



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

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Revision Number 1

1. Identification

1.1. Product identifier

Product Name DOXORUBICIN 10mg/5ml - 50mg/25ml - 200mg/100ml - NL20323-20325-20326

Pure substance/mixture Mixture

Contains Doxorubicin hydrochloride

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

Uses/ Identified uses Pharmaceutical

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

TEVA SANTE100-110
ESPLANADE DU GENERAL DE
GAULLE92931 PARIS LA DEFENSE
CEDEX
Tel +33 (0)1 55 91 78 00

Teva Corporate Headquarters
5 Bazel Street PO Box 3190
Petah Tikva, Israel

For further information, please contact

E-mail address SDS.TevaIL@teva.co.il

1.4. Emergency telephone number

Emergency Telephone United States/Canada/Puerto Rico: 1-800-424-9300 (Chemtrec) [24-hrs]
International: +1-703-741-5970 (Chemtrec) [24-hours]

2. Hazard(s) identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Germ cell mutagenicity	Category 1B - (H340)
Carcinogenicity	Category 1B - (H350)

2.2. Label elements

Contains Doxorubicin hydrochloride



Signal word
Danger

Hazard statements

H340 - May cause genetic defects
H350 - May cause 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/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/ container to an approved waste disposal plant

Additional information

Medicinal products in the finished state for human use, as defined in 2001/83/EC, are exempted from classification and other criteria of 1272/2008.

2.3. Other hazards

This product contains a material considered to be cytotoxic according to Teva's internal definition See section 11

3. Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH registration number
Water	231-791-2	7732-18-5	98.92	Not classified	No data available
Doxorubicin hydrochloride	EEC No. 246-818-3	25316-40-9	0.2	Muta. 1B (H340) Carc. 1B (H350) Repr. 1B (H360FD)	No data available

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

4. First-aid measures

4.1. Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance. IF exposed or concerned: Get medical advice/attention.

Inhalation

Remove to fresh air.

Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

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

Symptoms	No information available.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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5. Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	No information available.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.
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5.3. Advice for firefighters

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

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.
Other information	Refer to protective measures listed in Sections 7 and 8.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.
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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	Take up mechanically, placing in appropriate containers for disposal.
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.
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7. Handling and storage

7.1. Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.
General hygiene considerations	Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions	Store locked up.
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7.3. Specific end use(s)

Risk Management Methods (RMM)	The information required is contained in this Material Safety Data Sheet.
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8. Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical Name	TEVA OEL
Doxorubicin hydrochloride	Teva OEL (8hr-TWA): 0.2 µg/m ³

Derived No Effect Level (DNEL)	No information available.
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Predicted No Effect Concentration (PNEC)	No information available.
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8.2. Exposure controls

Personal protective equipment

Eye/face protection	No special protective equipment required.
Hand protection	Wear suitable gloves.
Skin and body protection	Wear suitable protective clothing.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.
Environmental exposure controls	No information available.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Appearance	No information available
Color	No information available
Odor	No information available.
Odor threshold	No information available

Property	Values	Remarks • Method
pH	No data available	None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	Soluble	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No information available	
Oxidizing properties	No information available	

Partition coefficient n-octanol /water (log KOW) No information available

9.2. Other information

Softening point	No information available
Molecular weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

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 Hazardous polymerization does not occur.

10.4. Conditions to avoid

Conditions to avoid Extremes of temperature and direct sunlight. Exposure to air or moisture over prolonged periods. Heat, flames and sparks.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

11.1. Information on toxicological effects

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Acute toxicity

Unknown acute toxicity 0 % of the mixture consists of ingredient(s) of unknown toxicity.
0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
0 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).
0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)		

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	Classification based on data available for ingredients. Contains a known or suspected mutagen.
Carcinogenicity	Classification based on data available for ingredients.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Cytotoxicity	Positive According to Teva's internal policy, a compound is considered cytotoxic if it possesses the ability to interact directly with DNA or DNA-associated macromolecules, resulting in cell death. In addition, a cytotoxic agent causes such damage in an indiscriminate manner, affecting healthy cells in addition to abnormal (e.g., tumor) cells and causing serious systemic toxicity

12. Ecological information

12.1. Toxicity

Ecotoxicity

Unknown aquatic toxicity	Contains 0 % of components with unknown hazards to the aquatic environment.
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12.2. Persistence and degradability

Persistence and degradability	No information available.
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12.3. Bioaccumulative potential

Bioaccumulation	No information available.
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12.4. Mobility in soil

Mobility in soil	No information available.
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12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment	No information available.
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12.6. Other adverse effects

Other adverse effects	No information available.
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13. Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused	Dispose of in accordance with local regulations. Dispose of waste in accordance with
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products environmental legislation.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

IMDG

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5	
14.6	
14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code	No information available

RID

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6	

ADR

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Hazard class	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6	

IATA

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6	

15. Regulatory information

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

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)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

TSCA	Contact supplier for inventory compliance status
DSL/NDL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AICS	Contact supplier for inventory compliance status

Legend:

TSCA	- United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL	- 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 and Evaluated Chemical Substances
PICCS	- Philippines Inventory of Chemicals and Chemical Substances
AICS	- Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

16. Other information

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

Full text of H-Statements referred to under section 3

H340 - May cause genetic defects
H350 - May cause cancer
H360FD - May damage fertility. May damage the unborn child

Legend

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Carcinogenicity	Calculation method

Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AELG(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
RTECS (Registry of Toxic Effects of Chemical Substances)
World Health Organization

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet