

### Medicines & Healthcare products Regulatory Agency

British Pharmacopoeia

**Quality standards** 

## SAFETY DATA SHEET

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

Revision date 19-Jun-2023

**Revision Number** 1

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

CAT 1229
Capecitabine
Not applicable

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

EC No (EU Index No)	604-948-1
CAS No	154361-50-9
Pure substance/mixture	Substance
Formula	C15 H22 F N3 O6
Molecular weight	359.35

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

Recommended use	Laboratory use

Uses advised against No information available

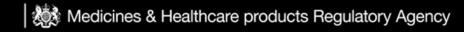
#### 1.3. Details of the supplier of the safety data sheet

#### Supplier

British Pharmacopoeia Commission MHRA 10 South Colonnade Canary Wharf London E14 4PU United Kingdom

Tel: +44 (0)20 3080 6561 eMail: bpcrs@mhra.gov.uk

For further information, please contact





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#### CAT 1229 - Capecitabine

E-mail address

bpcrs@mhra.gov.uk

#### 1.4. Emergency telephone number

**Emergency Telephone** 

+44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

Emergency Telephone - §45 - (EC)1272/2008		
Europe	112	
Austria	No information available	
Bulgaria		
Croatia		
Cyprus		
Czech Republic		
Denmark		
France		
Hungary		
Ireland		
Italy		
Lithuania		
Luxembourg		
Netherlands		
Norway		
Portugal		
Romania		
Slovakia		
Slovenia		
Spain		
Sweden		
Switzerland		

### **SECTION 2: Hazards identification**

#### 2.1. Classification of the substance or mixture

 Regulation (EC) No 1272/2008

 Skin corrosion/irritation
 Category 2 - (H315)

 Serious eye damage/eye irritation
 Category 2 - (H319)

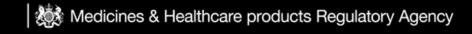
 Germ cell mutagenicity
 Category 2 - (H341)

 Carcinogenicity
 Category 1B - (H350)

 Reproductive toxicity
 Category 1B - (H360FD)

 Specific target organ toxicity — repeated exposure
 Category 2 - (H373)

2.2. Label elements





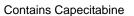
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Danger

#### Hazard statements

H315 - Causes skin irritation
H319 - Causes serious eye irritation
H341 - Suspected of causing genetic defects
H350 - May cause cancer
H360FD - May damage fertility. May damage the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure

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

P201 - Obtain special instructions before use

- P260 Do not breathe dust/fume/gas/mist/vapours/spray
- P264 Wash face, hands and any exposed skin thoroughly after handling
- P280 Wear protective gloves/protective clothing/eye protection/face protection
- P308 + P313 IF exposed or concerned: Get medical advice/attention

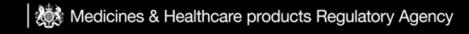
#### 2.3. Other hazards

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Endocrine Disruptor Information	This product does not contain any known or suspected endocrine disruptors.
Chemical name	EU - REACH (1907/2006) - Article 59(1) EU - REACH (1907/2006) - Endocrine
	- Candidate List of Substances of Very Disruptor Assessment List of
	High Concern (SVHC) for Authorisation Substances
Capecitabine	

### SECTION 3: Composition/information on ingredients

3.1 Substances





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Chemical name	Weight-%	REACH registration number		Classification according to Regulation (EC) No. 1272/2008 [CLP]	M-Factor	M-Factor (long-term)
Capecitabine 154361-50-9	90 - 100%	-	-	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Muta. 2 (H341) Carc. 1B (H350) Repr. 1B (H360FD) STOT RE 2 (H373)		

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

Acute Toxicity Estimate No information available

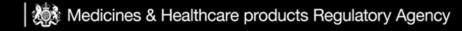
This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance. IF exposed or concerned: Get medical advice/attention.
Inhalation	Remove to fresh air. Get medical attention immediately if symptoms occur.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.
Skin contact	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a doctor.
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).
4.2. Most important symptoms and	effects, both acute and delayed

Symptoms May cause redness and tearing of the eyes. Burning sensation.





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

Note to doctors

Treat symptomatically.

<b>SECTION 5</b>	: Firefighting	measures

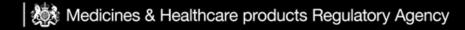
5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.	
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.	
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.	
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 and precautions 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. Avoid contact with skin, eyes or clothing.
Other information	Refer to protective measures listed in Sections 7 and 8.
For emergency responders	Use personal protection recommended in Section 8.
6.2. Environmental precautions	
Environmental precautions	Prevent further leakage or spillage if safe to do so.
6.3. Methods and material for containment and cleaning up	
Methods for containment	Prevent further leakage or spillage if safe to do so.





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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	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Ensure adequate ventilation. Take off contaminated clothing and shoes.
General hygiene considerations	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product.
7.2. Conditions for safe storage, inc	cluding any incompatibilities
Storage Conditions	Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA. Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place.

#### 7.3. Specific end use(s)

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

### SECTION 8: Exposure controls/personal protection

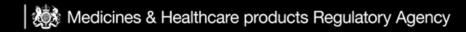
#### 8.1. Control parameters

Exposure Limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

#### **Biological occupational exposure limits**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific





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regulatory bodies

Derived No Effect Level (DNEL) No information available. Predicted No Effect Concentration (PNEC)

8.2. Exposure controls

Personal protective equipment

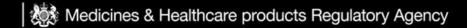
Eye/face protection	Avoid contact with eyes. Wear safety glasses with side shields (or goggles). If splashes are likely to occur, wear safety glasses with side-shields.
Hand protection	Wear protective butyl rubber gloves. The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear suitable gloves. Impervious gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved 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	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product.
Environmental exposure controls	Do not allow into any sewer, on the ground or into any body of water.

### **SECTION 9: Physical and chemical properties**

9.1. Information on basic physical and chemical properties		
Physical state	Solid	
Appearance	Solid	
Colour	white	
Odour	Odourless.	
Odour threshold	No information available	

Property	Valu	es		
Melting point / freezing point	116	-	117	°C
Initial boiling point and boiling range	eNo d	ata	a avai	lable

Remarks • Method None known None known





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Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
р	No data available	None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	Ethanol, Acetonitrile, Methanol	
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	
9.2. Other information		
Molecular weight	359.35	
Molecular formula	C15 H22 F N3 O6	

9.2.1. Information with regards to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Reactivity

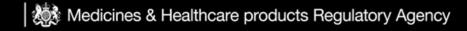
No information available.

10.2. Chemical stability

Stability

Stable under normal conditions.

**Explosion data** 





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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 avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong acids. Strong bases. Strong oxidising agents.

Hazardous decomposition products None known based on information supplied.

### **SECTION 11: Toxicological information**

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

#### **Product Information**

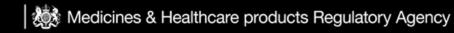
Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.
Symptoms related to the physical,	chemical and toxicological characteristics

Symptoms

Redness. May cause redness and tearing of the eyes.

#### Numerical measures of toxicity No information available

Acute toxicity



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



**Quality standards** 

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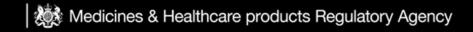
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belayed and initial defects as well as chronic effects from short and long-term exposure		
Skin corrosion/irritation	Classification based on data available for ingredients. Causes skin irritation. May cause skin irritation.	
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes serious eye irritation.	
Respiratory or skin sensitisation	No information available.	
Germ cell mutagenicity	Contains a known or suspected mutagen. Classification based on data available for ingredients. Suspected of causing genetic defects.	
Carcinogenicity	Contains a known or suspected carcinogen. Classification based on data available for ingredients. May cause cancer.	
Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May damage fertility or the unborn child.	
STOT - single exposure	No information available.	
STOT - repeated exposure	May cause damage to organs through prolonged or repeated exposure.	
Aspiration hazard	No information available.	
11.2. Information on other hazards		
11.2.1. Endocrine disrupting prop	erties	
Fude arise discusting preparties	No information quailable	

**Endocrine disrupting properties** No information available.





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11.2.2. Other information		
Other adverse effects	No information available.	
SECTION 12: Ecological i	nformation	
12.1. Toxicity		
Ecotoxicity	The environmental impact of this product has not been fully investig	gated.
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 ass	essment	
PBT and vPvB assessment	No information available.	
12.6. Endocrine disrupting prope	<u>ties</u>	
Endocrine disrupting properties	No information available.	
12.7. Other adverse effects		

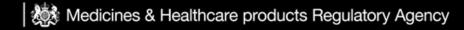
**12.7.** Other adverse effective No information available.

### **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.





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**Contaminated packaging** 

Do not reuse empty containers.

### **SECTION 14:** Transport information

#### <u>IATA</u>

<ul> <li>14.1 UN number or ID number</li> <li>14.2 UN proper shipping name</li> <li>14.3 Transport hazard class(es)</li> <li>14.4 Packing group</li> <li>14.5 Environmental hazards</li> <li>14.6 Special precautions for user Special Provisions</li> </ul>	Not regulated Not regulated Not regulated Not applicable None
IMDG14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Marine pollutant14.6Special precautions for user Special Provisions14.7Maritime transport in bulk according to IMO instruments	Not regulated Not regulated Not regulated Not regulated Not applicable None No information available No information available
RID14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Environmental hazards14.6Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated Not applicable None
ADR14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Environmental hazards14.6Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated Not applicable None





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

#### National regulations

Germany	
Water hazard class (WGK)	strongly hazardous to water (WGK 3)

Poland

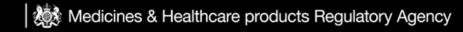
SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. 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, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650) . Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

#### **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.

#### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (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)





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DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors Not applicable

Persistent Organic Pollutants Not applicable

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

International Inventories	
TSCA	Complies under research and development exemption or is regulated by a different government agency.
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AIIC	Contact supplier for inventory compliance status

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

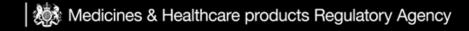
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report

A Chemical Safety Assessment is not required for this substance

**SECTION 16: Other information** 





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

#### Full text of H-Statements referred to under section 3

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H341 - Suspected of causing genetic defects

H350 - May cause cancer

H360FD - May damage fertility. May damage the unborn child

H373 - May cause damage to organs through prolonged or repeated exposure

#### Legend

SVHC: Substances of Very High Concern for Authorisation:

#### Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

#### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

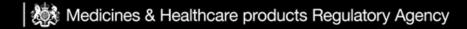
U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act





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U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme Organisation for Economic Co-operation and Development Screening Information Data Set World Health Organization

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

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