

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078944837

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078938895

# SAFETY DATA SHEET

# hikma.

## ADRIAMYCIN (DOXOrubicin HCl) Injection, USP

### Section 1. Identification

<b>GHS product identifier</b>	: ADRIAMYCIN (DOXOrubicin HCl) Injection, USP
<b>Chemical name</b>	: Doxorubicin hydrochloride is (8S,10S)-10-[(3-Amino-2,3,6-trideoxy- $\alpha$ -L-lyxo-hexopyranosyl)-oxy]-8-glycoloyl-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-5,12-naphthacene- $\gamma$ -dione hydrochloride
<b>Other means of identification</b>	: Doxorubicin Hydrochloride Injection, USP
<b>Product code</b>	: Not available.
<b>Product type</b>	: Regulated prescription drug.
<b>Container information</b>	: 5 mL vial, 10 mL vial, 25 mL vial, 100 mL vial

#### Relevant identified uses of the substance or mixture and uses advised against

<b>Identified uses</b>	: Adriamycin (DOXOrubicin HCl) Injection, USP is indicated as a component of multi-agent adjuvant chemotherapy for treatment of women with axillary lymph node involvement following resection of primary breast cancer.
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<b>Supplier's details</b>	: Hikma Pharmaceuticals USA Inc. 246 Industrial Way West Eatontown, New Jersey (NJ) 07724
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<b>Emergency telephone number (with hours of operation)</b>	: CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887 24/7
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### Section 2. Hazards identification

<b>OSHA/HCS status</b>	: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
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<b>Classification of the substance or mixture</b>	: CARCINOGENICITY - Category 1B
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#### GHS label elements

<b>Hazard pictograms</b>	: 
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<b>Signal word</b>	: Danger
<b>Hazard statements</b>	: H350 - May cause cancer.

#### Precautionary statements

<b>Prevention</b>	: P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P280 - Wear protective gloves. Wear eye or face protection. Wear protective clothing.
<b>Response</b>	: P308 + P313 - IF exposed or concerned: Get medical attention.
<b>Storage</b>	: P405 - Store locked up.
<b>Disposal</b>	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

## Section 2. Hazards identification

**Hazards not otherwise classified** : None known.

## Section 3. Composition/information on ingredients

**Substance/mixture** : Mixture

**Chemical name** : Doxorubicin hydrochloride is (8S,10S)-10-[(3-Amino-2,3,6-trideoxy- $\alpha$ -L-lyxo-hexopyranosyl)-oxy]-8-glycoloyl-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-5,12-naphthacene-dione hydrochloride

**Other means of identification** : Doxorubicin Hydrochloride Injection, USP

### CAS number/other identifiers

**CAS number** : Not applicable.

**Product code** : Not available.

Ingredient name	%	CAS number
(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	$\geq 1 - \leq 3$	25316-40-9
Water for Injection	90 - 100	7789-20-0
Sodium chloride	As needed	7647-14-5
Hydrochloric acid	As needed	7647-01-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

## Section 4. First aid measures

### Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Flush contaminated skin with plenty of water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

## Section 4. First aid measures

### Most important symptoms/effects, acute and delayed

#### Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

#### Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

### Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

## Section 5. Fire-fighting measures

### Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

**Specific hazards arising from the chemical** : No specific fire or explosion hazard.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
  - carbon dioxide
  - carbon monoxide
  - nitrogen oxides
  - halogenated compounds

**Special protective actions for fire-fighters** : No special measures are required.

**Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

### Methods and materials for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

## Section 7. Handling and storage

### Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

## Section 8. Exposure controls/personal protection

### Control parameters

#### Occupational exposure limits

Ingredient name	Exposure limits
(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	None.

- Appropriate engineering controls** : If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.
- Individual protection measures**
  - Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
  - Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
  - Skin protection**
    - Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
    - Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
    - Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
    - Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

## Section 9. Physical and chemical properties

### Appearance

- Physical state** : Liquid.
- Color** : Red-Orange.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point** : Not available.

## Section 9. Physical and chemical properties

<b>Boiling point</b>	: Not available.
<b>Flash point</b>	: Not available.
<b>Evaporation rate</b>	: Not available.
<b>Flammability (solid, gas)</b>	: Not available.
<b>Lower and upper explosive (flammable) limits</b>	: Not available.
<b>Vapor pressure</b>	: Not available.
<b>Vapor density</b>	: Not available.
<b>Relative density</b>	: Not available.
<b>Solubility</b>	: Not available.
<b>Partition coefficient: n-octanol/water</b>	: Not available.
<b>Auto-ignition temperature</b>	: Not available.
<b>Decomposition temperature</b>	: Not available.
<b>Viscosity</b>	: Not available.

