Safety Data Sheet

Cat. # API-05

Doxorubicin [2mM]

Size: 50µl

doxorubicin, hydrochloride

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Revision date: 5/11/2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	: Substance
Substance name	: doxorubicin, hydrochloride
EC-No.	: 246-818-3
CAS-No.	: 25316-40-9
Product code	: 235D
Type of product	: Pure substance
Formula	: C27H29NO11.HCl
Synonyms	: (8S-cis)-10-[(3-amino-2,3,6-trideoxy-alpha-L-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-8-(hydroxyacetyl)-1-methoxynaphthacene-5,12-dione hydrochloride / 10-[(3-amino-2,3,6-trideoxy-alpha-L-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-8-(hydroxyacetyl-1-methoxy-5,12-naphtacenedione hydrochloride, (8C-cis)- / 14-hydroxydaunomycin, HCl / 5,12-naphthacenedione, 10-[(3-amino-2,3,6-trideoxy-alpha-L-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-8-(hydroxyacetyl)-1-methoxy-, hydrochloride, (8S-cis)- / ADM hydrochloride / ADR hydrochloride / adriamycin, hydrochloride / adriblastin, hydrochloride / DOX, hydrochloride / FI 6804 / hydroxydaunorubicin, hydrochloride / KW-125
Product group	: Raw material
BIG No	: 26435

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Pharmaceutical product: active ingredient
Antibiotic
Chemical raw material
Medicine: active ingredient

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Geno Technology, Inc./ G-Biosciences
9800 Page Avenue
63132-1429 Saint Louis - United States
T 800-628-7730 - F 314-991-1504
technical@GBiosciences.com - www.GBiosciences.com

1.4. Emergency telephone number

Emergency number : Chemtrec **1-800-424-9300** (USA/Canada), **+1-703-527-3887** (Intl)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Poisons Information Service (Belfast Centre) Royal Victoria Hospital	Grosvenor Road BT12 6BA Belfast	0344 892 0111	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	
United Kingdom	National Poisons Information Service (Cardiff Centre) Gwenwyn Ward, Llandough Hospital	Penarth CF64 2XX Cardiff	0344 892 0111	
United Kingdom	National Poisons Information Service Edinburgh Royal Infirmary of Edinburgh	Little France Crescent EH16 4SA Edinburgh	0344 892 0111	
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	+44 20 7188 7188	
United Kingdom	National Poisons Information Service (Newcastle Centre) Regional Drugs and Therapeutics Centre, Wolfson Unit	Claremont Place Newcastle-upon-Tyne NE1 4LP Newcastle	0344 892 0111	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 4	H302
Carcinogenicity, Category 2	H351

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Suspected of causing cancer. Harmful if swallowed.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS07

GHS08

CLP Signal word : Warning

Hazard statements (CLP) : H302 - Harmful if swallowed.
H351 - Suspected of causing cancer.

Precautionary statements (CLP) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P330 - Rinse mouth.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
doxorubicin, hydrochloride	(CAS-No.) 25316-40-9 (EC-No.) 246-818-3	100	Acute Tox. 4 (Oral), H302 Carc. 2, H351

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Check the vital functions. Unconscious: maintain adequate airway and respiration. Respiratory arrest: artificial respiration or oxygen. Cardiac arrest: perform resuscitation. Victim conscious with laboured breathing: half-seated. Victim in shock: on his back with legs slightly raised. Vomiting: prevent asphyxia/aspiration pneumonia. Prevent cooling by covering the victim (no warming up). Keep watching the victim. Give psychological aid. Keep the victim calm, avoid physical strain. Depending on the victim's condition: doctor/hospital.

First-aid measures after inhalation : Remove the victim into fresh air. Respiratory problems: consult a doctor/medical service.

First-aid measures after skin contact : Soap may be used. Take victim to a doctor if irritation persists.

First-aid measures after eye contact : Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Do not apply neutralizing agents. Take victim to an ophthalmologist if irritation persists.

First-aid measures after ingestion : Rinse mouth with water. Immediately after ingestion: give lots of water to drink. Call Poison Information Centre (www.big.be/antigif.htm). Consult a doctor/medical service if you feel unwell. Ingestion of large quantities: immediately to hospital.

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

No additional information available

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Quick-acting ABC powder extinguisher. Class A foam extinguisher. Water (quick-acting extinguisher, reel). Water. Class A foam.
Unsuitable extinguishing media	: Quick-acting BC powder extinguisher. Quick-acting CO2 extinguisher.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released.

5.3. Advice for firefighters

Precautionary measures fire	: Exposure to fire/heat: keep upwind. Exposure to fire/heat: consider evacuation. Exposure to fire/heat: have neighbourhood close doors and windows.
Firefighting instructions	: Dilute toxic gases with water spray. Take account of toxic fire-fighting water. Use water moderately and if possible collect or contain it.
Protection during firefighting	: Heat/fire exposure: compressed air/oxygen apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment	: Gloves. Protective clothing.
Emergency procedures	: Mark the danger area. No naked flames. Wash contaminated clothes.

6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Prevent soil and water pollution. Prevent spreading in sewers.

6.3. Methods and material for containment and cleaning up

For containment	: Contain released product. Dam up the solid spill.
Methods for cleaning up	: Scoop solid spill into closing containers. Carefully collect the spill/leftovers. Take collected spill to manufacturer/competent authority. Clean contaminated surfaces with an excess of water. Wash clothing and equipment after handling.
Other information	: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Avoid raising dust. Keep away from naked flames/heat. Measure the concentration in the air regularly. Carry operations in the open/under local exhaust/ventilation or with respiratory protection. Comply with the legal requirements. Clean contaminated clothing. Do not discharge the waste into the drain. Keep container tightly closed.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store locked up. Store in a well-ventilated place. Keep cool.
Heat and ignition sources	: KEEP SUBSTANCE AWAY FROM: heat sources.
Information on mixed storage	: KEEP SUBSTANCE AWAY FROM: oxidizing agents. (strong) acids. (strong) bases.
Storage area	: Store in a cool area. Keep locked up. Unauthorized persons are not admitted. Meet the legal requirements.
Special rules on packaging	: SPECIAL REQUIREMENTS: closing. dry. correctly labelled. meet the legal requirements. Secure fragile packagings in solid containers.
Packaging materials	: SUITABLE MATERIAL: glass.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Hand protection:
Gloves

Eye protection:
Safety glasses. In case of dust production: protective goggles

Skin and body protection:
Protective clothing

Respiratory protection:
Dust production: dust mask with filter type P3. High dust production: self-contained breathing apparatus

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Needles. Powder. Solid in various shapes.
Molecular mass	: 579.99 g/mol
Colour	: Orange-red.
Odour	: Almost odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 205 °C
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: > 204 °C
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20 °C	: Not applicable
Relative density	: Not applicable
Solubility	: Soluble in water. Soluble in ethanol. Soluble in methanol. Water: soluble, Literature
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: Not applicable

9.2. Other information

VOC content	: 0 %

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Suspected of causing cancer.
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Potential adverse human health effects and symptoms	: Harmful by ingestion.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Ecology - air	: Not classified as dangerous for the ozone layer (Regulation (EC) No 1005/2009).
Ecology - water	: Severe water pollutant (surface water). No data available on ecotoxicity.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Not classified

12.2. Persistence and degradability

doxorubicin, hydrochloride (25316-40-9)	
Persistence and degradability	Biodegradability in water: no data available.

12.3. Bioaccumulative potential

doxorubicin, hydrochloride (25316-40-9)	
Bioaccumulative potential	No bioaccumulation data available.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Waste treatment methods.
Product/Packaging disposal recommendations	: Do not discharge into the sewer. Remove waste in accordance with local and/or national regulations. Hazardous waste shall not be mixed together with other waste. Different types of hazardous waste shall not be mixed together if this may entail a risk of pollution or create problems for the further management of the waste. Hazardous waste shall be managed responsibly. All entities that store, transport or handle hazardous waste shall take the necessary measures to prevent risks of pollution or damage to people or animals. Remove to an incinerator for chlorinated waste materials with energy recovery. Dissolve or mix with a combustible solvent.
Additional information	: Hazardous waste according to Directive 2008/98/EC, as amended by Regulation (EU) No 1357/2014 and Regulation (EU) No 2017/997.
European List of Waste (LoW) code	: 15 01 10* - packaging containing residues of or contaminated by dangerous substances 07 05 13* - solid wastes containing dangerous substances

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

UN-No. (ADR)	: Not applicable
UN-No. (IMDG)	: Not regulated
UN-No. (IATA)	: Not regulated
UN-No. (ADN)	: Not applicable
UN-No. (RID)	: Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not regulated
Proper Shipping Name (IATA)	: Not regulated
Proper Shipping Name (ADN)	: Not applicable
Proper Shipping Name (RID)	: Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	: Not applicable

IMDG

Transport hazard class(es) (IMDG)	: Not regulated

IATA

Transport hazard class(es) (IATA)	: Not regulated

ADN

Transport hazard class(es) (ADN)	: Not applicable

RID

Transport hazard class(es) (RID)	: Not applicable

14.4. Packing group

Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not regulated
Packing group (IATA)	: Not regulated
Packing group (ADN)	: Not applicable
Packing group (RID)	: Not applicable

14.5. Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: No supplementary information available

14.6. Special precautions for user

Overland transport

Transport regulations (ADR)	: Not subject

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Transport regulations (ADN)	: Not subject

Rail transport

Transport regulations (RID)	: Not subject

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions
doxorubicin, hydrochloride is not on the REACH Candidate List
doxorubicin, hydrochloride is not on the REACH Annex XIV List
doxorubicin, hydrochloride is not subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.
doxorubicin, hydrochloride is not subject to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC

VOC content : 0 %

15.1.2. National regulations

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Carc. 2	Carcinogenicity, Category 2
H302	Harmful if swallowed.
H351	Suspected of causing cancer.

Safety Data Sheet applicable for regions : GB - United Kingdom

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.