OF THE SIMPLEST CLEANROOM SOLVENTS FOR SURFACE CLEANING. WATER IS AN EXCELLENT SOLVENT FOR IONIC SALTS AND SUGARS WHICH ARE OFTEN USED IN PREPARATIONS. IN ADDITION, IT IS IDEAL FOR REMOVING DISINFECTANT RESIDUES.

- STERILE HIGH PURITY WATER FOR THE REMOVAL OF DISINFECTANT RESIDUES, IONIC SALTS AND SUGARS.
- TRIGGER SPRAY IS OPTIMISED TO HELP REDUCE EXCESSIVE STRAIN ON THE OPERATOR.
- BAG-IN-BOTTLE TO MAINTAIN STERILITY IN USE, 13 WEEK IN-USE VALIDATED.
- MANUFACTURED USING WFI QUALITY WATER GUARANTEEING A LOW ENDOTOXIN LEVEL (LESS THAN 0.25 EU / ML) AND SUITABILITY FOR PRODUCT CONTACT AREAS.
- MANUFACTURED IN CLASS 100 CLEANROOMS.
- DOUBLE BAGGED AND BATCH CODED.
- FULLY TRACEABLE WITH SUPPORTING ANALYSIS.
- GAMMA IRRADIATION FOR STERILITY.
- TWO-YEAR UNOPENED SHELF LIFE.
- 900ML TRIGGER, 1000ML & 5 LITRE BOTTLES.



THE INFORMATION CONTAINED IN THIS DATA SHEET IS ACCURATE TO THE BEST OF OUR KNOWLEDGE AND BELIEF. NO WARRANTY IS, HOWEVER, GIVEN OR IMPLIED. CONSULT AGMA LTD CONCERNING ALL NON-STANDARD APPLICATIONS.

ISSUE NO. 2-10/22



## STERILE HIGH PURITY WATER – 1000ML BOTTLE SPRAY (0011) WFI QUALITY FOR CLEANING PURPOSES ONLY

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- **STERILE HIGH PURITY WATER FOR THE REMOVAL OF DISINFECTANT RESIDUES, IONIC SALTS, AND SUGARS.**
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- **FULLY TRACEABLE WITH SUPPORTING ANALYSIS.**
- **GAMMA IRRADIATION FOR STERILITY.**
- **TWO-YEAR UNOPENED SHELF LIFE.**
- **ALSO AVAILABLE IN 900ML TRIGGER & 5 LITRE BOTTLES.**



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## STERILE HIGH PURITY WATER – 5L BOTTLE (0006) WFI QUALITY FOR CLEANING PURPOSES ONLY

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- **STERILE HIGH PURITY WATER FOR THE REMOVAL OF DISINFECTANT RESIDUES, IONIC SALTS AND SUGARS.**
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- **MANUFACTURED IN CLASS 100 CLEANROOMS.**
- **DOUBLE BAGGED AND BATCH CODED.**
- **FULLY TRACEABLE WITH SUPPORTING ANALYSIS.**
- **GAMMA IRRADIATION FOR STERILITY.**
- **TWO-YEAR UNOPENED SHELF LIFE.**
- **ALSO, AVAILABLE IN 900ML TRIGGER, 1000ML & 5 LITRE BOTTLES.**



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ISSUE NO. 2-10/22



Agma Ltd Gemini Works Haltwhistle Northumberland England NE49 9HA Telephone 01434 320598 Fax 01434 321650  
 email:enquiries@agma.co.uk – website: www.agma.co.uk

## Product Specification

Date:12 April 2023  
 Issue Number:02  
 Review Date: April 23

<b>Product Name / Code</b>	Sterile High Purity Water 900mL T/Spray (105669) Sterile High Purity Water 1L Bottle (0011) Sterile High Purity Water 5L (0006)
<b>Packaging Type</b>	900mL Trigger Spray 1L capped bottle 5L poly
<b>Water Grade Used for Manufacture</b>	Complies with pharmacopoeia requirements of the USP and EP as specified for WFI-quality water
<b>Appearance</b>	Clear, Colourless Liquid
<b>Specific Gravity (S.G)</b>	1.000 -1.010
<b>Total Organic Carbon (TOC)</b>	≤ 8000ppb
<b>Bacterial Endotoxin Test</b>	<0.25 EU/ml
<b>Gamma Irradiation Dose Applied for Terminal Sterilisation</b>	25 – 45kGy

Prepared by Name:	P Franklin	Date:	12 April 2023
Position:	Director		

The information contained in this data sheet is accurate to the best of our knowledge. No warranty is, however, given or implied. Consult Agma Ltd concerning all nonstandard applications.

