

Rucaparib Tablets 120mg, 200mg, 250mg, 300mg

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations



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SECTION 1: Identification

1.1. Identification

Product form : Mixture
Product name : Rucaparib Tablets 120mg, 200mg, 250mg, 300mg
Synonyms : rucaparib tablets, CO-338 tablets, CLO-001, PF-01367338-BW, AG-014699

1.2. Recommended use and restrictions on use

Recommended use : Pharmaceuticals
Restrictions on use : No additional information available

1.3. Supplier

Clovis Oncology, Inc.
5500 Flatiron Parkway
Boulder, Colorado 80301 - USA
T +1-303-625-5000
clovisoncology.com

1.4. Emergency telephone number

Emergency number : +1-844-258-7662
+1-415-409-7220

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Carc. 2 H351 Suspected of causing cancer
Repr. 1B H360 May damage fertility or the unborn child
STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure

Full text of hazard classes and H-statements : see section 16

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Hazard pictograms (GHS US) :



Signal word (GHS US) :

Danger

Hazard statements (GHS US) :

H351 - Suspected of causing cancer
H360 - May damage fertility or the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements (GHS US) :

P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust.
P280 - Wear protective gloves, protective clothing.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P314 - Get medical advice/attention if you feel unwell.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

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3.2. Mixtures

Name	Product identifier	%	GHS US classification
Rucaparib camsylate (Active)	(CAS-No.) 1859053-21-6	30 - 80	Repr. 1B, H360 STOT RE 2, H373
sodium starch glycolate	(CAS-No.) 9063-38-1	2 - 7	Eye Irrit. 2A, H319 STOT SE 3, H335
Titanium dioxide	(CAS-No.) 13463-67-7	0.1 - <1	Carc. 2, H351

*Chemical name, CAS number and/or exact concentration have been withheld as a trade secret

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. IF exposed or concerned: Get medical advice/attention.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2. Most important symptoms and effects (acute and delayed)

- Symptoms/effects : May cause damage to organs through prolonged or repeated exposure. May damage fertility or the unborn child.
- Symptoms/effects after inhalation : In high concentrations : Inhalation of dust. Suspected of causing cancer.
- Symptoms/effects after skin contact : Dust may cause irritation in skin folds or by contact in combination with tight clothing.
- Symptoms/effects after eye contact : Dust from this product may cause eye irritation.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Specific hazards arising from the chemical

- Fire hazard : Burning produces irritating, toxic and noxious fumes.

5.3. Special protective equipment and precautions for fire-fighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection. Wear a self-contained breathing apparatus. Wear fire/flame resistant/retardant clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid contact with skin, eyes and clothing. Do not breathe dust.

6.1.1. For non-emergency personnel

- Protective equipment : Refer to section 8.2.
- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Refer to section 8.2.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Contain and collect as any solid.

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Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

Section 13: disposal information. Section 7: safe handling. Section 8: personal protective equipment.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapor. Do not handle until all safety precautions have been read and understood. Obtain special instructions before use. Avoid contact with skin, eyes and clothing. Do not breathe dust.

Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed.

Incompatible products : Strong oxidizers.

Storage area : Store in dry, cool, well-ventilated area.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Rucaparib camsylate (1859053-21-6)		
Not applicable		
sodium starch glycolate (9063-38-1)		
OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ total dust
OSHA	OSHA PEL (STEL) (mg/m ³)	5 mg/m ³ respirable fraction
Titanium dioxide (13463-67-7)		
ACGIH	Local name	Titanium dioxide
ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
ACGIH	Remark (ACGIH)	TLV® Basis: LRT irr. Notations: A4 (Not classifiable as a Human Carcinogen)
ACGIH	Regulatory reference	ACGIH 2018
OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³
OSHA	Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1

8.2. Appropriate engineering controls

Appropriate engineering controls : Avoid dispersal of dust in the air (i.e. clearing dust surfaces with compressed air). Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure good ventilation of the work station.

Environmental exposure controls : Prevent leakage or spillage.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

Wear suitable gloves resistant to chemical penetration

Eye protection:

Chemical goggles or safety glasses

Respiratory protection:

In case of inadequate ventilation wear respiratory protection. Approved respirator

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Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Tablets.
Color	: Orange Blue white Yellow
Odor	: characteristic
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Non flammable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

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Rucaparib camsylate (1859053-21-6)	
LD50 oral rat	> 2000 mg/kg

Titanium dioxide (13463-67-7)	
LD50 oral rat	> 5000 mg/kg
LC50 inhalation rat (mg/l)	> 6.82 mg/l/4h

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified. Negative: Bacterial reverse mutation assay (e.g. Ames test)
Carcinogenicity	: Suspected of causing cancer.

