



SAFETY DATA SHEET

Revision date: 16-Oct-2014

Version: 2.1

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Palbociclib Capsules

Trade Name: IBRANCE
Compound Number: PD 0332991; PF-00080665
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Germ Cell Mutagenicity: Category 2
Specific target organ systemic toxicity (repeated exposure): Category 2

EU Classification:

EU Indication of danger: Xn - Harmful
Mutagenic: Category 3

EU Risk Phrases:

R68 - Possible risk of irreversible effects.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Label Elements

Signal Word: Warning
Hazard Statements: H341 - Suspected of causing genetic defects
H373 - May cause damage to organs through prolonged or repeated exposure: testes, bone marrow

Precautionary Statements: P201 - Obtain special instructions before use
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P314 - Get medical attention/advice if you feel unwell
P405 - Store locked up

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Other Hazards
Australian Hazard Classification (NOHSC):

No data available
Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Palbociclib (PD 0332991)	571190-30-2	Not Listed	Xn; R48/22 Muta. Cat.3;R68	Muta 2 (H341) STOT RE. 2 (H373)	20 - 30

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Cellulose microcrystalline	9004-34-4	Not Listed	Not Listed	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	Not Listed	*
Lactose Monohydrate	64044-51-5	Not Listed	Not Listed	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Sodium starch glycolate	9063-38-1	Not Listed	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Palbociclib (PD 0332991)
Pfizer OEL TWA-8 Hr:

1 µg/m³

Colloidal silicon dioxide

Australia TWA
Austria OEL - MAKs

2 mg/m³
4 mg/m³
0.3 mg/m³

Czech Republic OEL - TWA

0.1 mg/m³
4.0 mg/m³

Estonia OEL - TWA

2 mg/m³

Finland OEL - TWA

5 mg/m³

Germany - TRGS 900 - TWAs

4 mg/m³

Germany (DFG) - MAK

4 mg/m³

Ireland OEL - TWAs

6 mg/m³
2.4 mg/m³

Latvia OEL - TWA

1 mg/m³

OSHA - Final PELs - Table Z-3 Mineral D:

20 mppcf
Listed

Slovakia OEL - TWA

4.0 mg/m³

Switzerland OEL - TWAs

4 mg/m³
0.3 mg/m³

Magnesium Stearate

ACGIH Threshold Limit Value (TWA)

10 mg/m³

Lithuania OEL - TWA

5 mg/m³

Sweden OEL - TWAs

5 mg/m³

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:

Capsule

Color:

Yellow

Odor:

No data available.

Odor Threshold:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solvent Solubility:

No data available

Water Solubility:

No data available

pH:

No data available.

Melting/Freezing Point (°C):

No data available

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9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

PD 0332991-0054

No data available

Palbociclib (PD 0332991)

Predicted 7.4 Log D 0.05

Cellulose microcrystalline

No data available

Colloidal silicon dioxide

No data available

Sodium starch glycolate

No data available

Magnesium Stearate

No data available

Lactose Monohydrate

No data available

PD 0332991-0002

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties have not been thoroughly investigated. The information included in this section describes the potential hazards of various forms of the active ingredient.

Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: decreased white blood cells (leukopenia), neutropenia, decreased red blood cell count (anemia), fatigue, and nausea.

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11. TOXICOLOGICAL INFORMATION

Acute Toxicity: (Species, Route, End Point, Dose)

PD 0332991-0054

Rat Oral Maximally Tolerated Dose 500 mg/kg

Palbociclib (PD 0332991)

Rat (M) Oral Minimum Lethal Dose \geq 1000 mg/kg

Lactose Monohydrate

Rat Oral LD 50 29700 mg/kg

PD 0332991-0002

Dog Oral Maximum Asymptomatic Dose 10 mg/kg

Safety Pharmacology: PD 0332991-0054: Neurofunctional not significant Pulmonary decreased respiratory rate (5.0 mg/kg)

PD 0332991-0002 *In vitro* Cardiovascular and *In vivo* Cardiovascular increased QT interval

Irritation / Sensitization: (Study Type, Species, Severity)

Palbociclib (PD 0332991)

Eye Irritation (*In vitro*, BCOP) Not applicable Negative

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Non-irritating

Skin Sensitization - LLNA Mouse Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

PD 0332991-0054

3 Week(s) Rat Oral 50 mg/kg/day LOAEL Blood, Bone marrow, Lymphoid tissue, Male reproductive system

3 Week(s) Dog Oral 0.2 mg/kg/day NOAEL Blood, Bone Marrow, Lymphoid tissue, Male reproductive system

Palbociclib (PD 0332991)

15 Week(s) Rat Oral (M) 10 / (F) 200 mg/kg/day NOAEL Male reproductive system

15 Week(s) Dog Oral (M) 0.2 / (F) 2.0 mg/kg/day NOAEL Male reproductive system

Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Palbociclib (PD 0332991)

Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOAEL Maternal toxicity, Developmental toxicity

Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Maternal Toxicity, Developmental toxicity

Fertility & Early Embryonic Development-Females Rat Oral 300 mg/kg/day NOAEL Reproductive toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

PD 0332991-0054

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

In Vitro Cytogenetics Human Lymphocytes Negative

In Vivo Micronucleus Rat Bone Marrow Positive

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11. TOXICOLOGICAL INFORMATION

Palbociclib (PD 0332991)

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vitro Chromosome Aberration Rat Bone Marrow Positive
In Vitro Kinetochore Analysis Chinese Hamster Ovary (CHO) cells Positive

Lactose Monohydrate

In Vitro Bacterial Mutagenicity (Ames) Negative

PD 0332991-0002

In Vitro Micronucleus Chinese Hamster Ovary (CHO) cells Positive without activation
Bacterial Mutagenicity (Biolum Ames) *Salmonella* Negative

Genetic Toxicity Comments:

PD 0332991-0002 The above genetic toxicity studies (*In vitro* Micronucleus and Biolum Ames) were preliminary assays.

PD 0332991-0054: Investigation into the mechanism of the positive response in the *in vivo* micronucleus assay suggests an aneugenic rather than clastogenic mechanism.

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Colloidal silicon dioxide

IARC:

Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:

Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

Toxicity:

No data available

Persistence and Degradability:

No data available

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

Palbociclib (PD 0332991)

Predicted 7.4 Log D 0.05

Mobility in Soil:

No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

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14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture
Caution - Substance not fully tested (VIIA)

Canada - WHMIS: Classifications

WHMIS hazard class:

D1b toxic materials

D2a very toxic materials

D2b toxic materials



Palbociclib (PD 0332991)

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

EU EINECS/ELINCS List Not Listed

Cellulose microcrystalline

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

EU EINECS/ELINCS List Not Listed

Colloidal silicon dioxide

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS/ELINCS List 231-545-4

Lactose Monohydrate

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

Australia (AICS): Present

REACH - Annex IV - Exemptions from the obligations of Register: Present

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15. REGULATORY INFORMATION

EU EINECS/ELINCS List Not Listed

Magnesium Stearate

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS/ELINCS List 209-150-3

Sodium starch glycolate

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS/ELINCS List Not Listed

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects

Xn - Harmful
Mutagenic: Category 3

R68 - Possible risks of irreversible effects.

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

Revision date: 16-Oct-2014
Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet