**GeminiBio**
920 Stillwater Road, Suite 130
West Sacramento, CA 95605
United States of America
Phone: 1 (800) 543-6464
Fax: 1 (916) 273-5222
geminibio.com

# GemPure™ Select Water for Injection (WFI) Quality Water (USP Grade)

# 901-001-XXX

| | |
|---|---|
| **Supplier:** | GeminiBio |
| **Manufacturing Site Address:** | 920 Stillwater Road, Suite 130 |
| (Company Headquarters) | West Sacramento, CA 95605 |
| | United States of America |
| **Contact Information:** | David Terry, dterry@geminibio.com |

## Approval

Signed by:
Sarah Fogenburg
Signer Name: Sarah Fogenburg
Signing Reason: I approve this document
Signing Time: 09 January 2025 | 16:58 PST
904DEAAAAE0A40B0A59478F34E1F59B8

Sarah Fogenburg

Senior Director, Quality

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## cGMP Statement

This is to certify that GeminiBio has manufactured the above products in accordance with all applicable current Good Manufacturing Practices as established in Title 21 Part 820 of the Code of Federal Regulations. This statement does not constitute the permission to use these products for API, final formulations, or therapeutic use. GeminiBio's products are manufactured for Research and further manufacturing use only.

## GMO Statement

Since genetically modified materials (GMO) were introduced ~ 30 years ago, there have been approvals around the world for use in agriculture for pest control and crop yields. Since the use of GMO materials, there has also been passionate discussions related to the safe use of GMO materials and biodiversity.

GeminiBio supports the scientific evidence related to the use of GMO materials and acknowledges the work of the regulatory bodies around the world. GeminiBio also acknowledges the counter arguments and will continue to monitor the scientific information that is being generated and assess the impact to our product lines. The products that are listed above do not contain any GMO materials in the manufacture of the products.

## Elemental Impurities Statement

GeminiBio's GemPure™ Select Water for Injection (WFI) Quality Water (USP Grade), catalog numbers 901-001-XXX, is produced using reverse osmosis and de-ionization methodologies. GeminiBio does not intentionally add any of the elements listed in the International Counsel for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ICH Q3D or the United States Pharmacopeia USP<232>.

## Residuals Solvents Statement

No solvents listed in the United States Pharmacopeia (USP <467>) and ICH Q3C are used in the manufacture of the products listed above. 2 propanol (Isopropyl alcohol) at a concentration of 70% is used as a cleaning agent for material packaging as it transits into the production environment but is not used on material surfaces that come into contact with the final product.

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## Nitrosamine Statement

**Background:**

Nitrosamines or N-nitrosamines refer to any molecule containing the nitroso functional group according to the World Health Organization (WHO). These compounds are of concern because they are potential human carcinogens. It was unexpected that these compounds were found in approved drugs like angiotensin II receptor blockers (ARBs) and Metformin. Due to this, the European Medicines Agency (EMA) finalized a review of Regulation (EC) No. 726/2004 in June of 2020 providing guidance to marketing authorization holders (MAH) on how to prevent and detect nitrosamine impurities in human drug products. The Assessment Report EMA/ 369136/36/2020 was published in June 2020 and adopted by the Committee for Medicinal Products for Human Use (CHMP).

The Food and Drug Administration (FDA) put out the position guidance; *Guidance for Industry: Control of Nitrosamine impurities in Human Drugs* published in February 2021. This document recommends steps that manufacturers of active pharmaceutical ingredients (API) or final drug products should take to prevent and detect unacceptable levels of these compounds being present in final drug products.

**GeminiBio Statement:**

GeminiBio does not manufacture API or final drug products but does serve the pharmaceutical market with ancillary reagents used in the manufacture of drug products and takes seriously the health risk that nitrosamines can cause. GeminiBio can state that nitrosamines are not primary raw materials of product contact surfaces nor are they introduced into the manufacturing process of the products listed above. To the best of our knowledge, nitrosamines are not a component in the raw materials that GeminiBio purchases from our suppliers.

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## TSE/BSE Statement

All components used during the production of GemPure™ Select Water for Injection (WFI) Quality Water (USP Grade), catalog numbers 901-001-XXX, have been evaluated to have been produced in a manner that GeminiBio would indicate that there is negligible risk for Transmissible Spongiform Encephalopathy Bovine Spongiform Encephalopathy (TSE/BSE) contamination The product does not contain, nor is derived from, specified risk material as defined in Commission Decision EMA 410/01/rev. 3. Materials were sourced from vendors where the risk of TSE/BSE would be classified as negligible due to their composition or production methods.

There is a possibility that some materials used in the manufacturing process may come into contact with tallows. As tallow derived additives may be used in the manufacture of the raw material the elimination of the risk of Bovine Spongiform Encephalopathy (BSE), Transmissible Spongiform Encephalopathy (TSE), "Mad cow" is certified based on the manufacturing process of the raw material.

The tallow derivatives used for the production of the plastic materials undergo a series of severe process steps during manufacture:

- Normally, pre-treatment of tallow and/or animal fat with strong acids
- Hydrolytic cleavage at temperatures above 200°C, under pressure, for more than 20 minutes
- Transesterification of the fatty acids with methanol at temperatures above 200°C, under high pressure, for more than 20 minutes
- Reduction of fatty acid methyl esters with hydrogen at temperatures above 200°C, under pressure for more than 20 minutes.

According to revised opinion of the EU scientific steering committee on the safety of Tallow (June 2001) and the recommendation for inactivation of TSE included (among others) in the Commission Directive 2000/6/EC, in the report of APAG of April 2001 and also in the Regulation (EC) N.1774/2002, the above-mentioned treatments do ensure a complete inactivation of any TSE/BSE agent regardless of the source and type of material. The additional exposure of the plastic materials to temperatures ranging from 150°C to 300°C during 30 seconds up to several minutes, represents an additional safety factor ensuring the complete protection in respect of TSE/BSE for plastic materials.

Thus, tallow derived materials used in the raw material of the products fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMA/410/01, rev. 3". GeminiBio suppliers declare that the tallow derivatives are category 3 materials and are manufactured under conditions given in the aforementioned Note for Guidance.

**Specified risk material as defined by the EC include a) The skull, including the brain and eyes, tonsils and spinal cord of bovine animals aged over 12 months and of bovine and caprine animals which are aged over 12 months or have a permanent incisor tooth erupted through the gum; b) The spleens of bovine and caprine animals.*

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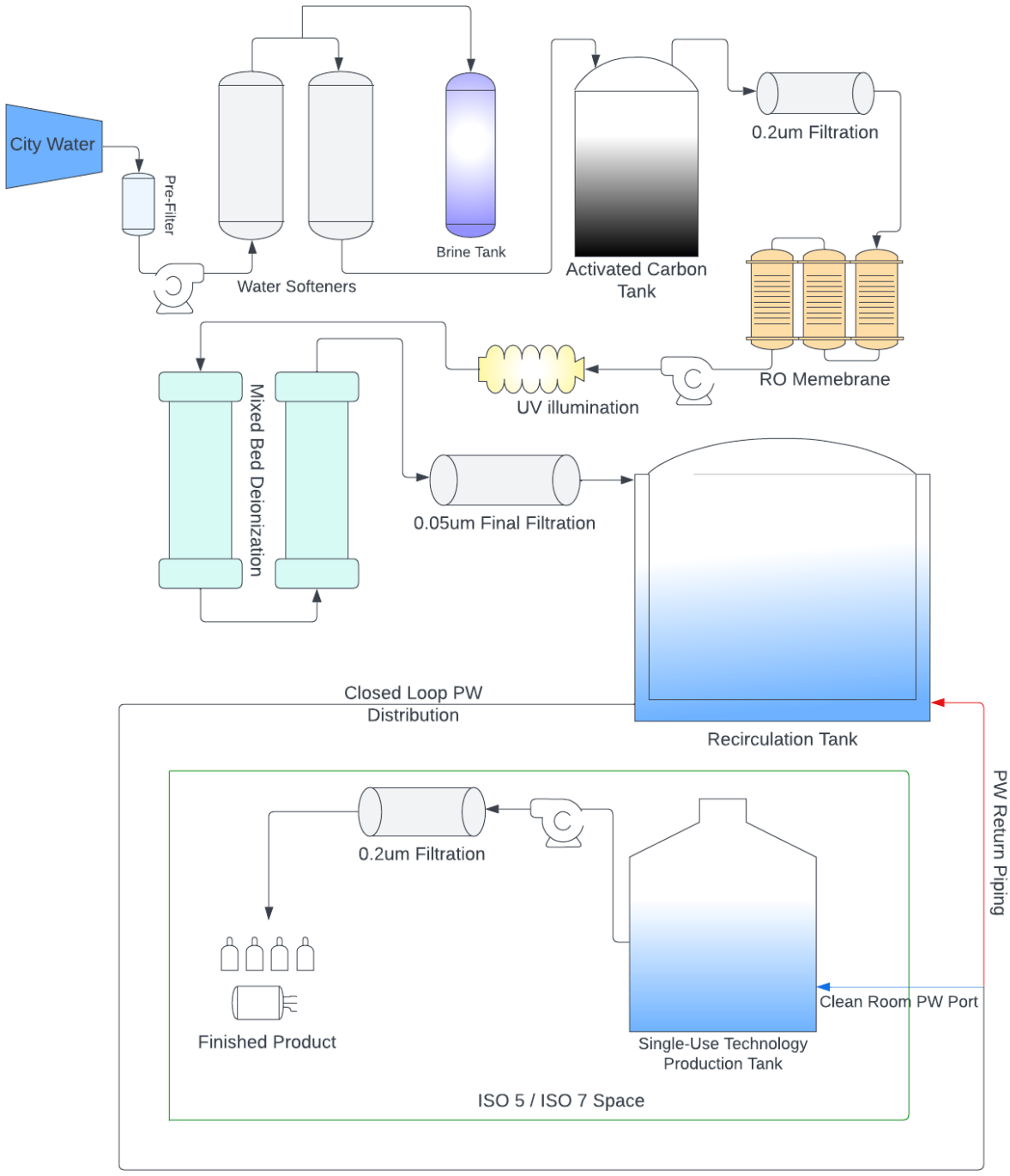
## Process Flow Diagram



