SAFETY DATA SHEET

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Idarubicin Hydrochloride Injection 1 mg/ml

Product Code(s) PZ01148
Synonyms Zavedos Injection
Trade Name: Zavedos; Idamycin
Chemical Family: Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as Antineoplastic

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Carcinogenicity Category 2 - (H351)
Reproductive toxicity Category 1B - (H360FD)

OSHA Classification

Hazards not otherwise classified (HNOC)
Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200
Not applicable

2.2. Label elements

Signal word Danger

Hazard statements
H360FD - May damage fertility. May damage the unborn child
H351 - Suspected of causing cancer

Precautionary Statements - EU (§28, 1272/2008)
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves and protective clothing
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Glycerin, USP (CAS #: 56-81-5)	*		200-289-5	Not classified	Not classified	No data available	No data available
Idarubicin Hydrochloride (CAS #: 57852-57-0)	0.1		260-990-7	Acute Tox.2 (H300) Carc.2 (H351) Muta.2 (H341) Repr. 1B (H360FD) STOT RE 1 (H372)	Not classified	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314) Acute Tox. 3	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25%	No data available	No data available

				(H331)	Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%		

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate No information available

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Glycerin, USP 56-81-5	27200	10000	5.85	No data available	No data available
Idarubicin Hydrochloride 57852-57-0	5.43	No data available	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

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. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation Remove to fresh air. Seek immediate medical attention/advice.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

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.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Not applicable.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

Explosion data
Sensitivity to mechanical impact No information available.
Sensitivity to static discharge No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Restrict access to work area. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. Use only 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.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product. Antineoplastic.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

Idarubicin Hydrochloride

Pfizer OEL TWA-8 Hr: 0.1 µg/m³

Glycerin, USP

Czech Republic	10 mg/m³
	Ceiling: 15 mg/m³
Estonia	TWA: 10 mg/m³;
Finland	TWA: 20 mg/m³;
France	10 mg/m³
Germany DFG	TWA-MAK: 200 mg/m³; I(2);inhalable fraction
	Peak: 400 mg/m³; inhalable fraction
Germany TRGS	TWA-AGW; 200 mg/m³ (exposure factor 2); inhalable fraction
Poland	TWA-NDS: 10 mg/m³; inhalable fraction
Slovakia	TWA: 10 mg/m³;
Spain	TWA-(VLA-ED): 10 mg/m³; mist
Switzerland	TWA-MAK: 50 mg/m³; inhalable dust
	STEL-KZGW: 100 mg/m³; inhalable dust
OSHA PEL	TWA: 15 mg/m³ mist, total particulate
	TWA: 5 mg/m³ mist, respirable fraction
	(vacated) TWA: 10 mg/m³ mist, total particulate
	(vacated) TWA: 5 mg/m³ mist, respirable fraction
United Kingdom	TWA: 10 mg/m³; mist
	STEL: 30 mg/m³; mist

+ Hydrochloric Acid

ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	TWA-TMW: 5 ppm;
	TWA-TMW: 8 mg/m³;
	STEL-KZGW: 10 ppm (8 X 5 min);
	STEL-KZGW: 15 mg/m³ (8 X 5 min);
Bulgaria	TWA: 5 ppm;
	TWA: 8.0 mg/m³;

	STEL: 10 ppm;
	STEL: 15.0 mg/m³;
Czech Republic	8 mg/m³
	Ceiling: 15 mg/m³
Denmark	STEL: 5 ppm;
	STEL: 8 mg/m³;
Estonia	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
European Union	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Finland	STEL: 5 ppm;
	STEL: 7.6 mg/m³;
Germany DFG	TWA-MAK: 2 ppm; I(2);
	TWA-MAK: 3.0 mg/m³; I(2);
	Peak: 4 ppm;
	Peak: 6 mg/m³;
Germany TRGS	TWA-AGW; 2 ppm (exposure factor 2);
	TWA-AGW; 3 mg/m³ (exposure factor 2);
Hungary	TWA-AK: 8 mg/m³;
	TWA-AK: 5 ppm;
	STEL-CK: 165 mg/m³;
	STEL-CK: 10 ppm;
Ireland	TWA: 8 mg/m³;
	TWA: 5 ppm;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Italy MDLPS	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Ceiling Limit Value	2 ppm
	3.0 mg/m³
Latvia	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Netherlands	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Poland	TWA-NDS: 5 mg/m³;
	STEL-NDSCh: 10 mg/m³;
Romania	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Russia	MAC: 5 mg/m³
Slovakia	TWA: 5 ppm;
	TWA: 8.0 mg/m³;
	Ceiling: 15 mg/m³;
Spain	TWA-(VLA-ED): 5 ppm;
	TWA-(VLA-ED): 7.6 mg/m³;
	STEL (VLA-EC): 10 ppm;
	STEL (VLA-EC): 15 mg/m³;

