

SAFETY DATA SHEET

Palbociclib

According to Regulation (EC) No 1907/2006, Annex II, as amended. Commission Regulation (EU) No 2015/830 of 28 May 2015.

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

1.1. Product identifier

Product name Palbociclib

Product number FA65120

Synonyms; trade names 6-Acetyl-8-cyclopentyl-5-methyl-2-{[5-(1-piperazinyl)-2-pyridinyl]amino}pyrido[2,3-d]pyrimidin-

7(8H)-one, PD 0332991, Ibrance

CAS number 571190-30-2 **EC number** 810-186-2

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

Identified uses Laboratory reagent. Manufacture of substances. Research and development.

1.3. Details of the supplier of the safety data sheet

Supplier Carbosynth Ltd

8&9 Old Station Business Park

Compton Berkshire RG20 6NE

+44 1635 578444 +44 1635 579444

info@carbosynth.com

1.4. Emergency telephone number

Emergency telephone +44 7887 998634

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Not Classified

Health hazards Acute Tox. 3 - H301

Environmental hazards Not Classified

2.2. Label elements

EC number 810-186-2

Pictogram



Signal word Danger

Hazard statements H301 Toxic if swallowed.

Palbociclib

Precautionary statements P264 Wash contaminated skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

P321 Specific treatment (see medical advice on this label).

P330 Rinse mouth.

P501 Dispose of contents/ container in accordance with national regulations.

2.3. Other hazards

No data available.

SECTION 3: Composition/information on ingredients

3.1. Substances

Product name Palbociclib

CAS number 571190-30-2

EC number 810-186-2

Chemical formula C24H29N7O2

SECTION 4: First aid measures

4.1. Description of first aid measures

General information Get medical advice/attention if you feel unwell.

Inhalation Remove person to fresh air and keep comfortable for breathing. If breathing stops, provide

artificial respiration. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Get medical attention if symptoms are severe or persist.

Ingestion Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse

mouth thoroughly with water. Give plenty of water to drink. Get medical attention if symptoms

are severe or persist.

Skin contact Remove contaminated clothing. Rinse with water. Continue to rinse for at least 15 minutes.

Wash contaminated clothing before reuse. Get medical attention if symptoms are severe or

persist.

Eye contact Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes. Get medical

attention if symptoms are severe or persist.

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

General information See Section 11 for additional information on health hazards.

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

Notes for the doctor Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog. Use fire-

extinguishing media suitable for the surrounding fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards None known.

Hazardous combustion Thern

Thermal decomposition or combustion products may include the following substances: Oxides

of carbon. Oxides of nitrogen.

5.3. Advice for firefighters

products

Palbociclib

Special protective equipment for firefighters

Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing. Firefighter's clothing conforming to European standard EN469 (including helmets, protective boots and gloves) will provide a basic level of protection for chemical incidents. Use protective equipment appropriate for surrounding materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Wear protective clothing as described in Section 8 of the section 8 of

Wear protective clothing as described in Section 8 of this safety data sheet. No action shall be taken without appropriate training or involving any personal risk. Do not touch or walk into spilled material. Avoid inhalation of dust and vapours. Provide adequate ventilation. Keep unnecessary and unprotected personnel away from the spillage.

6.2. Environmental precautions

Environmental precautions Avoid discharge into drains or watercourses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Wear protective clothing as described in Section 8 of this safety data sheet. Collect powder

using special dust vacuum cleaner with particle filter or carefully sweep into suitable waste disposal containers and seal securely. Clear up spills immediately and dispose of waste safely. Flush contaminated area with plenty of water. Wash thoroughly after dealing with a

spillage. For waste disposal, see Section 13.

6.4. Reference to other sections

Reference to other sections For personal protection, see Section 8. See Section 11 for additional information on health

hazards. See Section 12 for additional information on ecological hazards. For waste disposal,

see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions Wear protective clothing as described in Section 8 of this safety data sheet. Wash hands

thoroughly after handling. Provide adequate ventilation. Avoid generation and spreading of dust. Avoid contact with skin and eyes. Avoid inhalation of dust and vapours. Do not eat, drink

or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Keep container tightly closed. Store in a cool and well-ventilated place. Store away from

incompatible materials (see Section 10). Store at temperatures not exceeding -20°C.

7.3. Specific end use(s)

Specific end use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Occupational exposure limits

No exposure limits known for ingredient(s).

8.2. Exposure controls

Appropriate engineering

controls

Provide adequate ventilation. Observe any occupational exposure limits for the product or ingredients.

Eye/face protection Unless the assessment indicates a higher degree of protection is required, the following

protection should be worn: Tight-fitting safety glasses. Personal protective equipment for eye

and face protection should comply with European Standard EN166.

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Hand protection Wear protective gloves. To protect hands from chemicals, gloves should comply with

European Standard EN374.

Other skin and body

protection

Wear appropriate clothing to prevent repeated or prolonged skin contact.

Respiratory protection Respiratory protection complying with an approved standard should be worn if a risk

assessment indicates inhalation of contaminants is possible. Ensure all respiratory protective equipment is suitable for its intended use and is 'CE'-marked. Particulate filters should comply with European Standard EN143. Full face mask respirators with replaceable filter cartridges should comply with European Standard EN136. Half mask and quarter mask respirators with

replaceable filter cartridges should comply with European Standard EN140.

Environmental exposure controls

Keep container tightly sealed when not in use.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance Solid.

ColourOff-white. to Yellow.OdourNo data available.Odour thresholdNo data available.

pH No data available.

Melting point >246°C

Initial boiling point and range No data available.

Flash point No data available.

Evaporation rate No data available.

Flammability (solid, gas) No data available.

Upper/lower flammability or

explosive limits

No data available.

Vapour pressure No data available.

Vapour density No data available.

Relative density No data available.

Solubility(ies) No data available.

Partition coefficient No data available.

Auto-ignition temperature No data available.

Decomposition Temperature No data available.

Viscosity No data available.

Explosive properties No data available.

Oxidising properties No data available.

9.2. Other information

Molecular weight 447.53

SECTION 10: Stability and reactivity

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10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under the prescribed storage conditions.

10.3. Possibility of hazardous reactions

Possibility of hazardous

No data available.

reactions

10.4. Conditions to avoid

Conditions to avoid No data available.

10.5. Incompatible materials

Materials to avoid Strong oxidising agents.

10.6. Hazardous decomposition products

Hazardous decomposition

Oxides of carbon. Oxides of nitrogen.

products

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - oral

Notes (oral LD₅o) Acute Tox. 3 - H301 Toxic if swallowed.

ATE oral (mg/kg) 100.0

Acute toxicity - dermal

Notes (dermal LD₅₀) Based on available data the classification criteria are not met.

Acute toxicity - inhalation

Notes (inhalation LC50) Based on available data the classification criteria are not met.

Skin corrosion/irritation

Animal data Based on available data the classification criteria are not met.

Serious eye damage/irritation

Serious eye damage/irritation Based on available data the classification criteria are not met.

Respiratory sensitisation

Respiratory sensitisation Based on available data the classification criteria are not met.

Skin sensitisation

Skin sensitisation Based on available data the classification criteria are not met.

Germ cell mutagenicity

Genotoxicity - in vitroBased on available data the classification criteria are not met.

Carcinogenicity

Carcinogenicity Based on available data the classification criteria are not met.

IARC carcinogenicityNone of the ingredients are listed or exempt.

Reproductive toxicity

Reproductive toxicity - fertility Based on available data the classification criteria are not met.

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Reproductive toxicity -

Based on available data the classification criteria are not met.

development

Specific target organ toxicity - single exposure

STOT - single exposureNot classified as a specific target organ toxicant after a single exposure.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure
Not classified as a specific target organ toxicant after repeated exposure.

Aspiration hazard

Aspiration hazard Not relevant. Solid.

General information Dust may irritate the eyes and the respiratory system. The severity of the symptoms described

will vary dependent on the concentration and the length of exposure.

Inhalation Dust may irritate the respiratory system. Frequent inhalation of dust over a long period of time

increases the risk of developing lung diseases.

Ingestion May cause stomach pain or vomiting. May cause severe internal injury.

Skin contact Prolonged contact may cause dryness of the skin.

Eye contact Dust may cause slight irritation.

Route of exposure Ingestion Inhalation Skin and/or eye contact

Target organs No specific target organs known.

RTECS # UV1161907

SECTION 12: Ecological Information

Ecotoxicity Not regarded as dangerous for the environment. However, large or frequent spills may have

hazardous effects on the environment.

12.1. Toxicity

Toxicity Based on available data the classification criteria are not met.

12.2. Persistence and degradability

Persistence and degradability The degradability of the product is not known.

12.3. Bioaccumulative potential

Bioaccumulative potential No data available on bioaccumulation.

Partition coefficient No data available.

12.4. Mobility in soil

Mobility No data available.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB

No data available.

assessment

12.6. Other adverse effects

Other adverse effects None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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General information

Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority. This material and its container must be disposed of in a safe way. When handling waste, the safety precautions applying to handling of the product should be considered.

SECTION 14: Transport information

14.1. UN number

UN No. (ADR/RID) 2811
UN No. (IMDG) 2811
UN No. (ICAO) 2811
UN No. (ADN) 2811

14.2. UN proper shipping name

Proper shipping name

TOXIC SOLID, ORGANIC, N.O.S.

(ADR/RID)

Proper shipping name (IMDG) TOXIC SOLID, ORGANIC, N.O.S.

Proper shipping name (ICAO) TOXIC SOLID, ORGANIC, N.O.S.

Proper shipping name (ADN) TOXIC SOLID, ORGANIC, N.O.S.

14.3. Transport hazard class(es)

ADR/RID class 6.1

ADR/RID classification code T2

ADR/RID label 6.1

IMDG class 6.1

ICAO class/division 6.1

ADN class 6.1

Transport labels



14.4. Packing group

ADR/RID packing group III
IMDG packing group III
ADN packing group III
ICAO packing group III

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant No.

14.6. Special precautions for user

EmS F-A, S-A

ADR transport category 2

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Emergency Action Code 2X

Hazard Identification Number 60

(ADR/RID)

Tunnel restriction code (E)

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

SECTION 15: Regulatory information

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

National regulations Health and Safety at Work etc. Act 1974 (as amended).

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment

Regulations 2009 (SI 2009 No. 1348) (as amended) ["CDG 2009"].

EH40/2005 Workplace exposure limits.

EU legislation Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18

December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of

Chemicals (REACH) (as amended).

Commission Regulation (EU) No 2015/830 of 28 May 2015.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as

amended).

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Abbreviations and acronyms used in the safety data sheet

ADR: European Agreement concerning the International Carriage of Dangerous Goods by

Road.

ADN: European Agreement concerning the International Carriage of Dangerous Goods by

Inland Waterways.

RID: European Agreement concerning the International Carriage of Dangerous Goods by

Rail.

IATA: International Air Transport Association.

ICAO: Technical Instructions for the Safe Transport of Dangerous Goods by Air.

IMDG: International Maritime Dangerous Goods.

CAS: Chemical Abstracts Service. ATE: Acute Toxicity Estimate.

LC₅o: Lethal Concentration to 50 % of a test population.

LD₅₀: Lethal Dose to 50% of a test population (Median Lethal Dose).

EC₅: 50% of maximal Effective Concentration.

PBT: Persistent, Bioaccumulative and Toxic substance.

vPvB: Very Persistent and Very Bioaccumulative.

Training advice Only trained personnel should use this material.

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Revision 1

SDS number 144926

Hazard statements in full H301 Toxic if swallowed.

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.