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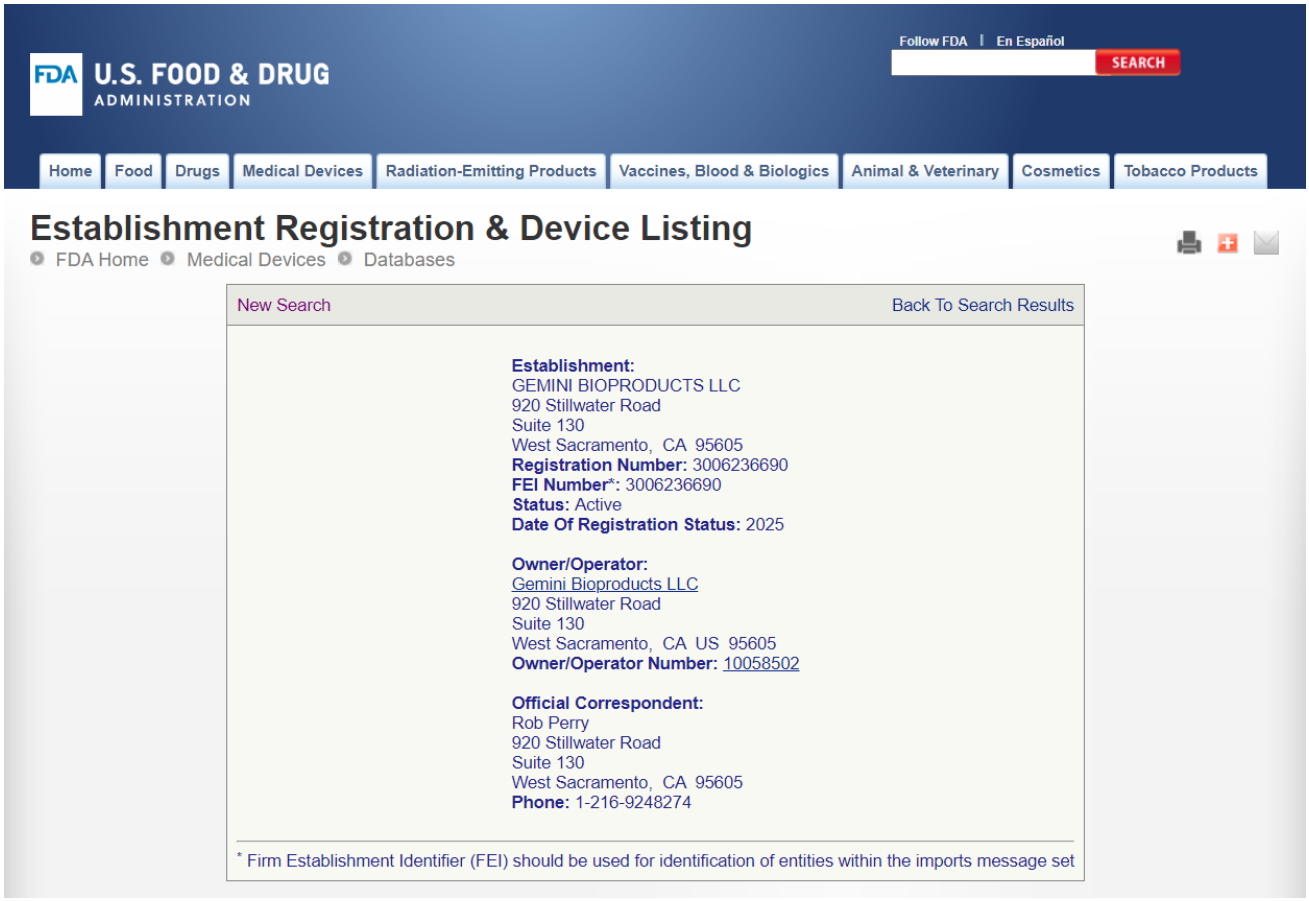
## FDA Registration



U.S. FOOD & DRUG ADMINISTRATION

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### Establishment Registration & Device Listing

FDA Home › Medical Devices › Databases

New Search — Back To Search Results

**Establishment:**
GEMINI BIOPRODUCTS LLC
920 Stillwater Road
Suite 130
West Sacramento, CA 95605
**Registration Number:** 3006236690
**FEI Number*:** 3006236690
**Status:** Active
**Date Of Registration Status:** 2025

**Owner/Operator:**
Gemini Bioproducts LLC
920 Stillwater Road
Suite 130
West Sacramento, CA US 95605
**Owner/Operator Number:** 10058502

**Official Correspondent:**
Rob Perry
920 Stillwater Road
Suite 130
West Sacramento, CA 95605
**Phone:** 1-216-9248274

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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## ISO 13485:2016 Certification

Certificate of Registration

nqa global assurance

This is to certify that the Quality Management System of:

**Gemini Bioproducts, LLC**
920 Stillwater Road, Suite 130
West Sacramento CA 95605
United States of America

Central function listed above. See appendix for additional locations

applicable to:

**Manufacture and supply cell culture media, sera, and other reagents**

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

**ISO 13485:2016**

For and on behalf of NQA, USA

ANAB
ANSI National Accreditation Board
ACCREDITED
ISO/IEC 17021-1
MANAGEMENT SYSTEMS
CERTIFICATION BODY

Certificate Number: 20173
EAC Code: 12
Certified Since: May 12, 2021
Valid Until: May 11, 2027
Reissued: May 14, 2024
Cycle Issued: May 14, 2024

Prior Cycle Exp Date: May 11, 2024

Page 1 of 2

This approval is subject to the company maintaining its system to the required standard, which will be monitored by NQA, USA, 289 Great Road, Suite 105, Acton, MA 01720, an accredited organization under the ANSI National Accreditation Board.

