

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Doxo-AUS/DP-005

Effective Date: 14th October 2024

DOXORUBICIN CONCENTRATED SOLUTION FOR INJECTION 10 MG/5 ML AND 200 MG/100 ML

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Doxorubicin Accord Concentrated Solution of Injection
10 mg/5 mL and 200 mg/100 mL

Sponsor	Manufacturer-1	Manufacturer-2
Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia Telephone: 1800 222 673 (hours 8:30am – 4:30pm)	Intas Pharmaceuticals Ltd. Plot No. 457, 458 Village-Matoda, Bavla Road, Ta. Sanand, Dist. Ahmedabad-382 210, Gujarat, India	Intas Pharmaceuticals Ltd. Plot No. 5, 6 and 7, Pharmez, Near Matoda Village, Ahmedabad-382 213, Gujarat, India

SECTION 2 – HAZARD(S) IDENTIFICATION

Classification of the Substance or Mixture:

GHS – Classification:

Germ Cell Mutagenicity : Category 1B
Reproductive Toxicity : Category 1B
Carcinogenicity : Category 1B
Skin corrosion/irritation : Category 1A
Acute Toxicity, Inhalation : Category 3

Label Elements:



Signal Word: Danger

Hazard Statements:

H314 - Causes severe skin burns and eye damage
H331 - Toxic if inhaled
H340 - May cause genetic defects
H350 - May cause cancer
H360FD - May damage fertility. May damage the unborn child

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Precautionary Statements:

- P201 - Obtain special instructions before use.
- P202 - Do not handle until all safety precautions have been read and understood.
- P281 - Use personal protective equipment as required
- P308 + P313 - If exposed or concerned: Get medical advice/attention.
- P405 - Store locked up.
- P501 - Dispose of contents/container in accordance with local, state, federal and provincial regulations.

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

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.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Active: Doxorubicin hydrochloride.

Inactive: Sodium chloride, Hydrochloric acid 37%, Water for Injection.

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Doxorubicin Hydrochloride	25316-40-9	246-818-3	Muta.1B (H340) Carc.1B (H350) Repr.1B (H360FD)	0.2
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Hydrochloric Acid	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	**
Water for Injection	7732-18-5	231-791-2	Not Listed	*

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.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

SECTION 4 - FIRST AID MEASURES

Description of Necessary First Aid Measures:

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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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.

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.

Medical Attention and Special Treatment: None.

SECTION 5 - FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture: Formation of toxic gases is possible during heating or fire.

Special Protective Equipment and Precautions for Fire-Fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

Methods and Material for Containment and Cleaning Up: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. 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.

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SECTION 7 - HANDLING AND STORAGE

Precautions for Safe Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

Conditions for Safe Storage, Including any Incompatibilities: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product used as Antineoplastic.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters – Exposure Standards, Biological Monitoring:

Doxorubicin hydrochloride:

OEL TWA-8 Hr : 0.5 µg/m³

Sodium chloride:

Latvia OEL - TWA : 5 mg/m³

Lithuania OEL - TWA : 5 mg/m³

Hydrochloric acid:

ACGIH Ceiling Threshold Limit : 2 ppm

Australia PEAK : 5 ppm
7.5 mg/m³

Austria OEL – MAKs : 5 ppm
8 mg/m³

Belgium OEL - TWA : 5 ppm
8 mg/m³

Bulgaria OEL - TWA : 5 ppm
8.0 mg/m³

Cyprus OEL - TWA : 5 ppm
8 mg/m³

Czech Republic OEL - TWA : 8 mg/m³

Estonia OEL - TWA : 5 ppm
8 mg/m³

Germany - TRGS 900 - TWAs : 2 ppm
3 mg/m³

Germany (DFG) - MAK : 2 ppm
3.0 mg/m³

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Hungary OEL - TWA	: 8 mg/m ³
Ireland OEL - TWAs	: 5 ppm 8 mg/m ³
Italy OEL - TWA	: 5 ppm 8 mg/m ³
Japan - OELs - Ceilings	: 2 ppm 3.0 mg/m ³
Latvia OEL – TWA	: 5 ppm 8 mg/m ³
Lithuania OEL - TWA	: 5 ppm 8 mg/m ³
Luxembourg OEL - TWA	: 5 ppm 8 mg/m ³
Malta OEL - TWA	: 5 ppm 8 mg/m ³
Netherlands OEL - TWA	: 8 mg/m ³
Poland OEL - TWA	: 5 mg/m ³
Portugal OEL - TWA	: 5 ppm 8 mg/m ³
Romania OEL - TWA	: 5 ppm 8 mg/m ³
Slovakia OEL - TWA	: 5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	: 5 ppm 8 mg/m ³
Spain OEL – TWA	: 5 ppm 7.6 mg/m ³
Switzerland OEL –TWAs	: 2 ppm 3.0 mg/m ³
Vietnam OEL - TWAs	: 5 mg/m ³

