



MATERIAL SAFETY DATA SHEET

Revision date: 15-Oct-2009

Version: 2.0

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

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Material Name: Cidofovir Solution for Injection

| | |
|------------------|--|
| Trade Name: | Vistide |
| Chemical Family: | Mixture |
| Intended Use: | Pharmaceutical product used as antiviral |

2. HAZARDS IDENTIFICATION

Appearance: Clear aqueous solution
Signal Word: WARNING

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

Additional Hazard Information:

Short Term: May cause eye and skin irritation (based on components) . Accidental ingestion may cause effects similar to those seen in clinical use.

Known Clinical Effects: Kidney dysfunction has been seen during clinical use. Effects on blood and blood-forming organs have also occurred.

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

Xn



EU Risk Phrases:

R40 - Limited evidence of a carcinogenic effect
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R68 - Possible risk of irreversible effects.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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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 | Classification | % |
|-------------------|-------------|-----------------------|---|-----|
| Cidofovir | 113852-37-2 | Not listed | Repr.Cat.3;R2-63 Carc.Cat.3;R40 Mut.Cat.3;R68 Xi;R38 | 7.5 |
| Hydrochloric Acid | 7647-01-0 | 231-595-7 | C;R35 T;R23 | ** |
| Sodium hydroxide | 1310-73-2 | 215-185-5 | C;R35 | ** |

| Ingredient | CAS Number | EU EINECS/ELINCS List | 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: Fine particles (such as dust and mists) may fuel fires/explosions.

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 hands and any exposed skin after removal of PPE. 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.

Hydrochloric Acid

| | |
|--------------------------------|---------------------------|
| ACGIH Ceiling Threshold Limit: | 2 ppm |
| Australia PEAK | 5 ppm |
| | 7.5 mg/m ³ |
| Austria OEL - MAKs | Listed |
| Belgium OEL - TWA | Listed |
| Bulgaria OEL - TWA | Listed |
| Cyprus OEL - TWA | Listed |
| Czech Republic OEL - TWA | Listed |
| Estonia OEL - TWA | Listed |
| Germany - TRGS 900 - TWAs | 2 ppm |
| | 3 mg/m ³ |
| Germany (DFG) - MAK | 2 ppm MAK |
| | 3.0 mg/m ³ MAK |
| Greece OEL - TWA | Listed |
| Hungary OEL - TWA | Listed |
| Ireland OEL - TWAs | Listed |
| Italy OEL - TWA | Listed |
| Japan - OELs - Ceilings | 5 ppm |
| | 7.5 mg/m ³ |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|-----------------------|--------|
| Latvia OEL - TWA | Listed |
| Lithuania OEL - TWA | Listed |
| Luxembourg OEL - TWA | Listed |
| Malta OEL - TWA | Listed |
| Netherlands OEL - TWA | Listed |
| Poland OEL - TWA | Listed |
| Romania OEL - TWA | Listed |
| Slovenia OEL - TWA | Listed |
| Spain OEL - TWA | Listed |

Sodium hydroxide

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

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

| | |
|---|--|
| 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. Keep airborne contamination levels below the exposure limits listed above in this section. |
| 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: | If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---------------------------|------------------|--------------------------|---------|
| Physical State: | Aqueous solution | Color: | Clear |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |
| pH: | 7.4 | | |

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10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Not determined
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

Sodium hydroxide

Mouse IP LD50 40 mg/kg

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

Cidofovir

Skin Irritation Rabbit Moderate

Skin Irritation Rabbit Severe

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

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

Cidofovir

Reproductive & Fertility-Males Rat Intravenous 15 mg/kg/day NOEL Fertility

Fertility & Early Embryonic Development-Females Rat Intravenous 1.2 mg/kg/week LOEL Fertility, Fetotoxicity

Embryo / Fetal Development Rat Intravenous 1.5 mg/kg/day LOEL Fetotoxicity, Maternal Toxicity

Embryo / Fetal Development Rabbit Intravenous 1 mg/kg/day LOEL Fetotoxicity, Teratogenic, Maternal Toxicity

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

Cidofovir

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

In Vivo Micronucleus Mouse Positive

In Vitro Chromosome Aberration Human Lymphocytes Positive

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

Cidofovir

26 Week(s) Rat Subcutaneous 0.6 mg/kg/week LOEL Tumors, Female reproductive system

26 Week(s) Rat Intravenous 0.6 mg/kg/week LOEL Tumors, Female reproductive system

Carcinogen Status:

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

Hydrochloric Acid

IARC: Group 3

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12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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

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
Carcinogenic: Category 3
Mutagenic: Category 3

EU Risk Phrases:
R40 - Limited evidence of a carcinogenic effect
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R68 - Possible risk of irreversible effects.

EU Safety Phrases:
S23 - Do not breathe gas, fumes, or vapour.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

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

Canada - WHMIS: Classifications

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

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15. REGULATORY INFORMATION



Cidofovir

California Proposition 65

Male Reproductive Toxicity
Female Reproductive Toxicity
Developmental Toxicity
Cancer
Schedule 4

Standard for the Uniform Scheduling
for Drugs and Poisons:

Water for injection

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

Listed
Listed
Present

231-791-2

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting

1.0% de minimis concentration acid aerosols including mists,
vapors, gas, fog, and other airborne forms of any particle size
2270 kg final RQ
5000 lb final RQ
500 lb TPQ gas only

CERCLA/SARA Hazardous Substances
and their Reportable Quantities:
CERCLA/SARA - Section 302 Extremely Hazardous
TPQs

CERCLA/SARA - Section 302 Extremely Hazardous
Substances EPCRA RQs

5000 lb

Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):

Listed
Listed
Schedule 5
Schedule 6
231-595-7

Standard for the Uniform Scheduling
for Drugs and Poisons:

EU EINECS/ELINCS List

Sodium hydroxide

CERCLA/SARA Hazardous Substances
and their Reportable Quantities:

1000 lb final RQ
454 kg final RQ

Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):

Listed
Listed

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

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R38 - Irritating to skin.
R40 - Limited evidence of a carcinogenic effect
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R68 - Possible risks of irreversible effects.
R35 - Causes severe burns.
R23 - Toxic by inhalation.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 7 - Handling and Storage. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and 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