Certificate of Registration

nqa global assurance

Appendix to Certificate Number: 20173

**Includes Facilities Located at:**

**Gemini Bioproducts, LLC**
Certificate Number 20173
920 Stillwater Road, Suite 130
West Sacramento CA 95605
United States of America

Main Office. Manufacturing. Testing

**Gemini Bioproducts, LLC**
Certificate Number 20173
3230 Reed Avenue
West Sacramento CA 95605
United States of America

Shipping, Receiving, Warehousing (In process for Manufacturing and Testing)

Certified Since: May 12, 2021
Valid Until: May 11, 2027
Reissued: May 14, 2024
Cycle Issued: May 14, 2024

Page 2 of 2

This approval is subject to the company maintaining its system to the required standard, which will be monitored by NQA, USA, 289 Great Road, Suite 105, Acton, MA 01720, an accredited organization under the ANSI National Accreditation Board.

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## Quality Manual Cover Page and Table of Contents

| | | |
|---|---|---|
| GeminiBio | **Document #: QA.SOP.001** | **Effective: 08MAY2023** |
| | **Revision: 009** | **Page 1 of 23** |
| **Title: Quality System Manual** | | |

# Gemini Bioproducts, LLC
# Quality System Manual

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## List of Standard Operating Procedures (SOPs)

| Document Title |
|---|
| Add Contact to CID |
| Appearance Testing |
| Area Clearance |
| Aseptic Process Simulations |
| Aseptic Technique and Cleanroom Operations |
| Authorized Signatures |
| Boxing Procedure for Bottled and Bagged Product |
| Business Continuity and Disaster Recovery Plan |
| Certificate of Analysis Generation |
| Certificate of Origin Generation |
| Change Control |
| Chapter 4A Health Certificate Preparation and Review |
| Chapter 4C Health Certificate Preparation and Review |
| Chapter 4D Health Certificate Preparation and Review |
| Chemical Hygiene Plan |
| Chemical-Chemical Compatibility |
| Clean Out of Place (COP) Standard Operating Procedure |
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| Closing of a Work Order for Make to Stock Items |
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| Complaint System |
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| ComplianceWire User Management |
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| Control of Labels Procedure |
| Controlled Document Development, Approval, and Periodic Review |
| Controlled Material and Finished Product Specifications |
| Corrective and Preventive Actions |
| COVID-19 Prevention Program |

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| Document Title |
|---|
| Creating a Work Order in Sage |
| Creating and Marking of BIN Locations |
| Creating New Components or Finished Goods Items in Sage |
| Creating New Warehouse Bins in Sage |
| Custom Sales Request (CPAP) Process |
| Customer Data Collection (CDC) SOP |
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| Emergency Action Plan |
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| Employee Training Program and Requirements |
| Endosafe nexgen-PTS Use and Maintenance |
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| Equipment Risk and Requalification Frequency |
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| External Document Use and Revision Check |
| Facility Flows |
| Facility Walkthrough |
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| Final Inspection of Finished Product |
| Final Product Label Template Generation and Use |
| Finding Lot Numbers in Sage |
| Fundamentals of Good Documentation Practices |