Sodium chloride:

Occupation Exposure Band (OEB) : OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Appropriate 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). 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.

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Hands: 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.)

Eyes: 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.)

Skin: 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.)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Solution
Colour	: Red
Odour	: No data available
Odour Threshold	: No data available
Solvent Solubility	: No data available
Water Solubility	: No data available
pH	: 3.0
Melting/Freezing Point (°C)	: No data available
Boiling Point and boiling range (°C)	: No data available
Partition Coefficient	
Doxorubicin hydrochloride	: No data available
Sodium chloride	: No data available
Hydrochloric acid	: No data available
Water for Injection	: No data available
Decomposition Temperature (°C)	: No data available
Evaporation Rate (Gram/s)	: No data available
Vapour Pressure (kPa)	: No data available
Vapour Density (g/ml)	: No data available
Relative Density	: No data available
Viscosity	: No data available
Auto-ignition Temperature (Solid) (°C)	: No data available
Flammability (Solids)	: No data available
Flash Point (Liquid) (°C)	: No data available
Upper Flammability or Explosive Limits (Liquid) (% by Vol.)	: No data available
Lower Flammability or Explosive Limits (Liquid) (% by Vol.)	: No data available

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SECTION 10 - STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical Stability: Stable under normal conditions of use.

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

Incompatible Materials and Possible Hazardous Reactions: As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition Products: No data available.

SECTION 11 – TOXICOLOGICAL INFORMATION

The information included in this section describes the potential hazards of the active ingredient.

Information on Toxicological Effects:

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 testes, the developing fetus.

Known Clinical Effects: Bone marrow suppression is the most serious adverse effect seen during clinical use. 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:

Doxorubicin hydrochloride:

Species	Route	End Point	Dose
Mouse	Oral	LD 50	698 mg/kg
Mouse	Para-periosteal	LD 50	1.2 mg/kg
Rat	Intravenous	LD 50	12.5 mg/kg
Rat	Intraperitoneal	LD 50	16 mg/kg

Sodium chloride:

Species	Route	End Point	Dose
Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

Irritation / Sensitization:

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Sodium chloride:

Study Type	Species	Severity
Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

Hydrochloric acid:

Study Type	Species	Severity
Skin	Irritation	Severe
Eye	Irritation	Severe

Reproduction & Development Toxicity:

Doxorubicin hydrochloride:

Study Type	Species	Route	Dose	End Point	Effect(s)
Reproductive & Fertility-Females	Rat	Intraperitoneal	0.05 mg/kg/day	LOAEL	Fertility
Reproductive & Fertility-Males	Rat	Intraperitoneal	0.1 mg/kg/day	LOAEL	Fertility
Embryo / Fetal Development	Rat	Intraperitoneal	0.8 mg/kg/day	LOAEL	Teratogenic, Embryotoxicity
Embryo / Fetal Development	Rabbit	Intraperitoneal	0.4 mg/kg/day	LOAEL	Embryotoxicity

Genetic Toxicity:

Doxorubicin hydrochloride:

Study Type	Cell Type/Organism	Result
Bacterial Mutagenicity (Ames)	Salmonella, E. coli	Positive
<i>In Vivo</i> Micronucleus	Mouse	Positive
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Positive
<i>In Vitro</i> Sister Chromatid Exchange	Human Lymphocytes	Positive
Dominant Lethal Assay	Mouse	Positive

Carcinogen Status: See below

Doxorubicin hydrochloride:

IARC: 2A

NTP: Reasonably anticipated to be a human carcinogen

Hydrochloric acid:

IARC: Group 3 (Not classifiable)

SECTION 12 – ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity: No data available.

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Persistence and Degradability: No data available.

Bio-accumulative Potential: No data available.

Mobility in Soil: No data available.

Other Adverse Effects: No data available.

SECTION 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.

SECTION 14 - TRANSPORTATION INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15 - REGULATORY INFORMATION

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

Doxorubicin hydrochloride:

CERCLA/SARA 313 Emission reporting	: Not Listed
California Proposition 65	: carcinogen 7/1/1987 developmental toxicity 1/29/1999 male reproductive toxicity 1/29/99
EU EINECS/ELINCS List	: 246-818-3

Sodium chloride:

CERCLA/SARA 313 Emission reporting	: Not Listed
California Proposition 65	: Not Listed
Inventory - United States TSCA - Sect. 8(b)	: Present
Australia (AICS)	: Present

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EU EINECS/ELINCS List : 231-598-3

Hydrochloric acid:

CERCLA/SARA 313 Emission reporting : 1.0%
CERCLA/SARA Hazardous substances and their reportable quantities : 5000 lb
2270 kg
CERCLA/SARA – Section 302 Extremely hazardous TPQs : 500 lb
CERCLA/SARA – Section 302 Extremely hazardous substances : 5000 lb
EPCRA RQs
California Proposition 65 : Not Listed
Inventory - United States TSCA - Sect. 8(b) : Present
Australia (AICS) : Present
Standard for the Uniform Scheduling for Drugs and Poisons : Schedule 5
Schedule 6
EU EINECS/ELINCS List : 231-595-7

Water for Injection:

CERCLA/SARA 313 Emission reporting : Not Listed
California Proposition 65 : Not Listed
Inventory - United States TSCA - Sect. 8(b) : Present
Australia (AICS) : Present
REACH - Annex IV - Exemptions from the obligations of Register : Present
EU EINECS/ELINCS List : 231-791-2

SECTION 16 - OTHER INFORMATION

Abbreviations:

ACGIH : American Conference of Governmental Industrial Hygienists
AICS : Australian Inventory of Chemical Substances
AIHA : American Industrial Hygiene Association
ANSI : American National Standards Institute
CAS : Number Chemical Abstract Service Registry Number
CERCLA : Comprehensive Environmental Response Compensation and Liability Act
CHAN : Chemical Hazard Alert Notice
CHEMTREC : Chemical Transportation Emergency Center
DOT : Department of Transportation
DSL : Domestic Substances List
ECHA : European Chemicals Agency
EINECS : European Inventory of Existing Commercial Chemical Substances
ELINCS : European List of Notified Chemical Substances
EPA : Environmental Protection Agency
GHS : Globally Harmonized System of Classification and Labelling of Chemicals
HEPA : High Efficiency Particulate Air (Filter)
HMIS : Hazardous Materials Identification System
IARC : International Agency for Research on Cancer
ICAO/IATA : International Civil Aviation Organization/International Air Transport

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IMO	: International Maritime Organization
KOW	: Octanol/Water Partition Coefficient
LEL	: Lower Explosive Limit
MSDS	: Material Safety Data Sheet
MSHA	: Mine Safety and Health Administration
NA	: Not Applicable, except in Section 14 where NA = North America
NE	: Not Established
NADA	: New Animal Drug Application
NAIF	: No Applicable Information Found
NCI	: National Cancer Institute
NDSL	: Non-Domestic Substances List
NFPA	: National Fire Protection Association
NIOSH	: National Institute for Occupational Safety and Health
NPDES	: National Pollutant Discharge Elimination System
NOS	: Not Otherwise Specified
NTP	: National Toxicology Program
OSHA	: Occupational Safety and Health Administration
OEL	: Occupational Exposure Limit
PEL	: Permissible Exposure Limit (OSHA)
RCRA	: Resource Conservation and Recovery Act
RQ	: Reportable Quantity
RTECS	: Registry of Toxic Effects of Chemical Substances
SARA	: Superfund Amendments and Reauthorization Act
SDS	: Safety Data Sheet
STEL	: Short Term Exposure Limit
TLV	: Threshold Limit Value (ACGIH)
TPQ	: Threshold Planning Quantity
TSCA	: Toxic Substances Control Act
TWA	: Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	: Upper Explosive Limit
UN	: United Nations
USP	: United States Pharmacopeia
WEEL	: Workplace Environmental Exposure Level (AIHA)
WHMIS	: Workplace Hazardous Materials Information System

Data Sources: Information from published literature.

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