



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™ Plus Water for Injection (WFI) Quality Water (USP/EP/JP Grade)

901-002-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 | 17:00 PST
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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™ Plus Water for Injection (WFI) Quality Water (USP/EP/JP Grade), catalog numbers 901-002-XXX, is analyzed for heavy metals (EP <2.4.8>), nitrates (EP 10), ammonium (EP 10), chlorides (EP 10<2.4.4>), sulfates (EP 10), calcium and magnesium (EP 10). USP<1231> give limits for different grades of water and USP<232> and the Food and Drug Administrations (FDA) / International Counsel for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ICH Q3D Elemental Impurities Guidance for Industry (September 2015) specify limits for elemental impurities. GeminiBio does not intentionally add any of the elements listed in ICH Q3D or USP<232> to the product or the manufacturing process.

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:s

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.



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 tallow. 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:

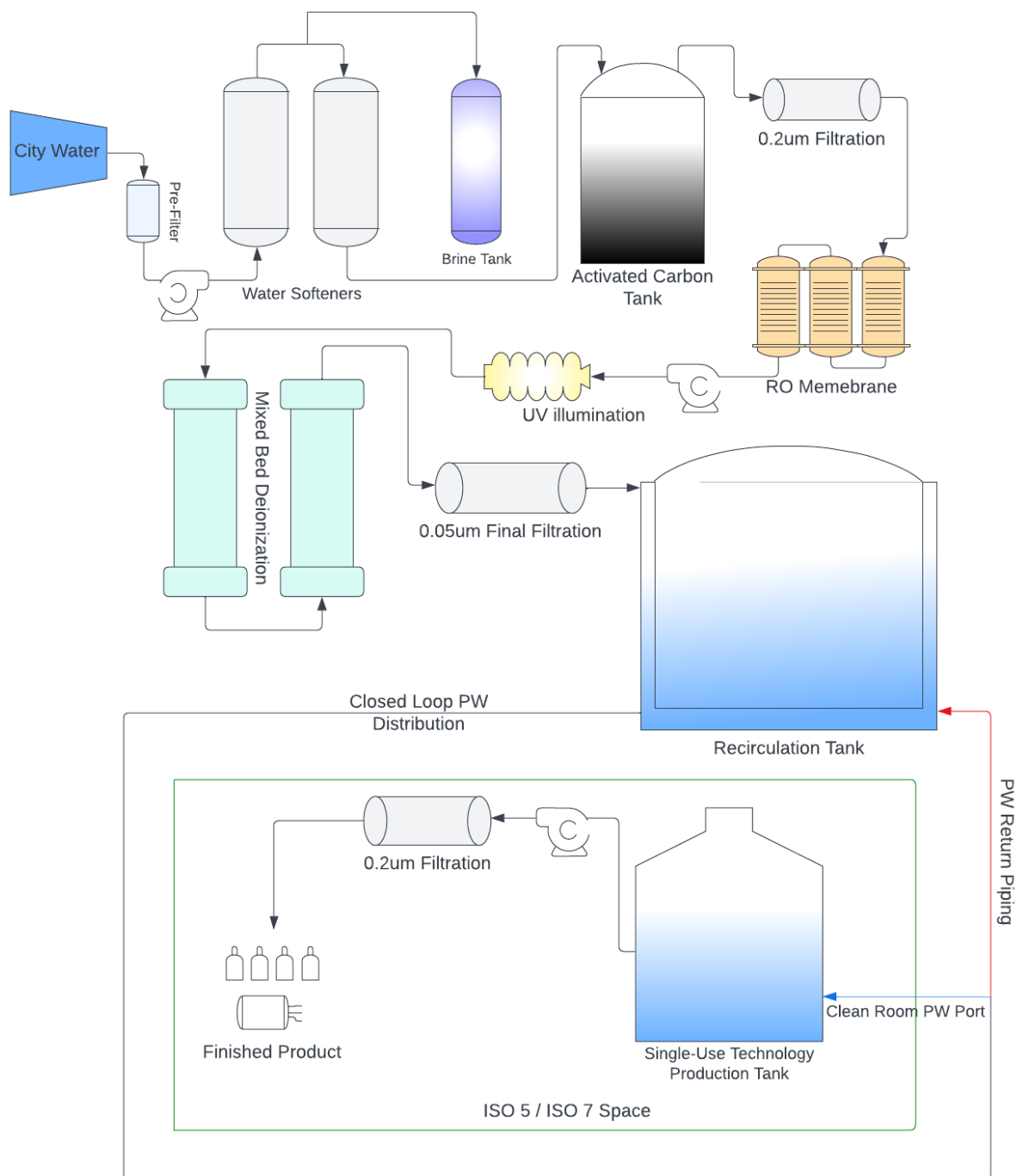
- Normally, pre-treatment of tallow and/or animal fat with strong acids
- Hydrolytic cleavage at temperatures above 200°C, under pressure, for more than 20 minutes
- Transesterification of the fatty acids with methanol at temperatures above 200°C, under high pressure, for more than 20 minutes
- Reduction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

Process Flow Diagram





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FDA Registration

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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



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

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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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 GeminiBio.	Document #: QA.SOP.001	Effective: 08MAY2023
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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
Cleaning Procedure of Warehouse Freezers and Refrigerators
Cleaning Process for Lab-ware and Utensils
Cleanroom Construction Maintenance and Monitoring Policy
Closing of a Work Order for Make to Stock Items
Collection and Testing of Water Monitoring Samples
Complaint System
ComplianceWire Training Management
ComplianceWire User Management
Component Number Assignment
Computer Systems Controls
Computerized Systems Validation
Contract Manufacturing Organization (CMO) SOP
Control of Customer Property
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
Data Integrity
Dedicated Shoe Cleaning Procedure
Determination and Measurement of Solution Density
Development Planning Procedure
Development/Tech Transfer of New Formulations
Deviation Reporting and Investigation
Device History Record Compilation
Distribution
Document Management Process Overview
EH&S Assessment for Large Volume Liquid Manufacturing
Electronic Signatures
Emergency Action Plan
Emergency Backup Generators
Emergency Shower and Eye Wash Test Procedure
Employee Training Program and Requirements
Endosafe nexgen-PTS Use and Maintenance
Environmental Monitoring Program
Eppendorf Micropipette Usage
Equipment Commissioning, Decommissioning and Tag Out
Equipment Risk and Requalification Frequency
EU Eligibility Separation Protocol
External Document Use and Revision Check
Facility Flows
Facility Walkthrough
Fall Protection Program
Filling of Bioprocess Liquids
Filter Selection Guideline
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
General Packaging
General Safety Rules
Gowning Qualification
Gowning Requirement for QC Lab
Gowning Requirements for Controlled Areas
Guidelines for Hazardous Materials Storage
Hazard Communication Program
Hazardous and Biological Waste Management
Heat Inactivation Process
How to Attach a Scanned Document to Sage
How to Check Sage Component Lot Number for Duplicates
How to Create a Purchase Order in SAGE
How to Invoice a Sales Order in Sage
How to Label Free Vendor Items
How to Link an External Testing PO to a WO
Importing Serum Into South Africa
Incoming Material
Injury and Illness Prevention Plan
In-Line Analysis using the M500 Sievers TOC and Conductivity Analyzer
Integrative Pest Management Plan
Internal Audit
Investigation and Reporting Out of Specification (OOS) Results
Issuance of Production Records for Product Manufacturing
Lot Disposition Procedure for GeminiBio Manufactured Products
Lot Disposition Procedure for OEM Products
Lot Number Assignment
Manufacturing Area Cleaning and Disinfection
Marketing Approval
Material Segregation and Status Labeling
Material-Chemical Compatibility
Memo Process
Monitoring and Review of Mesa ViewPoint Data and Alarms
N.I.S.T. Weight Traceability Procedure
New CID Creation
Nonconforming Material Reporting Procedure
NPS Customer Feedback Collection Process



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Document Title
Offboarding Procedure
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)
Operation and Maintenance of the Caron Environmental Chamber and Recirculating System
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 Sartochek 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
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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
Personal Protective Equipment
Preventive Maintenance and Calibration Program
Printing Receipt Labels and Material Disposition
Process Automation System (PAS) Recipe Development
Process Flow Between Sage/Scanco
Procurement Process
Product Execution Sheet (PES) SOP
Product Recall
Product Stability Testing
Product Transfer Between GeminiBio Locations
Purchasing Customer Supplied Materials
Purchasing Process
QC Inventory Management
QC Sampling Plan
Qualification and Routine Qualification Maintenance of CTU
Quality Metrics and Management Review
Quality Risk Management
Quality System Manual
Recruitment and Hiring Procedure
Relabeling Procedure
Reorder SOP
Repackaging Procedure
Request for Quote (RFQ) SOP
Reserves
Respiratory Protection Program
Retain Procedure for Finished Product
Review of In-Process Logs
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)
Standard Operating Procedure for the Pure Steam System
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Standard Operation of the OHAUS SD Series Bench Scale
Standard Operation Procedure for the 10,000L Solution Tank
Standard Operation Procedure for the 5,000L Solution Tank
Standard Operation Procedure for the Sterilize-in-Place System (SIP)
Standard Operation Procedure for the Water Purification System
Sterility Testing
Sticker Placement, Taping, and Storage of Shipping Boxes
Supplier Management
Supplier Reassessment
Temperature Monitoring for Controlled Temperature Units
Thrombin Challenge for Human Serum
Transfer Material in Sage
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



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Material Safety Data Sheet (MSDS)



GeminiBio
Empowering cell culture
and process liquid workflows

Safety Data Sheet
**GemPure™ Plus Water for
Injection (WFI) Quality Water
(USP/EP/JP Grade)**

SDS Revision
Date: 06/30/2023

1. Identification

1.1. Product identifier

Product Identity GemPure™ Plus Water for Injection (WFI) Quality Water (USP/EP/JP Grade)

Catalog Number 901-002-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
920 Stillwater Rd., Suite 130
West Sacramento, CA 95605

Emergency

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, CO₂, 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 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 Sub Class: Not Applicable	IMDG: Not Applicable Sub Class: Not Applicable	Air Class: Not Applicable 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.



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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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