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| Document Title |
|---|
| Gamma Irradiation Initiation, Processing, and Review |
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| Gowning Requirement for QC Lab |
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| How to Label Free Vendor Items |
| How to Link an External Testing PO to a WO |
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| Integrative Pest Management Plan |
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| Material-Chemical Compatibility |
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| Document Title |
|---|
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| Off-Site Physical Document Storage Program |
| Operation and Cleaning Procedures for the Precision Balances |
| Operation and Cleaning Procedures for the Water Baths |
| Operation and Maintenance of Biowelder Total Containment |
| Operation and Maintenance of Hot Lips Tube Sealer |
| Operation and Maintenance of Powered Industrial Trucks (PICs) |
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| Operation and Routine Maintenance of the BMT Sterivap 559 Sterilizer |
| Operation and Use of the Lasair III Aerosol Particle Counter |
| Operation and Use of the Sartocheck 4 plus Filter Integrity Tester |
| Operation of Atosa Freezers |
| Operation of Drive-In Freezer |
| Operation of Drive-In Refrigerator |
| Operation of Drum Lift |
| Operation of LVL Metolift |
| Operation of the Atosa Refrigerator |
| Operation of the Incubators |
| Operation of the Isonas Controlled Access System |
| Operation of the Labconco Biological Safety Cabinet |
| Operation of the Mesa ViewPoint Monitoring System |
| Operation of the OHAUS ES Series Bench Scale |
| Operation of the Peristaltic Pumps |
| Operation of the Process Refrigerated Glycol System |
| Operation of the Process Water System |
| Operation of the Walk-In Freezers |
| Operation of the Walk-In Refrigerator |
| Operation Procedure of the Heat Transfer Supply and Return (HTS-R) System Temperature Control Unit (TCU) |
| Operation Procedures for the Analytical Balances |
| Ordering Process |
| Orion Star A Series Conductivity Meter Use and Maintenance |
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| Osmette A, Model #5002 Use and Maintenance |
| Osmette XL, Model #5007 Use and Maintenance |
| Out of Tolerance (OOT) Procedure |
| Performance Management and Corrective Discipline Procedure |

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| Document Title |
|---|
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| Preventive Maintenance and Calibration Program |
| Printing Receipt Labels and Material Disposition |
| Process Automation System (PAS) Recipe Development |
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| Procurement Process |
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| Rework |
| Root Cause Investigation Procedure |
| Sales Order Shipping in Sage |
| Sales Request (SR) SOP |
| Sample Chain of Custody |
| Sartocheck 5 Filter Integrity Tester |
| Serum Reserve Rules |
| Sharps Policy and Procedure |
| Shipping with FedEx and UPS Applications |
| Significant Figures and Rounding |

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| Document Title |
|---|
| Site Master File |
| Sold Storage |
| Sold Storage Setup |
| Spectrophotometer Use and Maintenance |
| Standard Operating Procedure for Compressed Dry Air (CDA) System |
| Standard Operating Procedure for Filtration of Bioprocess Liquids |
| Standard Operating Procedure for Industrial Waste Water System |
| Standard Operating Procedure for Label Machine ID#1707 |
| Standard Operating Procedure for Sonitrol Access Controlled System |
| Standard Operating Procedure for the Clean-in-Place (CIP) Skid |
| Standard Operating Procedure for the MGA Technologies Aseptic Tube Sealer |
| Standard Operating Procedure for the Plant Steam System (Boilers) |
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| Standard Operation and Cleaning of 1000L Tank |
| Standard Operation of the OHAUS SD Series Bench Scale |
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| Supplier Reassessment |
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| Thrombin Challenge for Human Serum |
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| Tubing Set Assembly |
| USDA Tamper Proofing Process |
| Use and Maintenance of the Cary 3500 UV-Vis Spectrophotometer |
| Use and Maintenance of the Chemical Fume Hood |
| Use and Maintenance of the M9 Laboratory TOC Analyzer |
| Use and Maintenance of Torque Wrench |
| Use and Storage of LIGHTNIN Mixer |
| Validation Protocols and Reports |
| Warehouse and Inventory Management |
| Warehouse to Warehouse Inventory Transfer in Sage |

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| Document Title |
| --- |
| Work Alone Policy and Procedure |
| Work Order Template BOM Creation in Sage |
| Work Order Time Entry and Parts Usage |
| Workplace Violence Prevention Plan |

## Material Safety Data Sheet (MSDS)


**Safety Data Sheet**
**GemPure™ Select Water for Injection (WFI) Quality Water (USP Grade)**

**SDS Revision Date: 06/30/2023**

### 1. Identification

**1.1. Product identifier**

| | |
|---|---|
| **Product Identity** | GemPure™ Select Water for Injection (WFI) Quality Water (USP Grade) |
| **Catalog Number** | 901-001-XXX |

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

| | |
|---|---|
| **Intended use** | For further Manufacturing or Research use Only. Not for Direct Therapeutic Use. |

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

| | |
|---|---|
| **Company Name** | GeminiBio<br>920 Stillwater Rd., Suite 130<br>West Sacramento, CA 95605 |
| **Emergency**<br>**Customer Service: GeminiBio** | 1-800-543-6464 |

### 2. Hazard(s) identification

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

No applicable GHS categories.