Switzerland	TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m^3; STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m^3;
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m^3
OSHA PEL	Ceiling: 5 ppm Ceiling: 7 mg/m^3 (vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m^3
United Kingdom	TWA: 1 ppm; gas and aerosol mist TWA: 2 mg/m^3; gas and aerosol mist STEL: 5 ppm; gas and aerosol mist STEL: 8 mg/m^3; gas and aerosol mist

8.2. 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. It is recommended that all operations be fully enclosed and no air recirculated.
Personal protective equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Eye/face protection	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
Hand protection	Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).
Skin and body protection	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
Respiratory protection	Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).
Thermal hazards	No information available.
Environmental exposure controls	No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Solution
Physical state	Liquid
Color	Red-orange
Odor	No information available.
Odor threshold	No information available

Property	**Values**
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	3.5
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

9.2.1. Information with regard to physical hazard classes
No information available

9.2.2. Other safety characteristics
No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity	No information available.

10.2. Chemical stability

Stability	Stable up to .?°C.
Explosion data	
Sensitivity to mechanical impact	No information available.
Sensitivity to static discharge	No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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 Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitization Based on available data, the classification criteria are not met.

STOT - single exposure Based on available data, the classification criteria are not met.

STOT - repeated exposure Based on available data, the classification criteria are not met.

Reproductive toxicity May cause harm to the unborn child. May impair fertility. Classification is based on mixture calculation methods based on component data.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Suspected of causing cancer. Classification is based on mixture calculation methods based on component data.

Aspiration hazard Based on available data, the classification criteria are not met.

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

Glycerin, USP

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

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

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Glycerin, USP	= 27200 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 5.85 mg/L (Rat) 4 h

Idarubicin Hydrochloride	= 5430 µg/kg (Rat)	-	-
+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

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)
Glycerin, USP
Eye Irritation Rabbit Mild

+ Hydrochloric Acid
Skin irritation Severe
Eye irritation Severe

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 & Development Toxicity: (Duration, 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
+ Hydrochloric Acid
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative

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

+ Hydrochloric Acid
IARC Group 3

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

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

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout) N/A LC50 96 hours 50 mg/L

Daphnia magna (Water Flea) N/A 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.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment Based on available data, the classification criteria are not met.

Chemical name	PBT and vPvB assessment
Glycerin, USP	Not PBT/vPvB
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products
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 wastewater 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.

Section 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.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

Glycerin, USP

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-289-5
AICS	Present

Idarubicin Hydrochloride

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Developmental Male Reproductive
EINECS	260-990-7

+ Hydrochloric Acid

CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-595-7
AICS	Present
Standard for Uniform Scheduling of Medicines and	Schedule 5

Poisons (SUSMP) Schedule 6

National regulations

Germany
Chemical Prohibition Ordinance (ChemVerbotsV)
Not applicable

TRGS 905 Not applicable

Switzerland
Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable
Storage of Hazardous Material Not applicable
WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable
Major Accidents Ordinance SR 814.012 Not applicable

European Union
Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:
This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
+ Hydrochloric Acid 7647-01-0	75	-

Persistent Organic Pollutants
Not applicable

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid 7647-01-0	25	250

Ozone-depleting substances (ODS) Regulation (EU) 2024/590
Not applicable.

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Explosives Precursors Marketing and Use (2019/1148)
Not applicable

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15
H302 - Harmful if swallowed H331 - Toxic if inhaled H351 - Suspected of causing cancer H341 - Suspected of causing genetic defects H360FD - May damage fertility. May damage the unborn child H314 - Causes severe skin burns and eye damage H372 - Causes damage to organs through prolonged or repeated exposure

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information.
Reason for revision	Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.
Revision date	15-Jun-2025
Prepared By	Pfizer Global Environment, Health, and Safety

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