For health and safety and environmental information, please refer to the Agma Safety Data Sheet for this product. If you do not have this, we shall be pleased to send it on request



**AGMA Limited** Gemini Works, Haltwhistle, Northumberland, NE49 9HA, United Kingdom Tel: #44 1434 320598  
Email: enquiries@agma.co.uk - Website: www.agma.co.uk

## CERTIFICATE OF CONFORMITY

Customer:

Delivery Note / Certificate No.:

Despatch Note:

Customer PO:	Item Code: <b>105669</b>	Product Description & Pack Size: <b>STERILE WATER HIGH PURITY - 6 X 900 ML PER CASE</b>	Quantity:
Batch Number:	Date of Manufacture:	Expiry Date:	

### DECLARATION OF CONFORMITY

It is hereby certified that the supplies detailed hereon have been inspected and taken in accordance with the conditions and requirements of the contract or purchase order and, unless otherwise noted below, conform in all respects to the specification relevant thereto.

This certificate has been produced electronically by AGMA Limited in accordance to procedures documented via a quality management system certified to BSI ISO 9001:2015 registration FM 13868.

Issue Date:

## CERTIFICATE OF ANALYSIS

<b>Product</b>	Sterile High Purity Water (6 x 900 ml)	<b>Certificate No.</b>
<b>Product Code</b>	105669	
<b>Batch No.</b>		
<b>Date of Manufacture</b>		
<b>Date of Irradiation</b>		
<b>Date of Expiry</b>		
<b>TEST</b>	<b>SPECIFICATION</b>	<b>PASS/FAIL (RESULTS)</b>
<b>Appearance</b>	Clear colourless liquid	Pass
<b>SG @ 20°C</b>	1.000 – 1.010	Pass (     )
<b>DECLARATION OF CONFORMITY</b> It is hereby certified that the supplies detailed hereon have been inspected and are in compliance in all respects to the specification relevant thereto		

WFI-Quality Component: Externally Tested to EP/USP WFI Specifications		
<b>Test Results for Sample ID</b>		<b>Result Summary :</b>
<b>TEST</b>	<b>SPECIFICATION</b>	<b>RESULTS ( PASS/FAIL )</b>
<b>Conductivity</b>	< 5 µS	Pass (     )
<b>Bioburden Analysis</b>	<10cfu/100 ml	Pass ( cfu/100ml)

<b>Irradiation Certificate No.</b>		<b>Confirm irradiation dose complies with 25 – 45kGy:</b>	Complies	<b>Checked by:</b>	
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<b>Authorised Signatures</b>			<b>DATE</b>	
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It is hereby certified that above test results were carried out in accordance to procedures documented via a quality management system certified to BS ISO 9001:2015 registration FM 13868

**Agma Ltd**, Gemini Works, Haltwhistle, Northumberland NE49 9HA    Tel: # 44 1434 320598 Fax: #44 1434 321650 Email: [enquiries@agma.co.uk](mailto:enquiries@agma.co.uk)

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**SAFETY DATA SHEET**

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

- Product Name: WFI Grade Water
- Product Part Number: 0006, 0011, 203802, 203804, 105669

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

- Use of the substance/mixture: All Sectors

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

- Name of Supplier: Agma Ltd
- Address of Supplier: Gemini Works  
Haltwhistle  
Northumberland  
NE49 9HA  
UK
- Telephone: Tel: +44(0) 1434 320598
- Responsible Person: Malcolm Franklin
- Email: Sds@agma.co.uk

**1.4 Emergency telephone number**

- Emergency Telephone: Tel: +44(0) 1434 320598  
Monday - Thursday : 8:30 - 17:00 (GMT)  
Friday: 8:30 - 14:30(GMT)  
(office hours only)  
Out-of-hours Contact: Alan Barnes  
Tel: +44 (0)7936 966108

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**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture**

- CLP: The product is not classified as hazardous according to directive 1999/45/EEC

**2.2 Label elements**

- Signal Word: Not hazardous according to current CLP Regulations

**Hazard statements****Precautionary statements****2.3 Other hazards**

- Not a PBT according to REACH Annex XIII

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**SECTION 3: Composition/information on ingredients****3.2 Mixtures**

**SECTION 3: Composition/information on ingredients (....)****Water**

CAS Number:	7732-18-5
EC Number:	231-791-2
Concentration:	100%
Specific Concentration Limits:	None assigned
M factor:	Not available
Acute toxicity estimate:	Not available
Categories:	Not applicable

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**SECTION 4: First aid measures****4.1 Description of first aid measures****Contact with eyes**

Not applicable

**Contact with skin**

Not applicable

**Ingestion**

Not applicable

**Inhalation**

Not applicable

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

- Not hazardous

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

- Not applicable
- 

**SECTION 5: Firefighting measures****5.1 Extinguishing media**

- Not flammable. In case of fire use extinguishing media appropriate to surrounding conditions

**5.2 Special hazards arising from the substance or mixture**

- No hazard expected under normal conditions of use

**5.3 Advice for firefighters**

- No special precautions are required for this product
- 

**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

- No special precautions are required for this product

**6.2 Environmental precautions**



## **SECTION 6: Accidental release measures (....)**

- No special precautions are required for this product

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

- No special precautions are required for this product

### **6.4 Reference to other sections**

- None
- 

## **SECTION 7: Handling and storage**

### **7.1 Precautions for safe handling**

- No special precautions are required for this product

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

- No special precautions are required for this product

### **7.3 Specific end use(s)**

- No information available
- 

## **SECTION 8: Exposure controls/personal protection**

### **8.1 Control parameters**

- None assigned

### **8.2 Exposure controls**

- No special precautions are required for this product
- 

## **SECTION 9: Physical and chemical properties**

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

- Physical state: Liquid
- Colour: Colourless
- Odour: Odourless
- Melting point/Range: 0 C
- Boiling Point/Range: 100 C
- Flammability: Not flammable
- pH: 6-8
- Solubility in water: Completely soluble in water
- Density: 1.00 g/cm<sup>3</sup> at 20 °C
- Flashpoint: Not applicable

### **9.2 Other information**

- No information available
- 

## **SECTION 10: Stability and reactivity**

### **10.1 Reactivity**

- No hazardous reactions known if used for its intended purpose
-

## **SECTION 10: Stability and reactivity (....)**

### **10.2 Chemical stability**

- This article is considered stable under normal conditions

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

- No hazardous reactions known if used for its intended purpose

### **10.4 Conditions to avoid**

Extreme high or low temperatures

### **10.5 Incompatible materials**

- Contact with alkali metals may form explosive gases

### **10.6 Hazardous decomposition products**

- Decomposition products may include hydrogen
- 

## **SECTION 11: Toxicological information**

### **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

#### **Acute toxicity**

Not applicable

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

See Section 4.1.2

#### **Serious eye damage/irritation**

See Section 4.1.1

#### **Respiratory or skin sensitisation**

See Section 4.1

#### **Germ cell mutagenicity**

No evidence of mutagenic effects

#### **Carcinogenicity**

No evidence of carcinogenic effects

#### **Reproductive toxicity**

Not hazardous

#### **STOT (specific target organ toxicity) - single exposure**

Not hazardous

#### **STOT (specific target organ toxicity) - repeated exposure**

Not hazardous

#### **Aspiration hazard**

See Section 4.1.4

### **11.2 Information on other hazards**

- Not applicable
-

## **SECTION 12: Ecological information**

### **12.1 Toxicity**

- On available data, substance is not harmful to aquatic life

### **12.2 Persistence and degradability**

- Biodegradable

### **12.3 Bioaccumulative potential**

- No information available

### **12.4 Mobility in soil**

- Miscible with water

### **12.5 Results of PBT and vPvB assessment**

- Not identified as a PvB

### **12.6 Other adverse effects**

- No information available
- 

## **SECTION 13: Disposal considerations**

### **13.1 Waste treatment methods**

- Disposal should be in accordance with local, state or national legislation
- 

## **SECTION 14: Transport information**

### **Not classified as hazardous for transport**

#### **14.1 UN number or ID number**

- UN No.: Not applicable

#### **14.2 UN proper shipping name**

- Proper Shipping Name: Not applicable

#### **14.3 Transport hazard class(es)**

- Hazard Class: Not applicable

#### **14.4 Packing group**

- Packing Group: Not applicable

#### **14.5 Environmental hazards**

- Not Classified

#### **14.6 Special precautions for user**

- Not Classified

#### **14.7 Maritime transport in bulk according to IMO instruments**

- Not Classified
- 

## **SECTION 15: Regulatory information**

## **SECTION 15: Regulatory information (....)**

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

- This Safety Data Sheet is provided in compliance with the EC Regulation 1907/2006-2015/830
- and CLP (Regulation 1272/2008)

### **15.2 Chemical safety assessment**

- A chemical safety assessment (CSA) for this product has not yet been completed
- 

## **SECTION 16: Other information**

### **Legal Disclaimer**

- The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

--- end of safety datasheet ---

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