## Section 10. Stability and reactivity

<b>Reactivity</b>	: No specific test data related to reactivity available for this product or its ingredients.
<b>Chemical stability</b>	: The product is stable.
<b>Possibility of hazardous reactions</b>	: Under normal conditions of storage and use, hazardous reactions will not occur.
<b>Conditions to avoid</b>	: No specific data.
<b>Incompatible materials</b>	: Not available.
<b>Hazardous decomposition products</b>	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

There is no data available.

#### Irritation/Corrosion

There is no data available.

#### Sensitization

There is no data available.

#### Mutagenicity

There is no data available.

#### Carcinogenicity

There is no data available.

#### Reproductive toxicity

There is no data available.

#### Teratogenicity

## Section 11. Toxicological information

There is no data available.

**Specific target organ toxicity (single exposure)**

There is no data available.

**Specific target organ toxicity (repeated exposure)**

There is no data available.

**Aspiration hazard**

There is no data available.

**Information on the likely routes of exposure** : Dermal contact. Eye contact. Inhalation. Ingestion.

**Potential acute health effects**

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

**Symptoms related to the physical, chemical and toxicological characteristics**

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

**Delayed and immediate effects and also chronic effects from short and long term exposure**

**Short term exposure**

- Potential immediate effects** : No known significant effects or critical hazards.
- Potential delayed effects** : No known significant effects or critical hazards.

**Long term exposure**

- Potential immediate effects** : No known significant effects or critical hazards.
- Potential delayed effects** : No known significant effects or critical hazards.

**Potential chronic health effects**

- General** : No known significant effects or critical hazards.
- Carcinogenicity** : May cause cancer. Risk of cancer depends on duration and level of exposure.
- Mutagenicity** : No known significant effects or critical hazards.
- Teratogenicity** : No known significant effects or critical hazards.
- Developmental effects** : No known significant effects or critical hazards.
- Fertility effects** : No known significant effects or critical hazards.

**Numerical measures of toxicity**

**Acute toxicity estimates**

Route	ATE value
Oral	25000 mg/kg



## Section 12. Ecological information

**Toxicity**

There is no data available.

**Persistence and degradability**

There is no data available.

**Bioaccumulative potential**

There is no data available.

**Mobility in soil**

**Soil/water partition coefficient (K<sub>oc</sub>)** : Not available.

**Other adverse effects** : No known significant effects or critical hazards.

## Section 13. Disposal considerations

**Disposal methods** : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

## Section 14. Transport information

	DOT Classification	IMDG	IATA
<b>UN number</b>	Not regulated.	Not regulated.	Not regulated.
<b>UN proper shipping name</b>	-	-	-
<b>Transport hazard class(es)</b>	-	-	-
<b>Packing group</b>	-	-	-
<b>Environmental hazards</b>	No.	No.	No.
<b>Additional information</b>	-	-	-

**AERG** : Not applicable.

## Section 14. Transport information

**Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

## Section 15. Regulatory information

**U.S. Federal regulations** : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined  
**United States inventory (TSCA 8b):** Not determined.

**Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)** : Not listed

**Clean Air Act Section 602 Class I Substances** : Not listed

**Clean Air Act Section 602 Class II Substances** : Not listed

**DEA List I Chemicals (Precursor Chemicals)** : Not listed

**DEA List II Chemicals (Essential Chemicals)** : Not listed

**SARA 302/304**

**Composition/information on ingredients**

No products were found.

**SARA 304 RQ** : Not applicable.

**SARA 311/312**

**Classification** : Delayed (chronic) health hazard

**Composition/information on ingredients**

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
(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	$\geq 1 - \leq 3$	No.	No.	No.	Yes.	Yes.

**SARA 313**

There is no data available.

**State regulations**

**Massachusetts** : None of the components are listed.

**New York** : None of the components are listed.

**New Jersey** : None of the components are listed.

**Pennsylvania** : The following components are listed: (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

**California Prop. 65**

**Section 15. Regulatory information**

**WARNING:** This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

<b>Ingredient name</b>	<b>Cancer</b>	<b>Reproductive</b>	<b>No significant risk level</b>	<b>Maximum acceptable dosage level</b>
(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	Yes.	Yes.	No.	No.

**Section 16. Other information**

Procedure used to derive the classification

<b>Classification</b>	<b>Justification</b>
CARCINOGENICITY - Category 1B	Calculation method

History

- Revision date mm/dd/yyyy** : 11/15/2018
- Version** : 2
- Prepared by** : KMK Regulatory Services Inc.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.