Titanium dioxide (13463-67-7)	
NOAEL (chronic,oral,animal/male,2 years)	5 mg/kg body weight rat
Additional information	Carcinogen Inhalation of dust
IARC group	2B - Possibly carcinogenic to humans

Reproductive toxicity	: May damage fertility or the unborn child.
Specific target organ toxicity – single exposure	: Not classified

sodium starch glycolate (9063-38-1)	
Specific target organ toxicity – single exposure	May cause respiratory irritation.

Specific target organ toxicity – repeated exposure	: May cause damage to organs through prolonged or repeated exposure.
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Rucaparib camsylate (1859053-21-6)	
NOAEL (oral,rat,90 days)	10 mg/kg bodyweight/day (oral, rat, 28 days) 50 mg/kg/day ; bone marrow, spleen, lymphoid tissues (thymus, gut-associated lymphoid tissue [GALT], and lymph nodes), cecum
Specific target organ toxicity – repeated exposure	May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard	: Not classified
Viscosity, kinematic	: No data available
Likely routes of exposure	: Inhalation. Skin and eye contact. Ingestion.
Symptoms/effects	: May cause damage to organs through prolonged or repeated exposure. May damage fertility or the unborn child.
Symptoms/effects after inhalation	: In high concentrations : Inhalation of dust. Suspected of causing cancer.
Symptoms/effects after skin contact	: Dust may cause irritation in skin folds or by contact in combination with tight clothing.
Symptoms/effects after eye contact	: Dust from this product may cause eye irritation.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

Rucaparib Tablets 120mg, 200mg, 250mg, 300mg	
Persistence and degradability	Not established.

Rucaparib camsylate (1859053-21-6)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Rucaparib Tablets 120mg, 200mg, 250mg, 300mg	
Bioaccumulative potential	Not established.

Rucaparib camsylate (1859053-21-6)	
Log Pow	3.34
Log Kow	0.71

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Rucaparib camsylate (1859053-21-6)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not regulated.

Transportation of Dangerous Goods

Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

Rucaparib camsylate (1859053-21-6)	
EPA TSCA Regulatory Flag	Exempt from TSCA : Pharmaceutical/drug substance

15.2. International regulations

CANADA

Rucaparib camsylate (1859053-21-6)	
Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)	
sodium starch glycolate (9063-38-1)	
Listed on the Canadian DSL (Domestic Substances List)	
Titanium dioxide (13463-67-7)	
Listed on the Canadian DSL (Domestic Substances List)	

EU-Regulations

Rucaparib camsylate (1859053-21-6)	
Not listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)	
sodium starch glycolate (9063-38-1)	
Not listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)	
Titanium dioxide (13463-67-7)	
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)	

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National regulations

Titanium dioxide (13463-67-7)

Listed on IARC (International Agency for Research on Cancer)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
Listed on KECI (Korean Existing Chemicals Inventory)
Listed on NZIoC (New Zealand Inventory of Chemicals)
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
Listed on Taiwan National Chemical Inventory
Listed on the AICS (Australian Inventory of Chemical Substances)
Listed on the TCSI (Taiwan Chemical Substance Inventory)
Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory
Listed on the Japanese ISHL (Industrial Safety and Health Law)

15.3. US State regulations

 **WARNING:** This product can expose you to Titanium dioxide, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Component	State or local regulations
Titanium dioxide(13463-67-7)	U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

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Revision date : 02/21/2019
Data sources : ACGIH (American Conference of Government Industrial Hygienists).
European Chemicals Agency (ECHA) C&L Inventory database. Accessed at <http://echa.europa.eu/web/quest/information-on-chemicals/cl-inventory-database>.
Krister Forsberg and S.Z. Mansdorf, "Quick Selection Guide to Chemical Protective Clothing", Fifth Edition.
National Fire Protection Association. Fire Protection Guide to Hazardous Materials; 10th edition.
OSHA 29CFR 1910.1200 Hazard Communication Standard. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H-phrases:

Carc. 2	Carcinogenicity Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Repr. 1B	Reproductive toxicity Category 1B
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H351	Suspected of causing cancer
H360	May damage fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure

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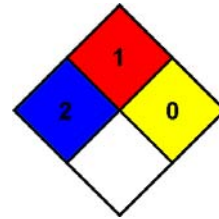
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Abbreviations and acronyms:

ATE: Acute Toxicity Estimate
CAS (Chemical Abstracts Service) number
EC50: Environmental Concentration associated with a response by 50% of the test population.
GHS: Globally Harmonized System (of Classification and Labeling of Chemicals).
LD50: Lethal Dose for 50% of the test population
OSHA: Occupational Safety & Health Administration
STEL: Short Term Exposure Limits
TSCA: Toxic Substances Control Act
TWA: Time Weighted Average

NFPA health hazard	: 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.
NFPA fire hazard	: 1 - Materials that must be preheated before ignition can occur.
NFPA reactivity	: 0 - Material that in themselves are normally stable, even under fire conditions.



Indication of changes:

Section	Changed item	Change	Comments
11	Toxicological information	Modified	Bacterial reverse mutation assay (e.g. Ames test)

SDS US (GHS HazCom 2012)

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