



SAFETY DATA SHEET

Revision date: 03-Mar-2015

Version: 2.0

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

Product Identifier

Material Name: Idarubicin Hydrochloride Capsules (25mg)

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

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Pfizer Pharmaceuticals Group

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2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 2

Germ Cell Mutagenicity: Category 2

Reproductive Toxicity: Category 1B

Carcinogenicity: Category 2

EU Classification:

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.

Label Elements

Signal Word: Danger

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2. HAZARDS IDENTIFICATION

Hazard Statements:
H341 - Suspected of causing genetic defects
H351 - Suspected of causing cancer
H360FD - May damage fertility. May damage the unborn child.
H301 - Toxic if swallowed

Precautionary Statements:
P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P281 - Use personal protective equipment as required
P301+ P310 - IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician
P321 - Specific treatment (see supplemental first aid instructions on this label)
P330 - Rinse mouth
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards
Australian Hazard Classification (NOHSC):

No data available
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)	10
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*

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

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Additional Information: * Proprietary
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: Fine particles (such as dust and mists) may fuel fires/explosions.

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

Prevent exposure by any route. Personnel must wear appropriate protective equipment (see Section 8).

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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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.

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

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. 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. Restrict access to work area.

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/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	2 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Russia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL - TWAs	3 mg/m ³
Vietnam OEL - TWAs	10 mg/m ³
	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. 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).

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 cap; white body
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:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)	
Glyceryl Palmito-Stearate	
No data available	
Hard gelatin capsules	
No data available	
Microcrystalline cellulose	
No data available	
Idarubicin Hydrochloride	
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

Flammability:

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

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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 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 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.

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

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

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

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))

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11. TOXICOLOGICAL INFORMATION

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
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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.
Toxicity:	No data available
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.

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This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 2811
UN proper shipping name: Toxic solid, organic, n.o.s. (Idarubicin hydrochloride)
Transport hazard class(es): 6.1
Packing group: II

Limited Quantity Exceptions apply to small quantities packed in combination packaging. See applicable modal regulations for specific limitations.

15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 1, Subdivision B



Idarubicin Hydrochloride

CERCLA/SARA 313 Emission reporting
California Proposition 65

Not Listed
developmental toxicity initial date 8/20/99
male reproductive toxicity initial date 8/20/99
260-990-7

EU EINECS/ELINCS List

Glyceryl Palmito-Stearate

CERCLA/SARA 313 Emission reporting
California Proposition 65
EU EINECS/ELINCS List

Not Listed
Not Listed
Not Listed

Hard gelatin capsules

CERCLA/SARA 313 Emission reporting
California Proposition 65
EU EINECS/ELINCS List

Not Listed
Not Listed
Not Listed

Microcrystalline cellulose

CERCLA/SARA 313 Emission reporting
California Proposition 65
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):

Not Listed
Not Listed
Present
Present

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15. REGULATORY INFORMATION

REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9

16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.

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

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 7 - Handling and Storage. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 11 - Toxicology Information. Updated Section 14 - Transport Information. Updated Section 16 - Other Information. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures.

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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