Version	Revision Date:	SDS Number:	Date of last issue: 05.10.2018
1.1	10.01.2019	10922	Date of first issue: 05.10.2018

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

LYNPARZA TABLETS

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
PO Box 131
66 Talavera Rd, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone
+44 (0) 1235 239 670

Alternative Names
KU-0059436 Tablets
INN Olaparib Tablets
AZD2281 Melt extruded tablets

CAS No. : Not applicable

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

Use of the Substance/Mixture : Potential anti-cancer agent

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral)	:	Category 4
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Bone marrow, lymph node, spleen, Liver, Gastrointestinal tract)
Long-term (chronic) aquatic hazard	:	Category 3

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements :
H302 Harmful if swallowed.
H360 May damage fertility or the unborn child.
H372 Causes damage to organs (Bone marrow, lymph node, spleen, Liver, Gastrointestinal tract) through prolonged or repeated exposure if swallowed.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P281 Use personal protective equipment as required.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

Evidence of genotoxicity and should be treated with caution.
May cause reduced resistance to infection and increased risk of bleeding.
May form explosible dust-air mixture if dispersed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Olaparib	763113-22-0	24.1 -24.4
Celluloses	9004-34-6	1.5 -2.1

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure, keep warm and at rest.
Obtain medical attention if ill effects occur.

In case of skin contact : Wash skin with soap and water.
If symptoms (irritation or blistering) occur obtain medical attention.

In case of eye contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes.
Obtain medical attention.

If swallowed : Wash out mouth with water and give 200-300ml of water to drink.
Do NOT induce vomiting as a First-Aid measure.
Obtain medical attention.

Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11

Notes to physician : Symptomatic treatment and supportive therapy as indicated.
For further detail consult the prescribing information.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : water spray, foam, dry powder or CO2.
Water spray should be used to cool containers.

Unsuitable extinguishing media : Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

Specific hazards during firefighting : If involved in a fire, it may burn and emit noxious and toxic fumes.

Special protective equipment for firefighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.
Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Avoid dispersal of dust in the air.
Ensure suitable personal protection during removal of spillages.
See Section 8.

Environmental precautions : Prevent entry into drains, sewers or watercourses.
Collect spillage.

Methods and materials for containment and cleaning up : Avoid dust generation.
Transfer spilled tablets to a suitable container for disposal.
Wash the spillage area with water.
Avoid release to the environment.

See section 13.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Avoid contact with skin and eyes.
Minimize dust generation and accumulation.
The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.

Conditions for safe storage : Keep container tightly closed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Olaparib	763113-22-0	TWA	0.0005 mg/m3	COM

Celluloses	9004-34-6	TWA	10 mg/m3	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m3	ACGIH

Engineering measures : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains, sewers or watercourses.
See Section 6 for environmental precautions.

Personal protective equipment

Respiratory protection : Use an air fed hood if the risk assessment does not support the selection of other protection.

Eye protection : Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.

Skin and body protection : Use full chemical protective suit to protect against direct contact with the product if the risk assessment does not support the selection of other protection. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.

Protective measures : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc.
All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : coated tablets

Colour	:	green, or, yellow
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	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
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No known reactivity hazard under normal conditions.

Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	None known.
Conditions to avoid	:	No conditions producing hazardous situations known.
Incompatible materials	:	None known.
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity

Product:

Acute oral toxicity	:	Assessment: The component/mixture is moderately toxic after single ingestion.
Acute inhalation toxicity	:	Remarks: May cause effects as described under single exposure.(STOT)
Acute dermal toxicity	:	Remarks: No information available.

Components:

Olaparib:

Acute oral toxicity	:	Oral minimum lethal dose (rat) is approximately: 240 - 300 mg/kg Assessment: The component/mixture is toxic after single ingestion.
Acute inhalation toxicity	:	Remarks: May cause effects as described under repeated exposure.(STOT)
Acute dermal toxicity	:	Remarks: No information available.

11.2 Skin corrosion/irritation

Components:

Olaparib:

Remarks	:	Unlikely to be corrosive to the skin.

11.3 Serious eye damage/eye irritation

Components:

Olaparib:

Remarks	:	Unlikely to be a severe irritant to the eye.

