

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 23-Dec-2022 Revision Number 1

100-1169 - Olaparib

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Document Number 10000019513

Product Name Olaparib

Synonyms AZD-2281; KU-59436;

4-(3-(4-(cyclopropanecarbonyl)piperazine-1-carbonyl)-4-fluorobenzyl)phthalazine-1(2H)-one

,

Pure substance/mixture Substance

Contains 4-[[3-[4-(cyclopropanecarbonyl)piperazine-1-carbonyl]-4-fluorophenyl]methyl]-2H-phthalazin-1-one

Molecular weight 434.5

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

Recommended Use Laboratory chemical

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

STEMCELL Technologies SARL

40 Rue des Berges, Miniparc Polytec, Bâtiment Sirocco, 38000 Grenoble, France

+33 (0) 4 76 04 75 30

STEMCELL Technologies Germany GmbH

Stolberger Str. 200, 50933, Köln, Germany

+33 (0) 4 76 04 75 30

STEMCELL Technologies UK Ltd.

Building 7100, Cambridge Research Park, Beach Drive, Waterbeach, Cambridge, UK, CB25 9TL

+33 (0) 4 76 04 75 30

For further information, please contact

1.4. Emergency telephone number

Emergency Telephone No information available

Emergency Telephone - §45 - (EC)1272/2008 Europe | 112

Section 2: HAZARDS IDENTIFICATION



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2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 3 - (H301)
Reproductive toxicity	Category 1B - (H360)
Specific target organ toxicity (repeated exposure)	Category 1 - (H372)

2.2. Label elements

Contains 4-[[3-[4-(cyclopropanecarbonyl)piperazine-1-carbonyl]-4-fluorophenyl]methyl]-2H-phthalazin-1-one



Signal word Danger

Hazard statements

Hazard statements

H301 - Toxic if swallowed

H360 - May damage fertility or the unborn child

H372 - Causes damage to organs through prolonged or repeated exposure

Precautionary Statements - EU (§28, 1272/2008)

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P314 - Get medical advice/attention if you feel unwell

P501 - Dispose of contents/container to industrial incineration plant

Additional information

This product requires tactile warnings if supplied to the general public This product requires child resistant fastenings if supplied to the general public

2.3. Other hazards

No information available

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Synonyms



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Chemical name	EC No.	CAS No.	Weight-%	Classification according to Regulation (EC) No.	REACH Registration
				1272/2008 [CLP]	Number
4-[[3-[4-(cyclopropanecarbonyl)piper	-	763113-22-0	100	Acute Tox. 3 (H301)	No data available
azine-1-carbonyl]-4-fluorophenyl]met				Repr. 1 (H360)	
hyl]-2H-phthalazin-1-one				STOT RE 1 (H372)	

Full text of H- and EUH-phrases: see section 16

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

Skin contact Wash skin with soap and water. In the case of skin irritation or allergic reactions see a

physician.

Ingestion Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water.

Never give anything by mouth to an unconscious person. Get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physiciansTreat symptomatically.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

surrounding environment.

Unsuitable Extinguishing Media No information available.



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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

No information available.

5.3. Advice for firefighters

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. Use personal protective equipment as required. Evacuate

personnel to safe areas.

Other Information Refer to protective measures listed in Sections 7 and 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

product. Remove contaminated clothing and shoes. Handle in accordance with good

industrial hygiene and safety practice. Ensure adequate ventilation.

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and

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immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store in accordance with information listed on the Product Information Sheet (PIS). Keep

out of the reach of children. Store locked up.

7.3. Specific end use(s)

Identified Uses

Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration

(PNEC)

No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection No special protective equipment required.

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and

immediately after handling the product.



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Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

None known

9.1. Information on basic physical and chemical properties

Physical state Solid
Appearance Powder
Color off-white

Odor No data available.
Odor threshold No data available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pHNo data availableNone knownMelting point / freezing pointNo data availableNone knownBoiling point / boiling rangeNo data availableNone knownFlash pointNo data availableNone knownEvaporation rateNo data availableNone known

Flammability (solid, gas) Product is not flammable.

Flammability Limit in Air
Upper flammability limit:
No data available

Lower flammability limit: No data available

Apor pressure No data available

Vapor pressureNo data availableNone knownVapor densityNo data availableNone knownRelative densityNo data availableNone knownWater solubilityNo data availableNone known

Solubility(ies) DMSO: 33 mg/mL; Ethanol: 1.7

mg/mL;

Partition coefficientNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNo data availableNone knownKinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone known

Explosive properties No information available

Oxidizing properties No information available

9.2. Other information

Softening point No information available

Molecular weight 434.5

Molecular formula C24H23FN4O3

VOC Content (%)

Liquid Density

Bulk density

No information available
No information available

Section 10: STABILITY AND REACTIVITY



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10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under recommended transport or storage conditions.

Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions
None under normal processing.

10.4. Conditions to avoid

Conditions to avoidNone known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products Carbon oxides. Hydrogen fluoride. Nitrogen oxides (NOx).

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available. Toxic if swallowed. (based

on components).



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Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 100.00 mg/kg

Unknown acute toxicity 100 % of the mixture consists of ingredient(s) of unknown toxicity.

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Product Information

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	No information available.
Product Information	
Serious eye damage/eye irritation Product Information	No information available.
Respiratory or skin sensitization Product Information	No information available.
Germ cell mutagenicity Product Information	No information available.
Carcinogenicity Product Information	No information available.
Reproductive toxicity	Classification based on data available for ingredients.
	Product Information
STOT - single exposure	No information available.
Product Information	
STOT - repeated exposure Product Information	Causes damage to organs through prolonged or repeated exposure.



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Aspiration hazard No information available.

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity The environmental impact of this product has not been fully investigated.

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

Product Information

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Other adverse effects

Other adverse effects No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.



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Section 14: TRANSPORT INFORMATION

Note: When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity

Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous Goods/Excepted

Quantity.

IMDG

14.1 UN Number UN2811

14.2 UN proper shipping name TOXIC SOLID, ORGANIC, N.O.S. (Olaparib)

14.3 Transport hazard class(es) 6.1 Toxic substances

14.4 Packing Group

14.5 Marine pollutant Not applicable

14.6 Special Provisions None

14.7. Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

RID

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

14.6 Special Provisions None

ADR

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

14.6 Special Provisions None

IATA Not regulated

14.1 UN Number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Olaparib)

14.3 Transport hazard class(es) 6.1 Toxic substances

14.4 Packing Group

14.5 Environmental hazard Not applicable

14.6 Special Provisions None

Section 15: REGULATORY INFORMATION

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



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European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

TSCA	Does not comply
DSL/NDSL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet



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Full text of H-Statements referred to under section 3

H301 - Toxic if swallowed

H360 - May damage fertility or the unborn child

H372 - Causes damage to organs through prolonged or repeated exposure

Legend

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

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