

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Substance

Product Name: Sterile Water for Injection, USP

CAS-No.: 7732-18-5

1.2. Intended Use of the Product

Diluent water for injection

1.3. Name, Address, and Telephone of the Responsible Party

Manufacturer

Gland Pharma Limited

Unit-II, Plot No: 42-52

Sy.No. 166,171,172 & 177, TSIC,

Phase: IV Pashamylaram, Patancheru (M),

Sangareddy District, Hyderabad 502307 India

Tel +91-040-30510999

Distributor

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

<http://www.fresenius-kabi.com/us/>

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS

(800)255-3924 (North America)

+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Not classified

2.2. Label Elements

GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Name : Sterile Water for Injection, USP

CAS-No. : 7732-18-5

| Name | Synonyms | Product Identifier | % * | GHS Ingredient Classification |
|-------|----------|---------------------|-----|-------------------------------|
| Water | AQUA | (CAS-No.) 7732-18-5 | 100 | Not classified |

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

3.2. Mixture

Not applicable

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According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

Inhalation: Irritation is unlikely. When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists. If product is biologically contaminated, seek medical advice and follow all insitutional protocols concerning bodily contact with biological specimens.

Skin Contact: Irritation is unlikely. If product is biologically contaminated, seek medical advice and follow all insitutional protocols concerning bodily contact with biological specimens.

Eye Contact: Irritation is unlikely. If product is biologically contaminated, seek medical advice and follow all insitutional protocols concerning bodily contact with biological specimens.

Ingestion: If product is biologically contaminated, seek medical advice and follow all insitutional protocols concerning bodily contact with biological specimens.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation: Irritation is unlikely.

Skin Contact: Irritation is unlikely.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Irritation is unlikely.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Solutions do not burn. Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Non-combustible.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: None expected under normal conditions of use.

Other Information: No additional information available.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

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6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Soak up with inert absorbent material (for example sand, sawdust, a universal binder, silica gel). Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Material may be biologically contaminated with pathogenic organisms during use. Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

Handling Temperature: *Handle Sterile Water for Injection in the same manner as the Cetrorelix Acetate for Injection vial.* 8 – 30 °C (46 - 86 °F). Maximum cumulative time at temperatures >8°C (46 °F) is 24 hours. Do not use material exposed to temperature greater than 30 °C (86 °F).

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Water-reactive materials.

Storage Temperature: *Store Sterile Water for Injection in the same manner as the Cetrorelix Acetate for Injection vial.* 2 – 8 °C (36 - 46 °F). DO NOT FREEZE.

7.3. Specific End Use(s)

Diluent water for injection

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles or glasses.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical goggles or safety glasses.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Environmental Exposure Controls: Avoid unnecessary release into the environment.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid

Appearance : Clear, colorless solution

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| | |
|---|---------------------------|
| Odor | : Odorless |
| Odor Threshold | : No data available |
| pH | : 5 – 8 |
| Evaporation Rate | : No data available |
| Melting Point | : 0 °C (32 °F) |
| Freezing Point | : 0 °C (32 °F) |
| Boiling Point | : 100 °C (212 °F) |
| Flash Point | : No data available |
| Auto-ignition Temperature | : No data available |
| Decomposition Temperature | : No data available |
| Flammability (solid, gas) | : Not applicable |
| Lower Flammable Limit | : No data available |
| Upper Flammable Limit | : No data available |
| Vapor Pressure | : No data available |
| Relative Vapor Density at 20°C | : No data available |
| Relative Density | : 1.0 [Water = 1.0] |
| Specific Gravity | : 1.0 |
| Solubility | : Water: Miscible/soluble |
| Partition Coefficient: N-Octanol/Water | : No data available |
| Viscosity | : No data available |

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

Water-reactive materials.

10.6. Hazardous Decomposition Products:

None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Likely routes of exposure: Dermal, Eye Contact, Inhalation, Oral.

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

No additional information available

Skin Corrosion/Irritation: Not classified

pH: 5 – 7

Eye Damage/Irritation: Not classified

pH: 5 – 7

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Irritation is unlikely.

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Symptoms/Injuries After Skin Contact: Irritation is unlikely.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Irritation is unlikely.

Chronic Symptoms: None expected under normal conditions of use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data: No additional information available

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

No additional information available

12.2. Persistence and Degradability

| Sterile Water for Injection, USP (7732-18-5) | |
|--|--|
| Persistence and Degradability | Not expected to be harmful to aquatic organisms. |

12.3. Bioaccumulative Potential

| Sterile Water for Injection, USP (7732-18-5) | |
|--|--------------------------------|
| Bioaccumulative Potential | Not expected to bioaccumulate. |

12.4. Mobility in Soil

| Sterile Water for Injection, USP (7732-18-5) | |
|--|------------------------|
| Ecology - Soil | Adsorbs into the soil. |

12.5. Other Adverse Effects

Other Adverse Effects: None known.

Other Information: Avoid unnecessary release into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Treatment Methods: Can be landfilled, when in compliance with local regulations.

Sewage Disposal Recommendations: Do not dispose of waste into sewer. Do not empty into drains.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Additional Information: Biologically contaminated materials should be incinerated.

Ecology - Waste Materials: Avoid unnecessary release into the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

| Water (7732-18-5) | |
|--|--|
| Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active | |

15.2. US State Regulations

Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed.

15.3. Canadian Regulations

| Water (7732-18-5) | |
|---|--|
| Listed on the Canadian DSL (Domestic Substances List) | |

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SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest : 04/09/2024

Revision

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)

AU_WES: Australia WES

CHEMVIEW: ChemView (U.S. Environmental Protection Agency)

EC_RAR: European Commission Renewal Assessment Report

EC_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits

ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports

ECHA_API: European Chemicals Agency API

ECHA_RAC: ECHA Committee for Risk Assessment

EFSA: European Food Safety Authority

EPA: U.S. Environmental Protection Agency

EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)

EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)

EPA_HPVC: High Production Volume Chemicals (U.S. Environmental Protection Agency)

EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)

EU_CLH: European Union Harmonised Classification and Labelling Proposal

EU_RAR: European Union Risk Assessment Report

FOOD_JOURN: Food Research Journal (1956)

IARC: The International Agency for Research on Cancer

IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles

IUCLID: International Uniform Chemical Information Database

JAPAN_GHS: Japan GHS Basis for Classification Data

JP_J-CHECK: Japan J-Check

KR_NIER: South Korea National Institute of Environmental Research Evaluations

NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme

NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)

NLM_CIP: National Library of Medicine ChemID plus database

NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank

NLM_PUBMED: National Library of Medicine PubMed database

NTP: National Toxicology Program

NZ_CCID: New Zealand Chemical Classification and Information Database

OECD_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)

OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)

WHO: World Health Organization

NFPA Health Hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA Fire Hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

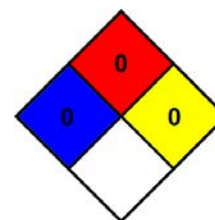
NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.

HMIS III Rating

Health : 0 Minimal Hazard - No significant risk to health

Flammability : 0 Minimal Hazard

Physical : 0 Minimal Hazard



This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)