



MATERIAL SAFETY DATA SHEET

Revision date: 13-May-2008

Version: 1.3

Page 1 of 9

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

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Material Name: Idarubicin Hydrochloride Capsules (5 mg)

Trade Name:	ZAVEDOS; IDAMYCIN
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Red hard gelatin capsules
Signal Word: DANGER

Statement of Hazard: Toxic if swallowed.
May damage fertility or the unborn child.
Suspected of causing genetic defects.
Suspected of causing cancer.

Additional Hazard Information:
Short Term: May cause skin irritation. (based on animal data) .
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, heart, and developing fetus.

Known Clinical Effects: Bone marrow suppression is the most serious adverse effect seen during clinical use. Adverse effects associated with the therapeutic use include effects on cardiovascular system, gastrointestinal system, liver, kidney, 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.

EU Indication of danger: Toxic
Toxic to Reproduction: Category 2
Mutagenic: Category 3
Carcinogenic: Category 3

EU Hazard Symbols:



MATERIAL SAFETY DATA SHEET

Material Name: Idarubicin Hydrochloride Capsules (5 mg)
Revision date: 13-May-2008

Page 2 of 9
Version: 1.3

2. HAZARDS IDENTIFICATION

EU Risk Phrases:

R25 - Toxic if swallowed.
R40 - Limited evidence of a carcinogenic effect.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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	%
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	5%
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Glyceryl Palmito-Stearate	None Assigned	Not listed	Not Listed	*
Hard gelatin capsules	MIXTURE	Not listed	Not Listed	*

Additional Information:

* Proprietary
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.

MATERIAL SAFETY DATA SHEET

Material Name: Idarubicin Hydrochloride Capsules (5 mg)
Revision date: 13-May-2008

Page 3 of 9
Version: 1.3

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. May include oxides of carbon. May include oxides of nitrogen. May include hydrogen chloride.
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:	Prevent exposure by any route. Personnel must wear appropriate protective equipment (see Section 8).
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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. Prevent product from entering drains.
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:	Restrict access to work area. Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling.
Storage Conditions:	Store as directed by product packaging.

MATERIAL SAFETY DATA SHEET

Material Name: Idarubicin Hydrochloride Capsules (5 mg)
Revision date: 13-May-2008

Page 4 of 9
Version: 1.3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Idarubicin Hydrochloride

Pfizer OEL TWA-8 Hr: 0.1µg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Belgium OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Ireland OEL - TWAs	= 10 mg/m ³ TWA = 4 mg/m ³ TWA
Latvia OEL - TWA	Listed
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total = 5 mg/m ³ TWA
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed

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

Analytical Method:

Analytical method available for idarubicin. Contact Pfizer Inc for further information.

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.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious, disposable gloves (double suggested) 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 disposable 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:	Capsule	Color:	Red
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability:

Stable under normal conditions of use.

Conditions to Avoid:

None known

Incompatible Materials:

As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: Nitrogen oxides (nox) Hydrogen chloride gas Carbon oxides

MATERIAL SAFETY DATA SHEET

Material Name: Idarubicin Hydrochloride Capsules (5 mg)
Revision date: 13-May-2008

Page 5 of 9
Version: 1.3

MATERIAL SAFETY DATA SHEET

Material Name: Idarubicin Hydrochloride Capsules (5 mg)
Revision date: 13-May-2008

Page 6 of 9
Version: 1.3

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)

Idarubicin Hydrochloride

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

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/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)

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

Idarubicin Hydrochloride

3 Month(s) Dog Oral 0.08 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

MATERIAL SAFETY DATA SHEET

Material Name: Idarubicin Hydrochloride Capsules (5 mg)
Revision date: 13-May-2008

Page 7 of 9
Version: 1.3

11. TOXICOLOGICAL INFORMATION

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

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. 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.

MATERIAL SAFETY DATA SHEET

Material Name: Idarubicin Hydrochloride Capsules (5 mg)
Revision date: 13-May-2008

Page 8 of 9
Version: 1.3

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic
Toxic to Reproduction: Category 2
Mutagenic: Category 3
Carcinogenic: Category 3

EU Risk Phrases:
R25 - Toxic if swallowed.
R40 - Limited evidence of a carcinogenic effect.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
Toxic if swallowed.
May damage fertility or the unborn child.
Suspected of causing genetic defects.
Suspected of causing cancer.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 1, Subdivision B



Idarubicin Hydrochloride
California Proposition 65
EU EINECS/ELINCS List

male reproductive toxicity, initial date 8/20/99
developmental toxicity, initial date 8/20/99
260-990-7

Microcrystalline cellulose
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
EU EINECS/ELINCS List

XU
Present
232-674-9

MATERIAL SAFETY DATA SHEET

Material Name: Idarubicin Hydrochloride Capsules (5 mg)
Revision date: 13-May-2008

Page 9 of 9
Version: 1.3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R28 - Very toxic if swallowed.
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 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information.

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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