



MATERIAL SAFETY DATA SHEET

Revision date: 29-Nov-2012

Version: 2.0

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Aciclovir Intravenous Infusion

Trade Name:	Aciclovir; Aciclovir Sodium
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antiviral

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless to pale yellow solution
Signal Word: WARNING

Statement of Hazard: Suspected of damaging fertility or the unborn child.
Suspected of causing genetic defects.

Additional Hazard Information:

Short Term: Not acutely toxic (based on animal data) .
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on testes, the developing fetus.

Known Clinical Effects: The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Kidney dysfunction has been seen during clinical use.

EU Indication of danger: Toxic to Reproduction: Category 3
Mutagenic: Category 3

EU Hazard Symbols:

Xn



EU Risk Phrases:

R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R68 - Possible risk of irreversible effects.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Acyclovir Sodium	69657-51-8	Not Listed	Mut. Cat.3;R68 Repr. Cat.3;R62 Repr. Cat.3;R63	2.5
Sodium chloride	7647-14-5	231-598-3	Not Listed	**
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*

Additional Information: * Proprietary
** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Sodium chloride

Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Clear, colorless to pale yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
Conditions to Avoid:	None known
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Acyclovir Sodium

Rat	Oral	LD50	> 20 g/kg
Rat	Para-periosteal	LD50	750 mg/kg
Rat	Intraperitoneal	LD50	860 mg/kg
Mouse	Oral	LD50	> 10 g/kg
Mouse	Intravenous	LD50	400 mg/kg

Sodium chloride

Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

Sodium hydroxide

Mouse	IP	LD50	40 mg/kg
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11. TOXICOLOGICAL INFORMATION

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Acyclovir Sodium

1 Month(s)	Rat	Intraperitoneal	320 mg/kg/day	LOAEL	Male reproductive system
1 Month(s)	Dog	Intravenous	100-200 mg/kg/day	LOAEL	Male reproductive system
1 Month(s)	Dog	Intravenous	50 mg/kg/day	NOAEL	Male reproductive system
6 Month(s)	Rat	Intraperitoneal	80 mg/kg/day	LOAEL	Male reproductive system
1 Year(s)	Dog	Intravenous	60 mg/kg/day	NOAEL	Male reproductive system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Acyclovir Sodium

Fertility and Embryonic Development	Rat	Subcutaneous	50 mg/kg/day	LOAEL	Fertility, Fetotoxicity
Reproductive & Fertility	Rat	Subcutaneous	25 mg/kg/day	NOAEL	Fertility
Embryo / Fetal Development	Mouse	Oral	450 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rabbit	Intravenous	50 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Subcutaneous	50 mg/kg/day	NOAEL	Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Acyclovir Sodium

<i>In Vitro</i> Mammalian Cell Mutagenicity	Mouse Lymphoma	Positive
<i>In Vivo</i> Chromosome Aberration	Rat	Positive
<i>In Vivo</i> Chromosome Aberration	Hamster	Positive
<i>In Vitro</i> Cell Transformation Assay	Equivocal	
Dominant Lethal Assay	Mouse	Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Acyclovir Sodium

2 Year(s)	Mouse	Oral	450 mg/kg/day	NOAEL	Not carcinogenic
2 Year(s)	Rat	Oral	450 mg/kg/day	NOAEL	Not carcinogenic

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
See below

Acyclovir Sodium

IARC:

Group 3 (Not Classifiable)

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12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Toxic to Reproduction: Category 3
Mutagenic: Category 3

EU Risk Phrases:
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R68 - Possible risk of irreversible effects.

EU Safety Phrases:
S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
Suspected of damaging fertility or the unborn child.
Suspected of causing genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

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15. REGULATORY INFORMATION



Water for injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R68 - Possible risks of irreversible effects.

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information. Commercial vendor MSDS.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 15 - Regulatory Information.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet