

SAFETY DATA SHEET



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SECTION 1. IDENTIFICATION

Substance name : INLEXZO™ (gemcitabine intravesical system)
Gemcitabine Minitablets
gemcitabine hydrochloride
TAR-200 device
256.3 mg gemcitabine hydrochloride (equivalent to 225 mg
gemcitabine free base)

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560

USA

Telephone : +16097302000

E-mail address of person responsible for the SDS : SDSJanssen@its.jnj.com

Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-741-5970

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 in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral) : Category 4

Acute toxicity (Dermal) : Category 3

Skin irritation : Category 2

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Eye irritation : Category 2A

Germ cell mutagenicity : Category 1B

Reproductive toxicity : Category 1B

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H302 Harmful if swallowed.
H311 Toxic in contact with skin.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H340 May cause genetic defects.
H360FD May damage fertility. May damage the unborn child.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P302 + P352 + P312 IF ON SKIN: Wash with plenty of water. Call a POISON CENTER/ doctor if you feel unwell.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

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disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
GEMCITABINE-HYDROCHLORIDE	122111-03-9	$\geq 70 - < 90$
CARBAMIDE	57-13-6	$\geq 10 - < 20$
Polyethylene glycol 8000, NF	25322-68-3	$\geq 1 - < 5$

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- If inhaled : If breathed in, move person into fresh air.
Artificial respiration and/or oxygen may be necessary.
Consult a physician.
- In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off immediately with plenty of water.
Call a physician immediately.
Wash contaminated clothing before reuse.
- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids,
for at least 15 minutes.
Remove contact lenses.
Consult a physician.
- If swallowed : If swallowed, rinse mouth with water (only if the person is
conscious).
Call a physician immediately.
- Most important symptoms and effects, both acute and delayed : Irritating to eyes.
Irritating to skin.
Toxic in contact with skin.
Harmful if swallowed.
Bloody urine
urinary tract infection
- Notes to physician : Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

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- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Hazardous combustion products : No information available.
- Further information : No information available.
- 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 : 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.
Evacuate personnel to safe areas.
Avoid dust formation.
Avoid breathing dust.
- Environmental precautions : Should not be released into the environment.
- Methods and materials for containment and cleaning up : Large spills: Sweep up or vacuum with HEPA filter 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.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No data available
- Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.
To avoid thermal decomposition, do not overheat.
Use personal protective equipment as required.
Keep away from heat and sources of ignition.
Avoid inhalation, ingestion and contact with skin and eyes.
- Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Store in original container.
Keep away from heat and sources of ignition.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep locked up.
Store at room temperature.

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Protect against light.
Do not store in the refrigerator or freezer.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
GEMCITABINE-HYDROCHLORIDE	122111-03-9	TWA	0.00014 mg/m ³	J&J OEL/PBOEL HHC
		STV	0,0014 mg/100cm ²	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, Notation CYTOTOXIC: has the potential to interact directly with DNA or DNA-associated macromolecules, resulting in cell death, affecting both healthy and abnormal (i.e., tumor) cells.			
CARBAMIDE	57-13-6	TWA	10 mg/m ³	US WEEL
Polyethylene glycol 8000, NF	25322-68-3	TWA (aerosol)	10 mg/m ³	US WEEL

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.
Engineering controls should be used as the primary means to control possible exposures. Use process enclosures, local exhaust ventilation or other engineering controls to keep exposure levels below recommended exposure limits.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection
Remarks : Disposable gloves

Eye protection : No special precautions required.

Skin and body protection : closed work clothing

Protective measures : The type of protective equipment must be selected based on

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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	: tablet
Colour	: white, off-white
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
Self-ignition	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability 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)	
<u>Water solubility</u>	: No data available
Partition coefficient: n-octanol/water	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

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SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under normal conditions.
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. Exposure to light.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity	:	Acute toxicity estimate: 625 mg/kg Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: 375 mg/kg Method: Calculation method

Components:

GEMCITABINE-HYDROCHLORIDE:

Acute oral toxicity	:	LD50 (Rat): > 500 mg/kg
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	LD50 (Rabbit): 205 - 1,000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): > 500 mg/kg Application Route: intravenous injection LD50 (Mouse): 333 mg/kg Application Route: intravenous injection

Polyethylene glycol 8000, NF:

Acute oral toxicity	:	LD50 (Rat): > 15,000 mg/kg
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Skin corrosion/irritation**Components:****GEMCITABINE-HYDROCHLORIDE:**

Species : Rabbit
Result : Skin irritation

Serious eye damage/eye irritation**Components:****GEMCITABINE-HYDROCHLORIDE:**

Species : Rabbit
Result : Eye irritation

Respiratory or skin sensitisation**Components:****GEMCITABINE-HYDROCHLORIDE:**

Result : Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity**Components:****GEMCITABINE-HYDROCHLORIDE:**

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: A mouse lymphoma test
Result: positive

Genotoxicity in vivo : Test Type: sister chromatid exchange assay
Result: negative

Test Type: In vivo micronucleus test
Result: positive

Germ cell mutagenicity - Assessment : In vivo tests showed mutagenic effects

Carcinogenicity**Components:****GEMCITABINE-HYDROCHLORIDE:**

Remarks : No data available

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Carcinogenicity - Assessment : No information available.

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:

GEMCITABINE-HYDROCHLORIDE:

Effects on foetal development : Species: Mouse
Application Route: intravenous injection
Dose: 0 - 0,05 - 0,25 - 1,5 mg/kg bw/day
Symptoms: Embryotoxic effects., Malformations were observed.

Species: Rabbit
Application Route: intravenous injection
Dose: 0 - 0,0015 - 0,005 - 0,1 mg/kg bw/day
Result: Fetotoxicity at highest dose were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Components:

GEMCITABINE-HYDROCHLORIDE:

Remarks : No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

Components:

GEMCITABINE-HYDROCHLORIDE:

Remarks : No data available

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Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

Components:

GEMCITABINE-HYDROCHLORIDE:

Remarks : Cytotoxic

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

GEMCITABINE-HYDROCHLORIDE:

Toxicity to fish : Remarks: No data available

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

Toxicity to algae/aquatic plants : Remarks: No data available

Persistence and degradability

Components:

GEMCITABINE-HYDROCHLORIDE:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

GEMCITABINE-HYDROCHLORIDE:

Bioaccumulation : Remarks: No data available

Partition coefficient: n- : Remarks: No data available

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octanol/water

Mobility in soil

Components:

Polyethylene glycol 8000, NF:

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Components:

Polyethylene glycol 8000, NF:

Environmental fate and pathways : No data available

Results of PBT and vPvB assessment : No information available.

Additional ecological information : 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

UN number : UN 3249
Proper shipping name : MEDICINE, SOLID, TOXIC, N.O.S.
(GEMCITABINE HYDROCHLORIDE)
Class : 6.1
Packing group : III
Labels : 6.1

IATA-DGR

UN/ID No. : UN 3249
Proper shipping name : Medicine, solid, toxic, n.o.s.
(GEMCITABINE HYDROCHLORIDE)

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Class : 6.1
Packing group : III
Labels : 6.1
Packing instruction (cargo aircraft) : 677
Packing instruction (LQ) : Y645
Packing instruction (EQ) : E1
Packing instruction (passenger aircraft) : 670
Packing instruction (LQ) : Y645
Remarks : This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package $\leq$ 1mL for liquids or $\leq$ 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of IATA DGR §2.6.10 are met.

IMDG-Code

UN number : UN 3249
Proper shipping name : MEDICINE, SOLID, TOXIC, N.O.S. (GEMCITABINE HYDROCHLORIDE)
Class : 6.1
Packing group : III
Labels : 6.1
EmS Code : F-A, S-A
Marine pollutant : no
Remarks : This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package $\leq$ 1mL for liquids or $\leq$ 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of ADR/RID/ADN/IMDG §3.5.1.4 are met.

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

UN/ID/NA number : UN 3249
Proper shipping name : Medicine, solid, toxic, n.o.s. (GEMCITABINE HYDROCHLORIDE)
Class : 6.1
Packing group : III
Labels : 6.1
ERG Code : 151
Marine pollutant : no
Remarks : This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package $\leq$ 1mL for liquids or $\leq$ 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of 49 CFR 173.4b are met.

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Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

GEMCITABINE-HYDROCHLORIDE	122111-03-9
CARBAMIDE	57-13-6
POVIDONE	9003-39-8

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California List of Hazardous Substances

POVIDONE	9003-39-8
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Other regulations

Restricted to professional users.

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

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
J&J OEL/PBOEL HHC / STV	:	STV: Surface Target Value
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC /	:	PBOEL-HHC
PBOEL-HHC		
US WEEL / TWA	:	8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response,

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Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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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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