

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations
Date of Issue: 06/18/2025

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier Product Form: Mixture

Product Name: Dexmedetomidine in 5% Dextrose Injection
1.2 Recommended Use and Restrictions on Use

Use Of The Substance/Mixture : Dexmedetomidine is a selective alpha 2-adrenergic receptor agonist used clinically

as a pre-operative adjunct of general anesthesia.

Restrictions On Use : No additional information available

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

Company

WG Critical Care, LLC 120 Route 17 North, Suite 115 Paramus, NJ 07652 USA + 1-888-493-0861

wgccquality@wgcriticalcare.com https://www.wgcriticalcare.com/

1.4. Emergency Telephone Number

Emergency Number: +1-866-562-4708 (ProPharma)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Not classified.

2.2. Label Elements

GHS-US Labeling

No labeling applicable according to 29 CFR 1910.1200.

2.3 Hazards associated with known or reasonably anticipated uses

This product is a pharmaceutical product designed for administration to a patient by a qualified medical professional. No other uses are anticipated. If this product is used in unforeseeable chemical processes and not used as intended or reasonable, the hazards listed in Section 2.3 cannot cover all chemistries. Therefore, a Process Hazard Analysis (PHA) or other hazard assessment for additional specific end uses should be performed to ensure that hazards are fully understood, and adequate safety measures are in place. See Section 10 for relevant reactivity and stability information.

2.4. Other Hazards

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

2.5. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS US classification
Water	AQUA	(CAS-No.) 7732-18-5	80 – 100	Not classified.
.alphaD- Glucopyranose, monohydrate	.alphad-Glucopyranose monohydrate	(CAS-No.) 14431-43-7	3-7	Combustible Dust
Dexmedetomidine hydrochloride	1H-Imidazole, 5-[(1S)-1-(2,3-dimethylphenyl)ethyl]-, hydrochloride (1:1) / (+)-4-(S)-[1-(2,3-Dimethylphenyl)ethyl]-1H-imidazole hydrochloride Dexmedetomidine hydrochloride	(CAS-No.) 145108-58-3	< 0.01	Acute Tox. 4 (Oral), H302 Repr. 2, H361 STOT SE 1, H370

^{*} The actual concentration of ingredient(s) is withheld as a trade secret in accordance with 29 CFR 1910.1200. 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%). Full text of H-statements: see section 16.

06/18/2025 EN (English US) 1/6

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

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.

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: None expected under normal conditions of use.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes. Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects. 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. Accidental injections should be treated as a medical emergency. Effects will vary dependent upon the type and quantity of material injected, but will generally include swelling, redness, and pain at the injection site. Treatment may require the administration of epinephrine; neostigmine may be useful in cases of bradycardia. Atropine usage poses the risks of hypertension and cardiac arrhythmia and should generally be avoided.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media suitable for surrounding type of fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

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: Oxides of carbon and nitrogen plus chlorine compounds.

Other Information: No additional information available.

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: 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. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

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.

06/18/2025 EN (English US) 2/6

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb liquid components with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). 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.

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. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with established protocols.

Handling Temperature: See Section 7.2, Storage, for suggested temperature range.

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: See Section 7.2, Storage, for suggested temperature range.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 20 – 25 °C (68 – 77 °F). Excursions permitted to 15 °C to 30 °C (59 °F to 86 °F). DO NOT FREEZE!

Storage Area: Keep away from heat.

7.3. Specific End Use(s)

Dexmedetomidine is a selective alpha 2-adrenergic receptor agonist used clinically as a pre-operative adjunct of general anesthesia

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), or OSHA (PEL).

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 Skin and Body Protection : Chemical goggles or safety glasses.: 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

Color : Clear, colorless liquid
Odor : No data available
pH : 4.5 – 7.0

pH : 4.5 – 7.0

Melting Point : No data available

06/18/2025 EN (English US) 3/6

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

Freezing Point : No data available **Boiling Point** : No data available **Flash Point** : No data available **Auto-ignition Temperature** : No data available **Decomposition Temperature** : No data available : Not flammable Flammability (solid, gas) **Vapor Pressure** : No data available : No data available Relative Vapor Density at 20°C **Relative Density** : No data available Density : No data available Solubility : Soluble in water. Partition Coefficient: N-Octanol/Water : No data available Viscosity, Kinematic : No data available **Particle characteristics** : No data available

9.2. Other Information

No additional information 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, Including those Associated with Foreseeable Emergencies

Hazardous polymerization will not occur. Under fire conditions, thermal decomposition products include the following: Oxides of carbon and nitrogen plus chlorine compounds.

10.4. Conditions to Avoid

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

10.5. Incompatible Materials

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products

Thermal decomposition may produce: Oxides of carbon and nitrogen plus chlorine compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Likely Routes of Exposure: Dermal, Ingestion, Inhalation, Eye contact

Acute Toxicity (Oral): Not classified.
Acute Toxicity (Dermal): Not classified.
Acute Toxicity (Inhalation): Not classified.

Water (7732-18-5)	
LD50 Oral Rat	> 90 ml/kg (Source: FOOD_JOURN)
Dexmedetomidine hydrochloride (145108-58-3)	
ATE (Oral)	500.00 mg/kg body weight

Skin Corrosion/Irritation: Not classified.

pH: 4.5 - 7.0

Serious Eye Damage/Irritation: Not classified.

pH: 4.5 – 7.0

Respiratory or Skin Sensitization: Not classified.

Germ Cell Mutagenicity: Not classified.

Carcinogenicity: Not classified. **Reproductive Toxicity:** Not classified.

Specific Target Organ Toxicity (Single Exposure): Not classified.

Specific Target Organ Toxicity (Repeated Exposure): Not classified.

Aspiration Hazard: Not classified.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation. **Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes. **Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

06/18/2025 EN (English US) 4/6

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

12.2. Persistence and Degradability

Dexmedetomidine in 5% Dextrose Injection	
Persistence and Degradability	Easily biodegradable.

12.3. Bioaccumulative Potential

Dexmedetomidine in 5% Dextrose Injection	
Bioaccumulative Potential	Inherently biodegradable.

12.4. Mobility in Soil

Dexmedetomidine in 5% Dextrose Injection	
Ecology - Soil	Leaches if exposed to water.

12.5. Other Adverse Effects

Other Adverse Effects : None known.

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Treatment Methods: Non hazardous waste – landfill or incinerate. **Sewage Disposal Recommendations:** Do not dispose of waste into sewer.

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 release to 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

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Dexmedetomidine in 5% Dextrose Injection		
SARA Section 311/312 Hazard Classes	Health hazard - Specific target organ toxicity (single or repeated exposure)	
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.

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

Date of Preparation or Latest Revision : 06/18/2025

Other Information : This document has been prepared in accordance with the SDS requirements of the

OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

H302	Harmful if swallowed
H361	Suspected of damaging fertility or the unborn child
H370	Causes damage to organs.

06/18/2025 EN (English US) 5/6

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

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

 ${\tt EC_SCOEL:} \ \ {\tt European \ Commission \ Scientific \ Committee \ on \ Occupational}$

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

EFSA: European Food Safety Authority EPA: U.S. Environmental Protection Agency

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

Agency)

 ${\sf EPA_FIFRA:}\ \ {\sf Federal\ Insecticide, Fungicide, and\ Rodenticide\ Act\ Reregistration}$

Eligibility Decision (U.S. Environmental Protection Agency)

EPA_HPV: 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

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.

SDS US (GHS HazCom)

06/18/2025 EN (English US) 6/6