

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Foscarnet Sodium Injection

1.2. Intended Use of the Product

Use Of The Substance/Mixture: Pharmaceutical.

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

Manufacturer Name: Fresenius Kabi Austria GmbH

Address: Hafnerstrasse 36

Graz, 8055

Austria

General Phone Number: +43.316.249.0

Website: www.fresenius-kabi.com

Distributor Name: Fresenius Kabi USA, LLC

Address: Three Corporate Drive

Lake Zurich, Illinois 60047

USA

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

Website: www.fresenius-kabi.com/us/

1.4. Emergency Telephone Number

Emergency Number : ChemTel LLC

(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

Muta. 2 H341

Repr. 2 H361

STOT RE 1 H372

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA) :



GHS08

Signal Word (GHS-US/CA) : Danger

Hazard Statements (GHS-US/CA) : H341 - Suspected of causing genetic defects.
H361 - Suspected of damaging fertility or the unborn child.
H372 - Causes damage to organs (kidneys) through prolonged or repeated exposure (oral).

Precautionary Statements (GHS-US/CA) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe vapors, mist, or spray.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.

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P280 - Wear protective gloves, protective clothing, and eye protection.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P314 - Get medical advice/attention if you feel unwell.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions. May cause damage to organs (blood, hematopoietic system, cardiovascular system, nervous system) through prolonged or repeated exposure (oral).

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

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	AQUA / water	(CAS-No.) 7732-18-5	> 97	Not classified
Foscarnet sodium	Phosphinecarboxylic acid, dihydroxy-, oxide, trisodium salt, Dihydroxyphosphinecarboxylic acid oxide trisodium salt, Phosphonoformic acid, trisodium salt, Trisodium carboxyphosphate, Trisodium phosphonoformate	(CAS-No.) 63585-09-1	2.4	Muta. 2, H341 Repr. 2, H361 STOT RE 1, H372
Hydrochloric acid	Hydrogen chloride / Muriatic acid / HYDROCHLORIC ACID / Hydrochloric acid, anhydrous / hydrochloric acid	(CAS-No.) 7647-01-0	Q.S. (<0.1%) (pH adjustment)	Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Nitrogen	Nitrogen gas / Nitrogen, liquefied / NITROGEN / Nitrogen, compressed / nitrogen	(CAS-No.) 7727-37-9	Q.S. (headspace)	Simple Asphyxiant

Full text of H-phrases: see section 16

*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%).

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).

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

Skin Contact: Remove contaminated clothing. Wash with plenty of soap and water. Obtain medical attention if irritation develops or persists.

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.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure. Suspected of causing genetic defects.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

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Injection: Common clinical side effects include: pain or swelling at injection site, nausea, vomiting, headache, diarrhea, dizziness, loss of appetite, diaphoresis, anxiety, urticaria, visual disturbances, tiredness, joint or muscle pain, abnormal renal function, hypotension, hyponatremia, albuminuria and seizures.

Chronic Symptoms: Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure. Suspected of causing genetic defects.

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: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

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: None expected under normal conditions of use.

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: Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray.

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

Avoid unnecessary release into environment.

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. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal.

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

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not handle until all safety precautions have been read and understood. Do NOT breathe (dust, vapor, mist, gas). Avoid contact with eyes, skin and clothing.

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. For Single Use Only. Foscarnet Sodium Injection, should be used only if the bottle and seal are intact, a vacuum is present, and the solution is clear and colorless.

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Storage Conditions: Protect from excessive heat (above 40°C) and from freezing. If refrigerated or exposed to temperatures below the freezing point, precipitation may occur. By keeping the bottle at room temperature with repeated shaking, the precipitate can be brought into solution again.

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

Storage Temperature: Store between 20° and 25°C (68° and 77°F) [See USP Controlled Room Temperature].

Storage Area: Do not freeze.

Special Rules on Packaging (From Package Insert): For Single Use Only. Store between 20° and 25°C (68° and 77°F) [See USP Controlled Room Temperature]. Protect from excessive heat (above 40°C) and from freezing. If refrigerated or exposed to temperatures below the freezing point, precipitation may occur. By keeping the bottle at room temperature with repeated shaking, the precipitate can be brought into solution again. Foscarnet Sodium Injection, should be used only if the bottle and seal are intact, a vacuum is present, and the solution is clear and colorless.

7.3. Specific End Use(s)

Pharmaceutical.

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.

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
USA OSHA	OSHA PEL C [ppm]	5 ppm
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	7 mg/m ³
USA NIOSH	NIOSH REL C [ppm]	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
Alberta	OEL Ceiling (mg/m ³)	3 mg/m ³
Alberta	OEL Ceiling (ppm)	2 ppm
British Columbia	OEL Ceiling (ppm)	2 ppm
Manitoba	OEL Ceiling (ppm)	2 ppm
New Brunswick	OEL Ceiling (mg/m ³)	7.5 mg/m ³
New Brunswick	OEL Ceiling (ppm)	5 ppm
Newfoundland & Labrador	OEL Ceiling (ppm)	2 ppm
Nova Scotia	OEL Ceiling (ppm)	2 ppm
Nunavut	OEL Ceiling (ppm)	2 ppm
Northwest Territories	OEL Ceiling (ppm)	2 ppm
Ontario	OEL Ceiling (ppm)	2 ppm
Prince Edward Island	OEL Ceiling (ppm)	2 ppm
Québec	PLAFOND (ppm)	2 ppm
Saskatchewan	OEL Ceiling (ppm)	2 ppm
Yukon	OEL Ceiling (mg/m ³)	7 mg/m ³
Yukon	OEL Ceiling (ppm)	5 ppm

Nitrogen (7727-37-9)		
USA ACGIH	ACGIH chemical category	Simple asphyxiant See Appendix F: Minimal Oxygen Content

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. Insufficient ventilation: wear respiratory protection.



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Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical 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.

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	: Colorless liquid
Odor	: Not determined
Odor Threshold	: Not available
pH	: 7.25 – 7.45
Evaporation Rate	: Not available
Melting Point	: Not available
Freezing Point	: Not available
Boiling Point	: Not available
Flash Point	: Not available
Auto-ignition Temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: Not available
Upper Flammable Limit	: Not available
Vapor Pressure	: Not available
Relative Vapor Density at 20°C	: Not available
Relative Density	: Not available
Specific Gravity	: Not available
Solubility	: Easily soluble.
Partition Coefficient: N-Octanol/Water	: Not available
Viscosity	: Not 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:** Strong acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products:** None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified (Based on available data, the classification criteria are not met)

Acute Toxicity (Dermal): Not classified (Based on available data, the classification criteria are not met)

Acute Toxicity (Inhalation): Not classified (Based on available data, the classification criteria are not met)

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified (Based on available data, the classification criteria are not met)

Eye Damage/Irritation: Not classified (Based on available data, the classification criteria are not met)

pH: 7.25 – 7.45

Respiratory or Skin Sensitization: Not classified (Based on available data, the classification criteria are not met)

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Germ Cell Mutagenicity: Suspected of causing genetic defects. Foscarnet sodium showed genotoxic effects in the BALB/3T3 in vitro transformation assay at concentrations greater than 0.5 ug/mL and an increased frequency of chromosome aberrations in the sister chromatid exchange assay at 1000 ug/mL.

Carcinogenicity: No evidence of carcinogenicity seen in unfasted rats and mice when dosed orally at 500 mg/kg/day and 250 mg/kg/day. (Based on available data, the classification criteria are not met)

Specific Target Organ Toxicity (Repeated Exposure): Causes damage to kidneys through prolonged or repeated exposure. Route of exposure: Oral. May cause damage to blood, hematopoietic system, cardiovascular system, and nervous system through prolonged or repeated exposure. Route of exposure: Oral.

Reproductive Toxicity: Suspected of damaging fertility or the unborn child. Daily subcutaneous doses up to 75 mg/kg administered to rabbits and 150 mg/kg administered to rats during gestation caused an increase in the frequency of skeletal anomalies/variations. On the basis of estimated drug exposure (as measured by AUC), the 150 mg/kg dose in rats and 75 mg/kg dose in rabbits were approximately one-eighth (rat) and one-third (rabbit) the estimated maximal daily human exposure. These studies are inadequate to define the potential teratogenicity at levels to which women will be exposed.

Specific Target Organ Toxicity (Single Exposure): Not classified (Based on available data, the classification criteria are not met)

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.

Chronic Symptoms: Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure. Suspected of causing genetic defects.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Hydrochloric acid (7647-01-0)	
LD50 Oral Rat	238 (238 – 277) mg/kg
LD50 Dermal Rabbit	> 5010 mg/kg
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h)
LC50 Inhalation Rat	1411 ppm
LC50 Inhalation Rat	0.42 mg/l/4h
ATE US/CA (gas)	700.00 ppmV/4h
ATE US/CA (vapors)	1.68 mg/l/4h
Hydrochloric acid (7647-01-0)	
IARC Group	3

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Hydrochloric acid (7647-01-0)	
EC50 Daphnia 1	0.492 mg/l

12.2. Persistence and Degradability

Foscarnet Sodium Injection	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Foscarnet Sodium Injection	
Bioaccumulative Potential	Not established.

12.4. Mobility in Soil Absorbs into soil.

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Treatment Methods: Incinerate at a licensed installation.

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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: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled.

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

14.4. In Accordance with TDG Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Foscarnet Sodium Injection	
SARA Section 311/312 Hazard Classes	Health hazard - Reproductive toxicity Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Germ cell mutagenicity
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the United States SARA Section 302 Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
Nitrogen (7727-37-9)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

Hydrochloric acid (7647-01-0)
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
Nitrogen (7727-37-9)
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List

15.3. Canadian Regulations

Water (7732-18-5)
Listed on the Canadian DSL (Domestic Substances List)
Hydrochloric acid (7647-01-0)
Listed on the Canadian DSL (Domestic Substances List)
Nitrogen (7727-37-9)
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 Revision : 01/18/2021

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.

GHS Full Text Phrases:

Acute Tox. 3 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 3
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Eye Dam. 1	Serious eye damage/eye irritation Category 1
HHNOC 1	Health hazard not otherwise classified, category 1
Muta. 2	Germ cell mutagenicity Category 2
Press. Gas (Comp.)	Gases under pressure Compressed gas
Repr. 2	Reproductive toxicity Category 2
Simple Asphy	Simple Asphyxiant
Skin Corr. 1A	Skin corrosion/irritation Category 1A
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H280	Contains gas under pressure; may explode if heated
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H331	Toxic if inhaled
H335	May cause respiratory irritation
H341	Suspected of causing genetic defects
H361	Suspected of damaging fertility or the unborn child
H372	Causes damage to organs through prolonged or repeated exposure
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

HMIS III Rating

Health : 3* Serious Hazard - Major injury likely unless prompt action is taken and medical treatment is given (Chronic Hazard)

Flammability : 0 No Hazard

Physical : 1 NoHazard

Personal protection : B

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)