

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Doc-AUS/DP-004

Effective Date: 14th October 2024

DOCETAXEL INJECTION
20 MG/1 ML, 80 MG/4 ML, AND 160 MG/8 ML

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Docetaxel Accord Concentrated Injection
20 mg/1 mL, 80 mg/4 mL, and 160 mg/8 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, Pharmedz, 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 2
Reproductive Toxicity : Category 1B

Label Elements:



Signal Word: Danger

Hazard Statements:

H225 - Highly flammable liquid and vapour
H319 - Causes serious eye irritation
H341 - Suspected of causing genetic defects
H360D - May damage the unborn child
H362 - May cause harm to breast-fed children

Precautionary Statements:

P202 - Do not handle until all safety precautions have been read and understood.
P210 - Keep away from heat/sparks/open flames/hot surfaces. No smoking

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- P233 - Keep container tightly closed
- P240 - Ground/Bond container and receiving equipment
- P242 - Use only non-sparking tools
- P243 - Take precautionary measures against static discharge
- P280 - Wear protective gloves/protective clothing/eye protection/face protection.
- P303 + P361 + P353 - If on Skin or hair: remove take/off immediately all contaminated clothing. Rinse skin with water/shower.
- P308 + P313 - If exposed or concerned: Get medical advice/attention.
- P370 + P378 - In case of fire: Use CO₂, extinguishing powder, foam, or water for extinction
- P403 + P235 - Store in a well-ventilated place. Keep cool.
- P405 - Store locked up.

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: Docetaxel.

Inactive: Anhydrous Citric acid, Dehydrated alcohol and Polysorbate 80.

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Docetaxel anhydrous	114977-28-5	Not Listed	Repr. 1B (H360D) Muta. 2 (H341) Eye Irrit. 2A (H319) Lact. (H362)	1
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	**
Ethyl alcohol (ethanol)	64-17-5	200-578-6	Flam. Liq. 2 (H225)	<40
Polysorbate 80	9005-65-6	500-019-9	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

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Description of Necessary First Aid Measures:

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

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.

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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.

SECTION 7 - HANDLING AND STORAGE

Precautions for Safe Handling: Flammable liquid and vapor- keep away from ignition sources and clean up spills promptly. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin, and clothing. Use appropriate personal protective equipment. Wash thoroughly after handling. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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:

Ethyl alcohol (ethanol):

ACGIH Threshold Limit Value (STEL)	:	1000 ppm
Australia TWA	:	1000 ppm 1880 mg/m ³
Austria OEL - MAKs	:	1000 ppm 1900 mg/m ³
Belgium OEL - TWA	:	1000 ppm 1907 mg/m ³
Bulgaria OEL - TWA	:	1000 mg/m ³
Czech Republic OEL - TWA	:	1000 mg/m ³
Denmark OEL - TWA	:	1000 ppm 1900 mg/m ³
Estonia OEL - TWA	:	500 ppm 1000 mg/m ³
Finland OEL - TWA	:	1000 ppm 1900 mg/m ³
France OEL - TWA	:	1000 ppm 1900 mg/m ³

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Germany - TRGS 900 - TWAs	: 500 ppm 960 mg/m ³
Germany (DFG) - MAK	: 500 ppm 960 mg/m ³
Greece OEL - TWA	: 1000 ppm 1900 mg/m ³
Hungary OEL - TWA	: 1900 mg/m ³
Latvia OEL - TWA	: 1000 mg/m ³
Lithuania OEL - TWA	: 500 ppm 1000 mg/m ³
Netherlands OEL - TWA	: 260 mg/m ³
OSHA - Final PELs - TWAs:	: 1000 ppm 1900 mg/m ³
Poland OEL - TWA	: 1900 mg/m ³
Portugal OEL - TWA	: 1000 ppm
Romania OEL - TWA	: 1000 ppm 1900 mg/m ³
Russia OEL - TWA	: 1000 mg/m ³
Slovakia OEL - TWA	: 500 ppm 960 mg/m ³
Slovenia OEL - TWA	: 1000 ppm 1900 mg/m ³
Sweden OEL - TWAs	: 500 ppm 1000 mg/m ³
Switzerland OEL -TWAs	: 500 ppm 960 mg/m ³
Vietnam OEL - TWAs	: 1000 mg/m ³

Docetaxel anhydrous:

Occupational Exposure Band (OEB): OEB 4 (control exposure to the range of 1ug/m³ to <10ug/m³).

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

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	: Clear, colourless to pale yellow
Odour	: No data available
Odour Threshold	: No data available
Solvent Solubility	: No data available
Water Solubility	: No data available
pH	: 4-7
Melting/Freezing Point (°C)	: No data available
Boiling Point and boiling range (°C)	: No data available
Partition Coefficient	
Docetaxel anhydrous	: No data available
Citric acid, anhydrous	: No data available
Polysorbate 80	: No data available
Ethyl alcohol (ethanol)	: 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)	: 24
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 irritation (based on components).

