

YONDELIS

Version	Revision Date:	SDS Number:	Date of last issue:
1.54	2017/09/21	100000010395	2017/03/28
			Date of first issue: 2014/07/10

SECTION 1. IDENTIFICATION

Product name : YONDELIS
 Substance name : YONDELIS 1mg for injection
 trabectedin

Manufacturer or supplier's details

Company name of supplier : Janssen Biotech Inc.

Address : 200 Great Valley Parkway
 Malvern, PA 19355
 US

Telephone : (610) 651-6000
 E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

**Emergency telephone number : CHEMTREC US: 1-800-424-9300
 CHEMTREC International: +1 703-527-3887**

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product
 This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
 This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Reproductive toxicity : Category 2

GHS label elements

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

Hazard pictograms :



Signal word : Warning

Hazard statements : H361 Suspected of damaging fertility or the unborn child.

YONDELIS

Version	Revision Date:	SDS Number:	Date of last issue: 2017/03/28
1.54	2017/09/21	100000010395	Date of first issue: 2014/07/10

Precautionary statements : **Prevention:**
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.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules. Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidentally leaking, broken or crushed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Chemical nature : Solid

Hazardous components

Chemical name	CAS-No.	Concentration (%)
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	>= 90 - <= 100
ECTEINASCIDINE 743	114899-77-3	>= 0.1 - < 1

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
Consult a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and water.
If symptoms persist, call a physician.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids,
for at least 5 minutes.
Remove contact lenses.
If eye irritation persists, consult a specialist.

If swallowed : If swallowed, rinse mouth with water (only if the person is conscious).
Call a physician immediately.

YONDELIS

Version	Revision Date:	SDS Number:	Date of last issue: 2017/03/28
1.54	2017/09/21	100000010395	Date of first issue: 2014/07/10

Most important symptoms and effects, both acute and delayed : Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

- Abdominal pain
- Blood disorders
- Breathing difficulties
- constipation
- Diarrhoea
- Dizziness
- Fatigue
- Fever
- hair loss
- Headache
- hypertension
- indigestion
- inflammation
- insomnia
- joint pain
- Nausea
- Nervous system
- Pain
- Pneumonia
- Vomiting
- anemia
- loss in appetite

Notes to physician : Treat symptomatically.
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Hazardous combustion products : No hazardous combustion products are known

Further information : Avoid dust formation.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Avoid breathing dust.
Evacuate personnel to safe areas.
In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.

Environmental precautions : Should not be released into the environment.

Version	Revision Date:	SDS Number:	Date of last issue:
1.54	2017/09/21	100000010395	2017/03/28
			Date of first issue: 2014/07/10

Methods and materials for containment and cleaning up : Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".
Large spills: Sweep up (intact) or vacuum with HEPA filter (broken or crushed) or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating dust. Keep in properly labelled containers.
Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid dust formation.

Advice on safe handling : Ensure all equipment is electrically grounded before beginning transfer operations.
To avoid thermal decomposition, do not overheat.
Keep away from heat and sources of ignition.
Avoid inhalation, ingestion and contact with skin and eyes.
Do not break, crush or spill this Finished Pharmaceutical Product.
Use personal protective equipment as required.

Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Store in original container.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep away from heat and sources of ignition.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0

SAFETY DATA SHEET

YONDELIS



Version 1.54 Revision Date: 2017/09/21 SDS Number: 100000010395 Date of last issue: 2017/03/28
 Date of first issue: 2014/07/10

		PEL (Total dust)	10 mg/m ³	CAL PEL
		PEL (respirable dust fraction)	5 mg/m ³	CAL PEL
ECTEINASCIDINE 743	114899-77-3	TWA	0.00025 mg/m ³	J&J OEL/PBOEL HHC
		PBOEL-HHC	4	J&J OEL/PBOEL HHC
Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 4., Notation REPRO: has the potential to have adverse effects on reproduction and fetal development				

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required. Engineering controls should always be the primary method of controlling exposures. If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.

Hand protection

Remarks : Gloves are recommended as a good hygiene measure if there is direct contact with the tablets.

Eye protection : No special precautions required.

Skin and body protection : No special precautions required.

Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder, Vial

Colour : white

SAFETY DATA SHEET

YONDELIS



Version 1.54 Revision Date: 2017/09/21 SDS Number: 100000010395 Date of last issue: 2017/03/28
Date of first issue: 2014/07/10

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : No information available.