**2.2. Label elements**

No applicable GHS categories.

**[Prevention]:**
No GHS prevention statements
**[Response]:**
No GHS response statements
**[Storage]:**
No GHS storage statements
**[Disposal]:**
No GHS disposal statements

### 3. Composition/information on ingredients

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

### Section 4. First aid measures

**4.1. Description of first aid measures**

| | |
|---|---|
| **General** | In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person. |
| **Inhalation** | Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious, place in the recovery position and obtain immediate medical attention. Give nothing by mouth. |
| **Eyes** | Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention. |
| **Skin** | Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser. |
| **Ingestion** | If swallowed obtain immediate medical attention. Keep at rest. Do NOT induce vomiting. |

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

| | |
|---|---|
| **Overview** | No specific symptom data available. Treat symptomatically. Check section 2.2 (GHS Label Elements) for further details. |

## Section 5. Fire-fighting measures

**5.1. Extinguishing media**

Recommended extinguishing media; alcohol resistant foam, $CO_2$, powder, water spray.
Unsuitable extinguishing media: Do not use; water jet.

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

Hazardous decomposition: No hazardous decomposition data available.

**5.3. Advice for fire-fighters**

As with all fires, wear positive pressure, self-contained breathing apparatus, (SCBA) with a full face piece and protective clothing. Persons without respiratory protection should leave area. Wear SCBA during clean-up immediately after fire. No smoking.

**ERG Guide No.** ----

## Section 6. Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**

Put on appropriate personal protective equipment (see section 8).

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

**6.2. Environmental precautions**

Do not allow spills to enter drains or waterways.

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

Ventilate the area and avoid breathing vapors. Take the personal protective measures listed in section 8. Contain and absorb spillage with non-combustible materials e.g. sand, earth, and vermiculite. Place in closed containers outside buildings and dispose of according to the Waste Regulations.

## Section 7. Handling and storage

**7.1. Precautions for safe handling**

Handle containers carefully to prevent damage and spillage.

Check section 2.2 (GHS Label Elements) for further details.

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

Incompatible materials: No available information

Check section 2.2 (GHS Label Elements) for further details. - [Storage]: Store product in 2°C - 30°C conditions.

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

No available information

## Section 8. Exposure controls / personal protection

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

**8.2. Exposure controls**

| | |
|---|---|
| **Respiratory** | If workers are exposed to concentrations above the exposure limit they must use the appropriate, certified respirators. |
| **Eyes** | Protective safety glasses recommended |
| **Skin** | Avoid skin contact. Protective gloves recommended. |
| **Engineering Controls** | Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn. |
| **Other Work Practices** | Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse. |

Check section 2.2 (GHS Label Elements) for further details.

## Section 9. Physical and chemical properties

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

| | |
|---|---|
| **Physical State** | Liquid |
| **Color** | Clear and colorless |
| **Odor** | No available information |
| **Odor threshold** | No available information |
| **pH** | 4.0 – 7.0 |
| **Melting point / freezing point** | No available information |
| **Initial boiling point and boiling range** | No available information |
| **Flash Point** | °F °C, Test method: (Open/Close cup) |
| **Evaporation rate (Ether = 1)** | No available information |
| **Flammability (solid, gas)** | No available information |
| **Upper/lower flammability or explosive limits** | **Lower Explosive Limit:** No available information<br>**Upper Explosive Limit:** No available information |
| **Vapor pressure (Pa)** | No available information |
| **Vapor Density** | No available information |
| **Relative Density** | No available information |
| **Solubility in Water** | No available information |
| **Partition coefficient n-octanol/water (Log Kow)** | No available information |
| **Auto-ignition temperature** | No available information |
| **Decomposition temperature** | No available information |

| | |
|---|---|
| **Viscosity (cSt)** | No available information |
| **Oxidising properties** | No available information |
| **Explosive properties** | No available information |

**9.2. Other information**

No other relevant information.