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on central nervous system, gastrointestinal system, blood and blood forming organs, and testes.

Known Clinical Effects: Common adverse effects include blood cell changes, nervous system/brain toxicity (neurotoxicity). Serious allergic reactions, including anaphylaxis, have been reported.

Acute Toxicity:

Docetaxel anhydrous:

Species	Route	End Point	Dose
Rat	Oral	LD50	> 2000 mg/kg
Mouse	IV	LD50	138mg/kg

Citric acid, anhydrous:

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

Ethyl alcohol (Ethanol):

Species	Route	End Point	Dose
Mouse	Oral	LD50	3450 mg/kg
Rat	Oral	LD50	7060mg/kg
Rat	Inhalation	LC50 10h	20,000ppm

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Polysorbate 80:

Species	Route	End Point	Dose
Rat	Intravenous	LD50	1790 mg/kg
Mouse	Oral	LD 50	25 g/kg

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization:

Docetaxel anhydrous:

Study Type	Species	Severity
Eye Irritation	Rabbit	Irritant
Skin Irritation	Rabbit	Non-irritating
Skin Sensitization		Negative

Citric acid, anhydrous:

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

Ethyl alcohol (Ethanol):

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

Repeated Dose Toxicity:

Docetaxel anhydrous:

Duration	Species	Route	Dose	End Point	Target Organ
28-31 Day(s)	Rat	Intravenous	mg/m ² /day	NOEL	Blood forming organs, Male reproductive system
6 Month(s)	Rat	Intravenous	0.2 mg/kg/day	NOEL	Blood forming organs, Male reproductive system
6 Month(s)	Dog	Intravenous	0.375 mg/kg/day	LOAEL	Male reproductive system

Reproduction & Development Toxicity:

Docetaxel anhydrous:

Study Type	Species	Route	Dose	End Point	Effect(s)
Reproductive & Fertility	Rat	Intravenous	mg/kg/day	LOAEL	Paternal toxicity
Embryo / Fetal Development	Rat	Intravenous	0.3 mg/kg/day	LOAEL	Maternal Toxicity, Embryotoxicity, Fetotoxicity, Not Teratogenic
Embryo / Fetal Development	Rabbit	Intravenous	0.03 mg/kg/day	LOAEL	Embryotoxicity, Fetotoxicity, Maternal Toxicity, Not Teratogenic

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Genetic Toxicity:

Docetaxel:

Study Type	Cell Type/Organism	Result
<i>In Vitro</i> Bacterial Mutagenicity (Ames)	Salmonella, E. coli	Negative
<i>In Vivo</i> Micronucleus	Mouse	Positive
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Positive

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

Ethyl alcohol (Ethanol):

IARC: Group 1 (Carcinogenic to Humans)

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:

Docetaxel:

Species	End Point	Duration	Result
<i>Daphnia magna</i> (Water Flea)	LC50	48 Hours	> 3.3 mg/L

Ethyl alcohol (Ethanol):

Species	End Point	Duration	Result
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LC50	96h	12,900-15,300 mg/L

A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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

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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.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 1170

UN proper shipping name: Ethanol solution

Transport hazard class(es): 3

Packing group: III

Flash Point (°C): 24

SECTION 15 - REGULATORY INFORMATION

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

Docetaxel anhydrous:

CERCLA/SARA 313 Emission reporting	: Not Listed
California Proposition 65	: Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons	: Schedule 4
EU EINECS/ELINCS List	: Not Listed

Citric acid, anhydrous:

CERCLA/SARA 313 Emission reporting	: Not Listed
California Proposition 65	: Not Listed
Inventory - United States TSCA - Sect. 8(b)	: Present
Australia (AICS)	: Present
EU EINECS/ELINCS List	: 201-069-1

Ethyl alcohol (Ethanol):

CERCLA/SARA 313 Emission reporting	: Not Listed
California Proposition 65	: carcinogen 4/29/2011 in alcoholic beverages developmental toxicity 10/1/1987 in alcoholic beverages
Inventory - United States TSCA - Sect. 8(b)	: Present
Australia (AICS)	: Present

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EU EINECS/ELINCS List : 200-578-6

Polysorbate 80:

CERCLA/SARA 313 Emission reporting : Not Listed

California Proposition 65 : Not Listed

Inventory - United States TSCA - Sect. 8(b) : Present

Australia (AICS) : Present

EU EINECS/ELINCS List : 500-019-9

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
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

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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.

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall INTAS be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if INTAS has been advised of the possibility of such damages.