



PRODUCT SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION

Name: Foscavir[®] (foscarnet sodium) Injection
Address: Clinigen Healthcare Limited
Pitcairn House
Crown Square
First Avenue
Burton-on-Trent
Staffordshire
DE14 2WW
United Kingdom
Phone Number: +44 (0) 1283 494 340
Emergency Phone Number: +44 (0) 7808 760 074

Distributor Address: Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045
USA
Phone Number: Hospira, Inc., Non-Emergency - 224-212-2055
Emergency Phone Number: CHEMTREC: North America: 800-424-9300;
International: 1-703-527-3887

Alternative Names: Foscarnet Trisodium Hexahydrate
CAS Number: None assigned for the product
EC Number: None assigned for the product
Use: Antiviral Agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredient(s)	%	CAS Number	EC Number	Symbol	R Phrases*
Foscarnet Trisodium Hexahydrate		34156-56-4		Xn	R68

*Refer to Section 16 'Other Information'

3. HAZARDS IDENTIFICATION

SOLUTIONS FOR INFUSION: The risk to health in normal handling is very low. Exposure to solutions from broken bottles/vials may cause adverse health effects.

4. FIRST-AID MEASURES

Inhalation:	Remove patient from exposure. Obtain medical attention if ill effects occur.
Skin contact:	Remove contaminated clothing. Wash skin with soap and water. If symptoms (irritation or blistering) occur obtain medical attention.
Eye contact:	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least ten minutes. Obtain medical attention.
Ingestion:	Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a first-aid measure. Obtain medical information if ill effects occur.

Further Advice for Physician

Symptomatic treatment and supportive therapy as indicated.
For further detail consult the prescribing information.

5. FIRE-FIGHTING MEASURES

Non-flammable. Risk of ignition at high temperatures

Extinguishing Media (suitable):	Water spray, foam, dry powder or CO ₂ .
Fire Fighting Protective Equipment:	A self-contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Ensure suitable personal protection during removal of spillages.
Environmental Precautions:	Do not empty into drains.
Clean Up Methods:	Clear up spillages. Transfer spilled vials to a suitable container for disposal. Take care to avoid needles and broken containers.

7. HANDLING AND STORAGE

Handling: No special precautions are necessary when handling packed product. In case of accident, avoid contact with skin and eyes.

Storage : Keep container tightly closed.

Storage Temperature: 8 - 30 °C

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit Values

HAZARDOUS INGREDIENT(S)	LTEL 8hr TWA	STEL 15min
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Foscarnet Trisodium Hexahydrate	0.5 mg/m ³	COM
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Exposure Controls: Use appropriate controls (e.g. containment, ventilation) as specified in the workplace risk assessment to ensure that the defined occupational exposure limit is not exceeded.

Personal Protection: Selection of personal protective equipment and procedures for use should be based on the workplace risk assessment and local legislations. Respiratory protective equipment and gloves etc. should be changed at appropriate intervals as specified in the workplace risk assessment and in accordance with manufacturers' information. Factors that affect breakthrough time are: Concentration of the material and duration of exposure, permeability, contact temperature, etc.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form: Aqueous solution.

Colour : Clear.

Odour: Odorless

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions.

Hazardous Reactions: Incompatible materials: None known.

Hazardous Decomposition Product(s): None known.

11. TOXICOLOGICAL INFORMATION

As a result of the physical presentation of the product, the risk to health is expected to be very low under normal conditions of handling and use. The following health hazard assessment is based on a consideration of the composition of this product.

Inhalation:	Unlikely route of exposure. Adverse effects similar to ingestion may occur following exposure to mist.
Skin Contact:	Repeated and/or prolonged contact may cause irritation.
Eye Contact:	May cause eye irritation.
Ingestion:	Therapeutic doses may produce adverse effects including headache, fatigue, nausea, vomiting, seizures and anemia. Oral Median Lethal Dose (rat) > 400

Possible risk of irreversible effects. Evidence of genotoxicity and should be treated with caution. Repeated exposure may produce adverse effects on the, kidneys, and, bone.

12. ECOLOGICAL INFORMATION

No information on this formulation. The following information refers to active ingredient:

Ecotoxicity:	EC50 green algae 72 H 170 mg/l EC50 Daphnia magna 48 H 108 mg/l LC0 Zebra Fish 96 H > 1,000 mg/l
Degradability:	Not readily biodegradable.
Bioaccumulation:	The substance has low potential for bioaccumulation. The substance has high mobility in soil. The substance has high mobility in sediment.

13. DISPOSAL CONSIDERATIONS

Chemical Disposal:	Disposal should be in accordance with local, state or national legislation.
Contaminated Packaging:	Empty container will retain product residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

Not Classified as Dangerous for Transport.

15. REGULATORY INFORMATION

Users should ensure that they comply with any relevant local, state or national legislation.

EC Classification:	Exempt.
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Foscavir[®] (foscarnet sodium) Injection

This data sheet was prepared in accordance with Directive 91/155/EEC (93/112/EEC 2001/58/EC)

The information contained in this Data Sheet provides assistance to employers on complying with their legal duty under:

COSHH & 'COSHH Essentials' Guidance

Health & Safety at Work Act 1974 (HSWA)

Dangerous Substance & Explosive Atmosphere Regulations (DSEAR)
(CLAW)

Control of Major Accident Hazards (COMAH)

16. OTHER INFORMATION

Risk Phrases: R68: Possible risk of irreversible effects.

GLOSSARY

WEL	:	Workplace Exposure Limit (UK HSE EH40)
COM	:	In-house occupational exposure limit
LTEL	:	Long-term exposure limit (8-hour TWA (time- weighted average))
STEL	:	Short-term exposure limit (15-minute TWA (time- weighted average))
TLV	:	Threshold Limit Value (ACGIH)
TLV-C	:	Threshold Limit Value - Ceiling limit (ACGIH)
MAK	:	Maximalen Arbeitsplatzkonzentration (Germany TRGS 900)
HYG	:	An in-house analytical method for occupational exposure monitoring is available.
Sk	:	Can be absorbed through skin, thus contributing to systemic effects
Sen	:	Capable of causing respiratory sensitisation
Carc Cat 1	:	EC category 1 Carcinogen
Carc Cat 2	:	EC category 2 Carcinogen
Carc Cat 3	:	EC category 3 Carcinogen
Muta Cat 1	:	EC category 1 Mutagen
Muta Cat 2	:	EC category 2 Mutagen
Muta Cat 3	:	EC category 3 Mutagen
Repr Cat 1	:	EC category 1 Toxic for Reproduction
Repr Cat 2	:	EC category 2 Toxic for Reproduction
Repr Cat 3	:	EC category 3 Toxic for Reproduction

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.