11.4 Respiratory or skin sensitisation

Components:

Olaparib:

Remarks : It is not a skin sensitiser in vivo.
Unlikely to cause skin sensitisation.

Chronic toxicity

11.5 Germ cell mutagenicity

Components:

Olaparib:

Germ cell mutagenicity - Assessment : Evidence of secondary genotoxicity due to negative impact on DNA repair.

11.6 Carcinogenicity

Components:

Olaparib:

Carcinogenicity - Assessment : No evidence of carcinogenicity in animal studies.

11.7 Reproductive toxicity

Components:

Olaparib:

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments., Studies in animals have shown that low doses produce teratogenic effects and can reduce early embryofetal survival.

11.8 STOT - single exposure

Components:

Olaparib:

Exposure routes : Oral
Remarks : May cause effects as described under repeated exposure.(STOT)

11.9 STOT - repeated exposure

Components:

Olaparib:

Exposure routes : Oral
Target Organs : Bone marrow, lymph node, spleen, Liver, Gastrointestinal tract
Assessment : Causes damage to organs through prolonged or repeated exposure.
Remarks : Studies in animals have shown that repeated doses cause

effects on red and white blood cells and platelet count.

Remarks : Common side effects reported from patients include gastrointestinal disorders, headache, dizziness, fatigue and anaemia.
May cause reduced resistance to infection and increased risk of bleeding.
Based on haematology and pathology findings in a study in rats the No Adverse Effect Level was 25 mg/kg/day for females and 250 mg/kg/day for males.

11.10 Aspiration toxicity

Components:

Olaparib:

No information available.

Further information

Product:

Remarks : This health hazard assessment is based on a consideration of the composition of this product.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.
Remarks: Information refers to
Olaparib

Components:

Olaparib:

Toxicity to daphnia and other aquatic invertebrates : NOEC (Daphnia magna (Water flea)): 74 mg/l
Exposure time: 48 H
Method: OECD Test Guideline 202

Toxicity to algae : NOEC (Pseudokirchneriella subcapitata (green algae)): 83 mg/l
Exposure time: 72 H
Test Type: Growth inhibition
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.32 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 0.32 mg/l

aquatic invertebrates (Chronic toxicity) : Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms : Respiration inhibition (Sewage sludge organisms): > 100 mg/l
Exposure time: 3 H
Test Type: EC50
Method: OECD Test Guideline 209

Ecotoxicology Assessment

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.

Persistence and degradability

Components:

Olaparib:

Biodegradability : Result: Not rapidly biodegradable
Biodegradation: < 6 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Stability in water : Method: OECD Test Guideline 111
Remarks: The substance is not significantly hydrolyzed in water.

Bioaccumulative potential

Components:

Olaparib:

Bioaccumulation : Remarks: The substance has low potential for bioaccumulation.

Mobility in soil

Components:

Olaparib:

Mobility : Remarks: No information available.

Distribution among environmental compartments : Remarks: No information available.

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Disposal should be in accordance with local, state or national legislation.
Waste, even small quantities, should never be poured down drains, sewers or water courses.

Dispose of contents/ container to an approved incineration plant.

Contaminated packaging : Empty container will retain product residue. Observe all hazard precautions.

SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

In order to comply with legal duties it is necessary to consult local and national legislation.

Standard for the Uniform Scheduling of Medicines and Poisons : No poison schedule number allocated

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:

REACH : Not listed

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Olaparib

AICS : Not listed

ENCS : Not listed

ISHL : Not listed

IECSC : Not listed

TCSI : Not listed

TSCA : Not On TSCA Inventory

SECTION 16. OTHER INFORMATION

Further information

Revision Date : 10.01.2019

Other information : Minor changes:
Administrative release.

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / TWA : 8-hour, time-weighted average
AU OEL / TWA : Exposure standard - time weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM – In-house occupational exposure limit; CPR - Controlled Products Regulations; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; HYG – Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; Sen – Capable of causing respiratory sensitization; Sk – Can be absorbed through skin, thus contributing to systemic effects; STEL – Short-term exposure limit 15-minutes time-weighted average; TLV – Threshold Limit Value (ACGIH); TLV-C – Threshold Limit Value Ceiling limit (ACGIH); TSCA - Toxic Substances Control Act (United States); TWA – Long-term exposure limit 8h time-weighted average; UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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