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

 Water solubility : No data available

 Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Decomposition temperature : No data available

Viscosity

 Viscosity, dynamic : Not applicable

 Viscosity, kinematic : Not applicable

Explosive properties : No data available

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : None reasonably foreseeable.

Chemical stability : Stable under normal conditions.

YONDELIS

Version	Revision Date:	SDS Number:	Date of last issue: 2017/03/28
1.54	2017/09/21	100000010395	Date of first issue: 2014/07/10

Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : To avoid thermal decomposition, do not overheat. Heat, flames and sparks.

Incompatible materials : None known.

Hazardous decomposition products : None known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Product:**

Acute oral toxicity : Acute toxicity estimate: 2,174 mg/kg
Method: Calculation method

Components:**ECTEINASCIDINE 743**

Acute oral toxicity : Assessment: The component/mixture is highly toxic after single ingestion.

Acute inhalation toxicity : Assessment: The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : Assessment: The component/mixture is moderately toxic after single contact with skin.

Acute toxicity (other routes of administration) : LD50 (Rat): ca. 100.8 mg/kg
Application Route: intravenous injection

Skin corrosion/irritation**Components:****ECTEINASCIDINE 743**

Remarks: No data available

Serious eye damage/eye irritation**Components:****ECTEINASCIDINE 743**

Remarks: No data available

Respiratory or skin sensitisation**Components:****ECTEINASCIDINE 743**

Remarks: No data available

YONDELIS

Version	Revision Date:	SDS Number:	Date of last issue:
1.54	2017/09/21	100000010395	2017/03/28
			Date of first issue: 2014/07/10

Germ cell mutagenicity**Components:****ECTEINASCIDINE 743**

Genotoxicity in vitro	:	Test Type: Ames test Result: positive
	:	Test Type: Chromosome aberration test in vitro Result: positive
Genotoxicity in vivo	:	Test Type: In vivo micronucleus test Species: Mouse Result: positive
Germ cell mutagenicity - Assessment	:	Suspected of causing genetic defects, based on positive evidence obtained from in vivo studies and expert judgment.

Carcinogenicity**Components:****ECTEINASCIDINE 743**

Carcinogenicity - Assessment	:	No information available.
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IARC

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity**Components:****ECTEINASCIDINE 743**

Teratogenicity - Assessment	:	Limited evidence of adverse effects on development in animal studies and/ or human studies.
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STOT - single exposure**Components:****ECTEINASCIDINE 743**

Remarks: No data available

STOT - repeated exposure**Components:****ECTEINASCIDINE 743**

Version	Revision Date:	SDS Number:	Date of last issue: 2017/03/28
1.54	2017/09/21	100000010395	Date of first issue: 2014/07/10

Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

No data available

Aspiration toxicity

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

ECTEINASCIDINE 743

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

Persistence and degradability

Components:

ECTEINASCIDINE 743

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

ECTEINASCIDINE 743

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

Components:

ECTEINASCIDINE 743

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

YONDELIS

Version	Revision Date:	SDS Number:	Date of last issue: 2017/03/28
1.54	2017/09/21	100000010395	Date of first issue: 2014/07/10

Components:**ECTEINASCIDINE 743**

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available
No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : In accordance with National, Federal, State and Local regulations.

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

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know Act**

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

YONDELIS

Version	Revision Date:	SDS Number:	Date of last issue: 2017/03/28
1.54	2017/09/21	100000010395	Date of first issue: 2014/07/10

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

US State Regulations**Massachusetts Right To Know**

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	90 - 100 %
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Pennsylvania Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	90 - 100 %
Phosphoric acid, monopotassium salt	7778-77-0	5 - 10 %

New Jersey Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	90 - 100 %
Phosphoric acid, monopotassium salt	7778-77-0	5 - 10 %

California Prop 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Other regulations

: Restricted to professional users.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

SAFETY DATA SHEET

YONDELIS

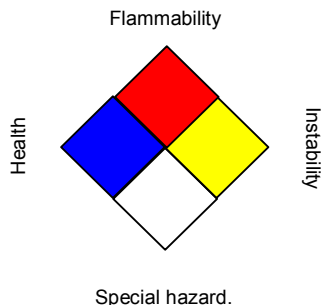


Version 1.54 Revision Date: 2017/09/21 SDS Number: 100000010395 Date of last issue: 2017/03/28
Date of first issue: 2014/07/10

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	
FLAMMABILITY	
PHYSICAL HAZARD	

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Revision Date : 2017/09/21

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date: Dec 31th, 2012 as 2012/12/31
Numbers: 123456,78 as 123,456.78

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.

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