SAFETY DATA SHEET

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

Product Identifier

Material Name: Idarubicin Hydrochloride Injection 1 mg/ml

Trade Name: Zavedos; Idamycin
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as Antineoplastic

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B

EU Classification:

EU Indication of danger: Harmful

EU Risk Phrases:

R22 - Harmful if swallowed.

Label Elements

Signal Word: Danger
Hazard Statements: H360FD - May damage fertility. May damage the unborn child.

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards No data available
Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	GHS Classification	%
Idarubicin Hydrochloride	57852-57-0	260-990-7	T+;R28 Repr.Cat.2;R60 Repr.Cat.2;R61 Carc.Cat.3;R40 Mut.Cat.3;R68	Acute Tox.2 (H300) Carc.2 (H351) Muta.2 (H341) Repr. 1B (H360FD)	0.1
Glycerin, USP	56-81-5	200-289-5	Not Listed	Not Listed	*
Hydrochloric Acid	7647-01-0	231-595-7	T; R23 C; R35	Press. Gas Skin Corr. 1A; H314 Acute Tox. 3; H331	**

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

Additional Information:
* Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Use with adequate ventilation. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Idarubicin Hydrochloride

Pfizer OEL TWA-8 Hr:	0.1µg/m^3

Glycerin, USP

Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Czech Republic OEL - TWA	10 mg/m^3
Estonia OEL - TWA	10 mg/m^3
Finland OEL - TWA	20 mg/m^3
France OEL - TWA	10 mg/m^3
Germany (DFG) - MAK	50 mg/m^3
Greece OEL - TWA	10 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Poland OEL - TWA	10 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Spain OEL - TWA	10 mg/m^3
Switzerland OEL -TWAs	50 mg/m^3

Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm 7.5 mg/m^3
Austria OEL - MAKs	5 ppm 8 mg/m^3
Belgium OEL - TWA	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	5 ppm 8.0 mg/m^3
Cyprus OEL - TWA	5 ppm 8 mg/m^3
Czech Republic OEL - TWA	8 mg/m^3
Estonia OEL - TWA	5 ppm 8 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m^3
Germany (DFG) - MAK	2 ppm 3.0 mg/m^3
Greece OEL - TWA	5 ppm 7 mg/m^3
Hungary OEL - TWA	8 mg/m^3
Ireland OEL - TWAs	5 ppm 8 mg/m^3
Italy OEL - TWA	5 ppm 8 mg/m^3
Japan - OELs - Ceilings	5 ppm 7.5 mg/m^3
Latvia OEL - TWA	5 ppm 8 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA	5 ppm 8 mg/m^3
Luxembourg OEL - TWA	5 ppm 8 mg/m^3
Malta OEL - TWA	5 ppm 8 mg/m^3
Netherlands OEL - TWA	8 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 ppm 8 mg/m^3
Romania OEL - TWA	5 ppm 8 mg/m^3
Slovakia OEL - TWA	5 ppm 8.0 mg/m^3
Slovenia OEL - TWA	5 ppm 8 mg/m^3
Spain OEL - TWA	5 ppm 7.6 mg/m^3
Switzerland OEL -TWAs	2 ppm 3.0 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3

Analytical Method: Analytical method available for Idarubicin. Contact Pfizer Inc for further information.

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

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 as minimum protection.

Skin: Wear impervious protective clothing when handling this compound.

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: Solution
Color: Red-orange
Odor: No data available.
Odor Threshold: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: 3.5
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Idarubicin Hydrochloride
No data available
Water for Injection
No data available
Hydrochloric Acid
No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

Glycerin, USP
No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** No data available
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
- **Oxidizing Properties:** No data available
- **Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: May cause eye and skin irritation (based on components)
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs, gastrointestinal system, lymphatic system, male reproductive system, liver, kidneys, and developing fetus.
Known Clinical Effects: Bone marrow suppression is the most serious adverse effect seen during clinical use. Adverse effects associated with therapeutic use include effects on cardiovascular system, kidney, liver, and skin rash. Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

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

Idarubicin Hydrochloride
Rat Oral LD50 5.43 mg/kg
Mouse Oral LD50 13.98 mg/kg
Rat Intravenous LD50 3.08mg/kg
Mouse Intravenous LD50 4.10mg/kg
Rabbit Dermal LD50 > 40mg/kg

Glycerin, USP

11. TOXICOLOGICAL INFORMATION

Mouse Oral LD50 4090 mg/kg
Rat Oral LD50 12.6 g/kg
Rabbit Dermal LD50 > 10 g/kg
Rat Inhalation LC50 1hr > 570 mg/m^3
Rat Dermal LD 50 > 21.9 g/kg

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)

Hydrochloric Acid
Skin Irritation Severe
Eye Irritation Severe

Glycerin, USP
Eye Irritation Rabbit Mild

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

Idarubicin Hydrochloride
3 Month(s) Dog Oral0.08 mg/kg/day NOAEL Blood forming organs, Immune system, Lymphatic system, Gastrointestinal System, Liver, Male reproductive system
13 Week(s) Rat Oral 0.192 mg/kg/day NOAEL Blood forming organs, Immune system, Lymphatic system, Kidney, Heart, Liver, Gastrointestinal system
13 Week(s) Dog Oral 0.15 mg/kg/day NOAEL Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Liver
13 Week(s) Rat Intravenous 0.064 mg/kg/day NOAEL Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Kidney, Heart
13 Week(s) Dog Intravenous 0.045 mg/kg/day NOAEL Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system

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

Idarubicin Hydrochloride
Embryo / Fetal Development Rat Intravenous 0.195 mg/kg/day LOAEL Embryotoxicity, Teratogenic, Fetotoxicity
Embryo / Fetal Development Rabbit Intravenous 0.203 mg/kg/day LOAEL Not Teratogenic, Embryotoxicity, Maternal Toxicity
Fertility and Embryonic Development Rat Intravenous 0.01 mg/kg/day LOAEL Maternal Toxicity, Paternal toxicity, Fetotoxicity

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

Idarubicin Hydrochloride
Bacterial Mutagenicity (Ames) *Salmonella* Positive
Mitotic Gene Conversion Not specified Positive
In Vitro Mammalian Cell Mutagenicity Hamster Positive
In Vitro Chromosome Aberration Human Lymphocytes Positive

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

Idarubicin Hydrochloride
30 Week(s) Rat Intravenous 0.06 mg/kg/month LOAEL Benign tumors, Malignant tumors

11. TOXICOLOGICAL INFORMATION

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 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Glycerin, USP
Oncorhynchus mykiss (Rainbow Trout) LD50 96 Hours 50 mg/L
Daphnia magna (Water Flea) EC50 24 Hours >500 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Idarubicin Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity initial date 8/20/99 male reproductive toxicity initial date 8/20/99
EU EINECS/ELINCS List	260-990-7

Glycerin, USP

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex V - Exemptions from the obligations of Register:	Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern
EU EINECS/ELINCS List	200-289-5

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
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	231-595-7

15. REGULATORY INFORMATION

Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.2; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

Carcinogenic: Category 3
Mutagenic: Category 3
Toxic to Reproduction: Category 2
C - Corrosive
T - Toxic
T+ - Very toxic

R23 - Toxic by inhalation.
R28 - Very toxic if swallowed.
R35 - Causes severe burns.
R40 - Limited evidence of a carcinogenic effect
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R68 - Possible risks of irreversible effects.

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 15 - Regulatory Information. Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 4 - First Aid Measures. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 02-Mar-2015

Product Stewardship Hazard Communication

Prepared by: 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