## Section 10. Stability and reactivity

**10.1. Reactivity**

Hazardous Polymerization will not occur.

**10.2. Chemical stability**

Stable under normal circumstances.

**10.3. Possibility of hazardous reactions**

No available information

**10.4. Conditions to avoid**

Avoid high temperatures and contact with incompatible material

**10.5. Incompatible materials**

No available information

**10.6. Hazardous decomposition products**

No hazardous decomposition data available.

## Section 11. Toxicological information

**Acute toxicity**

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

| Classification | Category | Hazard Description |
|---|---|---|
| Acute toxicity (oral) | --- | Not Applicable |
| Acute toxicity (dermal) | --- | Not Applicable |
| Acute toxicity (inhalation) | --- | Not Applicable |
| Skin corrosion/irritation | --- | Not Applicable |
| Serious eye damage/irritation | --- | Not Applicable |
| Respiratory sensitization | --- | Not Applicable |
| Skin sensitization | --- | Not Applicable |
| Germ cell mutagenicity | --- | Not Applicable |
| Carcinogenicity | --- | Not Applicable |
| Reproductive toxicity | --- | Not Applicable |
| STOT-single exposure | --- | Not Applicable |
| STOT-repeated exposure | --- | Not Applicable |
| Aspiration hazard | --- | Not Applicable |

## Section 12. Ecological information

**12.1. Toxicity**
No additional information provided for this product. See Section 3 for chemical specific data.
**Aquatic Ecotoxicity**
There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

**12.2. Persistence and degradability**
There is no data available on the preparation itself.
**12.3. Bioaccumulative potential**
No available information
**12.4. Mobility in soil**
No available information
**12.5. Results of PBT and vPvB assessment**
This product contains no PBT/vPvB chemicals.
**12.6. Other adverse effects**
No available information

## Section 13. Disposal considerations

**13.1. Waste treatment methods**
Observe all federal, state and local regulations when disposing of this substance.

## Section 14. Transport information

| | DOT (Domestic Surface Transportation) | IMO / IMDG (Ocean Transportation) | ICAO/IATA |
|---|---|---|---|
| **14.1. UN number** | Not Regulated | Not Regulated | Not Regulated |
| **14.2. UN proper shipping name** | Not Regulated | Not Regulated | Not Regulated |
| **14.3. Transport hazard class(es)** | **DOT Hazard Class:** Not Applicable<br>**Sub Class:** Not Applicable | **IMDG:** Not Applicable<br>**Sub Class:** Not Applicable | **Air Class:** Not Applicable<br>**Sub Class:** Not Applicable |
| **14.4. Packing group** | Not Applicable | Not Applicable | Not Applicable |

**14.5. Environmental hazards**
Marine Pollutant: No;
**14.6. Special precautions for user**
No available information

## Section 15. Regulatory information

| | |
|---|---|
| **Regulatory Overview** | The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented. |
| **Toxic Substance Control Act ( TSCA)** | All components of this material are either listed or exempt from listing on the TSCA Inventory. |

**EPCRA 302 Extremely Hazardous:**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**EPCRA 313 Toxic Chemicals:**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Carcinogens (>0.0%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Developmental Toxins (>0.0%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Female Repro Toxins (>0.0%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Male Repro Toxins (>0.0%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 Label Warning:**

This product contains no chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

## Section 16. Other information

**SDS Revision Date** 06/30/2023

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

Not Applicable

Disclaimer: The information presented herein is supplied as a guide to those who handle or use this product. Safe work practices must be employed when working with any materials. It is important that the end user makes a determination regarding the adequacy of the safety procedures employed during the use of this product.

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