

SAFETY DATA SHEET**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****Product identifier****LYNPARZA CAPSULES**

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Alternative Names

AZD2281 Capsules
 CO-CE 42
 KU-0059436 Capsules
 Olaparib capsules

CAS No. : Not applicable
 Use : Potential anti-cancer agent

2. HAZARDS IDENTIFICATION**Classification of the substance or mixture**

Classification UN GHS		
Hazard class	Category	Hazard statements
Acute toxicity	5	H303
Reproductive toxicity	1B	H360
Specific target organ toxicity - repeated exposure	1	H372
Chronic aquatic toxicity	3	H412
		# Refer to Section 16 'Other Information'

Label elements	
Signal word Danger	
Hazard statements	
H303	: May be harmful if swallowed.
H360	: May damage the unborn child.
H372	: Causes damage to organs through prolonged or repeated exposure.
H412	: Harmful to aquatic life with long lasting effects.

Precautionary statements

P201	Obtain special instructions before use.
P260	Do not breathe dust.
P273	Avoid release to the environment.
P308 + P313	: IF exposed or concerned: Get medical advice/ attention.
P391	: Collect spillage.
P501	: Dispose of contents/ container to an approved incineration plant.

Other hazards

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. See Section 11.

3. COMPOSITION/INFORMATION ON INGREDIENTS**Mixture:**

Component	%	CAS No.		
Olaparib	10	763113-22-0		
		Hazard class #	Category	Hazard statements #
		Acute toxicity	3	H301
		Reproductive toxicity	1B	H360D
		Specific target organ toxicity - repeated exposure	1	H372
		Acute aquatic toxicity	2	H401
		Chronic aquatic toxicity	2	H411

Refer to Section 16 'Other Information'

4. FIRST-AID MEASURES**Description of first aid measures**

Inhalation	:	Remove patient from exposure, keep warm and at rest. Obtain medical attention.
Skin Contact	:	Remove contaminated clothing. After contact with skin, wash immediately with plenty of water. If symptoms (irritation or blistering) occur obtain medical attention.
Eye Contact	:	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
Ingestion	:	Provided the patient is conscious, wash out mouth with water and give 200-300 ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain immediate medical attention.

Most important symptoms and effects, both acute and delayed

Refer to sections 2 and 11

Indication of any immediate medical attention and special treatment needed

Symptomatic treatment and supportive therapy as indicated. Emergency medical treatment advice varies within different countries. For further information consult the Local National Poisons Information Services.

5. FIRE-FIGHTING MEASURES

- Extinguishing Media (suitable) : water spray, foam, dry powder or CO₂.
Extinguishing Media (unsuitable) : Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
- Special hazards arising from the substance or mixture : If involved in a fire, it may burn and emit noxious and toxic fumes.
- Special protective actions for fire-fighters : A self contained breathing apparatus and full protective clothing must be worn in fire conditions. Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages. See Section 8. Avoid dispersal of dust in the air.
- Environmental Precautions : Prevent entry into drains, sewers or watercourses. Collect spillage.
- Methods and material for containment and cleaning up : Transfer spilled capsules to a suitable container for disposal. Wash the spillage area with water. Avoid release to the environment. See section 13.

7. HANDLING AND STORAGE

- Precautions for safe handling : In case of accident, avoid contact with skin and eyes. Wash hands after use. Minimize dust generation and accumulation. The product may form flammable dust clouds in air, if dust from capsules is allowed to accumulate .
- Conditions for safe storage, including any incompatibilities : Keep container tightly closed.
- Specific end use(s) : Storage temperature : 20 - 25 °C
Not applicable, refer to Section 1

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

Components	Value	Control parameters	Comments
Olaparib	0,0005 mg/m ³	LTEL 8hr TWA	COM

Exposure Controls

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.

Occupational exposure controls

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.

The information below 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.

Respiratory protection

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

Skin 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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form : capsules

Other information

No other data available

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.

11. TOXICOLOGICAL INFORMATION

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

Inhalation	:	May cause effects as described under repeated exposure.(STOT)
Skin Contact	:	Unlikely to be corrosive to the skin.
Eye Contact	:	Unlikely to be a severe irritant to the eye.
Ingestion	:	Low acute oral toxicity.
Specific Target Organ Toxicity (STOT)	:	<p>Single exposure Exposure routes: Oral May cause effects as described under repeated exposure.(STOT)</p> <p>Repeated exposure Exposure routes: Oral Target Organs: Bone marrow, Lymphoid organs, Spleen, Liver, Gastro-intestinal system Causes damage to organs through prolonged or repeated exposure. Studies in animals have shown that repeated doses cause effects on red and white blood cells and platelet count., 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.</p>
Sensitisation	:	It is not a skin sensitiser in vivo. Unlikely to cause skin sensitisation.
Carcinogenicity	:	No evidence of carcinogenicity in animal studies.
Mutagenicity	:	Evidence of secondary genotoxicity due to negative impact on DNA repair.
Reproductive toxicity	:	May damage the unborn child. Studies in animals have shown that low doses produce teratogenic effects and can reduce early embryofetal survival.

12. ECOLOGICAL INFORMATION

Harmful to aquatic life with long lasting effects. No information on this preparation. The following information refers to active ingredient: Olaparib

Toxicity	:	<p>EC50 green algae 72 H > 83 mg/l (OECD 211) NOEC green algae 72 H 83 mg/l (OECD 211) EC50 Daphnia magna 48 H > 74 mg/l (OECD 202) NOEC Daphnia magna 48 H 74 mg/l (OECD 202) NOEC Daphnia magna 21 d 0,32 mg/l (OECD 211) NOEC fathead minnow 32 d 0,32 mg/l (OECD 210)</p>
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Effect on Effluent Treatment	:	There is no evidence of inhibition to the aerobic treatment process at a concentration of 100 mg/l (OECD 209)
Persistence and degradability	:	Not rapidly degradable. Biodegradability (OECD 301F) <6%. 28 d The substance is not significantly hydrolyzed in water. (OECD 111)
Bioaccumulative potential	:	No information available.
Mobility in soil	:	The substance has low potential for bioaccumulation.
Other adverse effects	:	No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods	:	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. Normal waste disposal is via incineration operated by an accredited disposal contractor.
Contaminated Packaging	:	Empty container will retain residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

NOT RESTRICTED FOR TRANSPORT

15. REGULATORY INFORMATION

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

This material and its container must be disposed of as hazardous waste.

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

16. OTHER INFORMATION

Hazard statements	H301 : Toxic if swallowed. H303 : May be harmful if swallowed. H360 : May damage the unborn child. H372 : Causes damage to organs through prolonged or repeated exposure. H401 : Toxic to aquatic life. H411 : Toxic to aquatic life with long lasting effects. H412 : Harmful to aquatic life with long lasting effects.
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GLOSSARY

COM	:	In-house occupational exposure limit
LTEL	:	Long-term exposure limit (8 hour TWA (time-weighted average))
STEL	:	Short-term exposure limit (15-minute TWA (time-weighted average))
TLV	:	Threshold Limit Value (ACGIH)
TLV-C	:	Threshold Limit Value - Ceiling limit (ACGIH)
HYG	:	An in-house analytical method for occupational exposure monitoring is available
Sk	:	Can be absorbed through skin, thus contributing to systemic effects
Sen	:	Capable of causing respiratory sensitisation

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.